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Breast cancer

200 EVALUATION OF A PROPOSED TRASTUZUMAB BIOSIMILAR COMPARED WITH TRASTUZUMAB IN NEOADJUVANT BREAST CANCER TREATMENT
Marina Vitorino, Catarina Santos, Sofia Braga. Hospital Prof. Doutor Fernando Fonseca
10.1136/ijgc-2020-ESGO.1

Introduction/Background The use of trastuzumab in the treatment of HER2-positive breast cancer has changed the natural history of this disease. Trastuzumab was approved as a component of neoadjuvant treatment as well as adjuvant and metastatic. Biosimilars demonstrate chemical similarity and clinical efficacy to a reference product and are an option to provide access to high-quality systemic therapy alternatives.

Methodology This is a retrospective observational study revising patients treated with neoadjuvant therapy with trastuzumab (proposed biosimilar or trastuzumab) between January 2017 (period of introduction of the drug in our institution) - January 2020. All patients were treated with the same trastuzumab biosimilar drug.

Results Twenty-two patients (n=22) were included, with mean age at diagnosis of 55 years (range 31-84). Fifteen (n=15) patients were treated with proposed biosimilar and 7 patients with trastuzumab. Regarding histologic type, 82% (n=18) of patients had invasive carcinoma of no special type (NST), 5% (n=1) apocrine, 5% (n=1) invasive lobular and 5% (n=1) mucinous carcinomas. Sixteen patients had HER2 positive, hormone receptor (HR) positive tumors and 6 patients a HER2 positive, HR negative tumors. Regarding treatment, 86% of patients were treated with anthracyclines and in 5% (n=1) pertuzumab was used. In the trastuzumab group, 2 patients presented grade 1 toxicity (heart failure); in the proposed biosimilar group, 2 patients presented grade 1 toxicities (heart failure and dyspnea). Infusion reactions were not documented, namely hyperthermia. Axillary pCR was achieved in 86% (n=6) and 53% (n=8) in trastuzumab and proposed biosimilar groups respectively. Breast pCR was achieved in 86% (n=6) and 33% (n=5) in trastuzumab and proposed biosimilar groups respectively. There was no statistically significant difference between the two groups.

Conclusion Reiki may pose a viable alternative medical treatment option to sport as a supportive therapy option to combat side effects of neoadjuvant Epirubicin, Cyclophosphamide and Taxane chemotherapy for breast cancer treatment. To better understand the beneficial influence of this therapy, further research is needed to compare Reiki with a control group receiving no additional therapy.

Disclosures No disclosure.

382 COMPARISON OF THE EFFICACY OF REIKI VERSUS SPORT AS SUPPORTIVE CARE DURING NEOADJUVANT CHEMOTHERAPY OF EARLY BREAST CANCER: SUB ANALYSIS OF THE RANDOMIZED CONTROLLED REASSURE (REIKI AS SUPPORTIVE TREATMENT DURING CHEMOTHERAPY OF EARLY BREAST CANCER) STUDY

Introduction/Background Breast cancer (BC) is one of the most common tumours in the globe. Since 2011, BC in Kazakhstan has been ranked first in the structure of the treatment of HER2-positive breast cancer has changed the natural history of this disease. Trastuzumab was approved as a component of neoadjuvant treatment as well as adjuvant and metastatic. Biosimilars demonstrate chemical similarity and clinical efficacy to a reference product and are an option to provide access to high-quality systemic therapy alternatives.

Methodology This is a retrospective observational study revising patients treated with neoadjuvant therapy with trastuzumab (proposed biosimilar or trastuzumab) between January 2017 (period of introduction of the drug in our institution) - January 2020. All patients were treated with the same trastuzumab biosimilar drug.

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Introduction/Background Breast cancer is the most common cancer of the female, and the second most common cancer overall. While chemotherapy is standard of care for many patients with this type of cancer, it is associated with various side effects that require supportive care. In addition to standard medical therapies, patients may benefit from complementary treatments, such as sport therapy or Reiki. Reiki is a far eastern method that promotes healing on a physical, mental and emotional level and activates self-healing powers. Aim of this study was to compare the efficacy of Reiki versus Sport as supportive care during primary systemic therapy of early breast cancer within the REASSURE study.

Methodology REASSURE was a prospective, randomized, controlled, two-armed clinical trial, in which patients with breast cancer received chemotherapy and Reiki (18 times) or chemotherapy and sport (18 times). This evaluation specifically focused on patients who received neoadjuvant chemotherapy with four cycles of Epirubicin and Cyclophosphamide followed by 12 cycles of a Taxane. All patients were enrolled in the REASSURE-study and randomized before their first chemotherapy cycle. While sport therapy was delivered as conventional physiotherapy, Reiki was delivered by a trained Reiki practitioner. We conducted a statistical analysis using Wilcoxon Rank sum tests to compare incidence of adverse events (febrile neutropenia (FNP), fever, infection, blood count variation, hospitalization), dose modifications (therapy discontinuation, dose interruption, dose reduction) and use of conventional medical supportive care treatments (G-CSF, antibiotics, blood transfusion, platelet transfusion).

Results A total of 48 subjects were included, of which 27 received Reiki and 21 received sport treatment. When comparing FNP events between both groups, we found 3 events in the sport group, whereas there were none in the Reiki group (p = 0.047). The median number of GCSF-application was 4 (range 0 to 8) in the sport group versus 0 (range 0 to 8) in the Reiki group (p = 0.006). For all other parameters, calculation of 95 percent confidence intervals showed no clinically significant difference between the two groups.

Conclusion Reiki may pose a viable alternative medical treatment option to sport as a supportive therapy option to combat side effects of neoadjuvant Epirubicin, Cyclophosphamide and Taxane chemotherapy for breast cancer treatment. To better understand the beneficial influence of this therapy, further research is needed to compare Reiki with a control group receiving no additional therapy.

Disclosures REASSURE Studie - This study is a collaborative study between Frauenklinik Rechts der Isar, Frauenklinik des Rotkreuzklinikums, Frauenklinik der München Klinik Harlaching, and ProReiki – Berufsverband e.V. There was no funding. There are no conflicts of interest.

531 12-YEARS RESULTS OF THE KAZAKHSTAN BREAST CANCER SCREENING PROGRAMME

Introduction/Background Breast cancer (BC) is one of the most common cancers in the globe. Since 2011, BC in Kazakhstan has been ranked first in the structure of the...
A RETROSPECTIVE STUDY OF STERNAL METASTASES IN BREAST CANCER

Cherifa Fazila Ghomari, Abdelkader Medjahedi. Tlemcen University Hospital. Dr Tiţăni Damerdji; Université Tlemcen; Medicine Department; Nuclear Medicine

Introduction/Background Sternal metastases of breast cancer are rare. Their occurrence is due to the spread of malignant cells via the hematogeneous route or via a local pathway from the internal mammary nodes.

The aim of this study is to define the different pattern of sternal malignant abnormalities on bone scan.

Methodology It is a retrospective study including breast cancer patients, referred for bone scan during 2019, at the Nuclear Medicine department of Tlemcen University Hospital in Algeria.

Two hours after the intravenous injection of 8–10 MBq/kg 99mTc-HMDP, whole body scanning is accomplished by dual head hybrid gamma camera with low energy high resolution collimator. The SPECT/CT (single photon emission tomography/computed tomography) acquisition is used to better characterize the presence, location, and extent of disease in some patients.

Results A total of 54 malignant sternal abnormalities were found in 500 breast cancer patients (10.8%).

Half of the lesions (27 cases) were located in the sternal body, 17 (32%) in the manubrium and 10 (18%) in the entire bone structure.

The majority of sternal abnormalities (47 cases; 87%) was found as a part of multiple metastases, while only 2 cases (4%) as a part of oligometastases and 5 cases (9%) as the initial site of bone metastases.

A solitary sternal uptake on bone scan is difficult to interpret due to various etiologies, both benign and malignant. The SPECT/CT acquisition has allowed us to define the secondary origin of the radioactivity uptake after cross sectional study and confrontation with morphological imaging.

The predominant scintigraphic pattern was that of hot lesions (48 cases; 89%), which highlights an osteoblastic hyperactivity. A cold lesion representing an osteoclastic activity, is rarely seen in bone scan until it is surrounded by an increased radioactivity uptake. The latter aspect was found in 6 patients (11%).

Conclusion Radiouclide bone scintigraphy is a useful tool for recognizing sternal abnormalities in breast cancer patients.

Disclosures We have no disclosures.

Abstracts

A RETROSPECTIVE STUDY OF STERNAL METASTASES IN BREAST CANCER

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Conclusion Radiouclide bone scintigraphy is a useful tool for recognizing sternal abnormalities in breast cancer patients.

Disclosures We have no disclosures.

AYLIXY LYPHADENECTOMY VS. SENTINEL NODE BIOPSY FOR EARLY-STAGE CLINICALLY NODE-NEGATIVE BREAST CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Introduction/Background Axillary lymph node dissection has been for years the gold standard for surgical staging and locoregional control of axilla in early-stage breast cancer patients. However, sentinel node biopsy has been placed in early 1990s as an effective alternative method of surgical staging. Main objective of the study is to compare oncological and survival outcomes between systematic axillary lymph node dissection (ALND) vs sentinel lymph node and axillary lymphadenectomy only if sentinel positive (SLN ± ALND) in early-stage, clinically node-negative breast cancer patients.

Methodology A systematic review and meta-analysis adhered to PRISMA guidelines was performed. Included studies were prospective randomized controlled trials (RCTs) comparing survival outcomes of ALND vs. SLN ± ALND in early-stage, node-negative breast cancer patients. Patients enrolled were only those with tumor size lower than 4 cm, clinically negative nodes and treated with breast-conservative surgery. Primary outcomes were locoregional recurrence, overall death and cancer-related death.
Results There were four studies included in the analysis, enrolling overall 2,982 patients, of which 1,494 in ALND arm and 1,488 in the SLN ± ALND arm. No statistically significant difference was observed in locoregional recurrence, breast cancer-related death and overall death. Locoregional recurrence was observed in 2.8% (ALND) vs. 4.1% (SLN±ALND), (RR: 0.69, 95% CI: 0.20–2.30). Overall death rate was 7.0% vs. 6.8% respectively, (RR:1.00, 95% CI: 0.73–1.39, I²=28.7%). Breast cancer-related death was 3.6% vs.3.5% respectively (SLN ± ALND), (RR: 1.11, 95% CI: 0.70–1.78, I²=0%). No statistically significant difference was observed in any of secondary study outcomes.

Conclusion Systematic axillary lymphadenectomy provides no survival and oncological benefit compared with sentinel lymph node dissection for early-stage clinically node-negative breast cancer patients.

Disclosures Authors report no conflict of interest.

Cervical cancer

40 TRAINING PARAMEDICAL STAFF TO PERFORM CERVICAL CANCER SCREENING WITH AID OF SPECIALLY DESIGNED VIDEO BASED TUTORIALS AND COMPARATIVE EVALUATION OF HPV VERSUS CYTOLOGY AS TRIAGE TEST AMONG VIA POSITIVE WOMEN

Vasundhara Kulkarni, Heena Shaikh, Gauravi Mishra, Styasree, Santosh Noronha, Pramesh Cs, Shamila Pimple, Hemalatha, Pratiksha, Sharmila Pimple

Introduction/Background Visual Inspection after application of 5% acetic acid (VIA) has been recommended for primary cervical cancer screening in India. The objectives were to develop and validate video based training tool for capacity building of paramedical staff in cancer awareness and screening, thereby reducing expert time requirement and duration of training and to comparatively evaluate performance of HPV Hybrid Capture 2 (HC2) and Cytology as triage tests among VIA screen positive women, thus aiming to reduce referral burden.

Methodology Video based tutorials were prepared in 14 modules. These videos included conducting cancer awareness, performing VIA, collecting samples for HPV and Cytology. The paramedical staff were invited for training. The training sessions were reduced to 2 weeks using new tool. Practical demonstration and micro-teaching was combined with tutorials training on pre-loaded tablets.

Community based cervical cancer screening with VIA was conducted among women aged 30–65, residing in Mumbai, India, by trained Primary Health Workers (PHWs). After obtaining informed consent, delivering cancer awareness, participants were offered VIA screening by trained PHWs. All VIA screen positive women underwent Cytology and HPV HC2 and later diagnostic Colposcopy at nodal hospital. Women with positive Colposcopy underwent cervical biopsies.

Results Fifty trainees were evaluated with theory and practical evaluation. All trainees found training to be informative, easy to understand and felt confident to deliver cancer awareness, perform VIA and collect samples for HPV and Cytology.

231 VIA positive women underwent Cytology and HPV HC2 test, followed by Colposcopy. Cervical biopsies were obtained in 83 cases. The sensitivity and specificity in detecting ≥ CIN 2 were 77.8 and 92.3 for HC2 and 66.7 and 98.2 for cytology. The false positivity and negativity rates were 7.7 and 22.2 for HC2 and 1.8 and 33.3 for cytology.

Conclusion With India now being on roll out mode of cancer control programme, it’s outcome will depend on quality of training that will be imparted to health services staff. The preparation and validation of these indigenously prepared video based tutorials has opened new avenue by which vast majority of paramedical staff could be trained in relatively shorter duration and utilizing least expert time.

The study shows that paramedical staff can be trained to collect HPV samples and that HPV HC2 reduces referrals to larger extent and misses fewer cases compared to cytology, thus appearing a better triage test among VIA positive women.

Disclosures TMH-IIT Collaborative projects through Tata Trusts and DAE Grants

73 LESSONS FROM RADIOCHEMOTHERAPY AND MODERN IMAGE-GUIDED ADAPTIVE BRACHYTHERAPY FOLLOWED BY HYSTERECTOMY

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Introduction/Background To analyze the clinical outcomes and the safety of radiochemotherapy (RCT) and image-guided adaptive brachytherapy (IGABT) and to evaluate the impact of hysterectomy (HT) as completion of treatment for cervical cancer.

Methodology 145 patients with locally advanced cervical cancer were treated at our institution. Patients underwent RCT and IGABT, then hysterectomy (HT) as completion of treatment was performed, with the exception of patients with surgical contraindications, para aortic metastatic disease or patients who refused surgery. Clinical outcomes and morbidity were retrospectively reviewed in both groups. Local relapse free survival (LRFS), pelvic relapse free survival (PRFS) and overall survival (OS) were analyzed.

Results Completion HT was performed in 90 (62.1%) patients. Complete histological response and microscopic disease were found in 77 patients (85.6%). Local relapse was observed in 14 patients (9.6%) without differences between completion HT group and the definitive RCT and IGABT group (Odds Ratio OR=1.73 [0.57–5.23], p=0.33). The estimated 3-year LRFS and PRFS for the entire population were respectively 90% [84%-94%] and 93% [87%-96%], with no significant differences between them (respectively Hazard Ratio HR=0.57 [0.20–1.64], p=0.30 and HR=0.37 [0.10–1.31], p=0.12). The estimated 3-year OS rate for the whole population was 84% [75%-91%] with no significant differences between groups (HR=0.81 [0.32–2.06], p=0.65). Regarding morbidity, grade ≥2 vaginal toxicity was more frequent in the definitive RCT and IGABT group (43.6% vs 26.7%, p=0.04). All grade 4 toxicity events were reported in the completion HT group.

Conclusion Due to high severe toxicity, RCT and IGABT with dose escalation followed by completion hysterectomy don’t seem compatible. No benefit and increased severe late morbidity were observed. Combined intracavitary/interstitial technique is mandatory in large target volume at brachytherapy.

Disclosures All authors declare no conflict of interest.

There was no founding source for this study.
IS PRIMARY CHEMORADIATION A BETTER TREATMENT? A RETROSPECTIVE STUDY OF EARLY STAGE NODE-POSITIVE CERVICAL CANCER

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10.1136/ijgc-2020-ESGO.8

Introduction/Background Cervical cancer is the second most frequently diagnosed cancer and the third leading cause of cancer death for women in developing countries. Radical hysterectomy with bilateral pelvic lymph node dissection is usually preferred for patients of stage IB1-IIA2. Currently, image examinations have certain limitations in diagnose of lymph node metastasis and their detection accuracies are not satisfactory. Only the pathological examination after removal of the suspected metastatic lymph nodes during surgery can conclusively identify the presence of metastasis. If there is a positive result of lymphatic metastasis, there is no clear guideline whether to complete a radical surgery, or to only conduct a systematic lymphadenectomy, followed by adjuvant Concurrent Chemoradiotherapy (CCRT). This retrospective study aimed to compare the efficacy and safety of the two treatment modalities.

Methodology 49 stage IB1-IIA2 cervical cancer patients with lymphatic metastasis confirmed by systemic pelvic and para-aortic lymph node dissection from 2007 to 2018 were reviewed. The patients were treated with either primary chemoradiation or radical hysterectomy followed by adjuvant chemoradiation after lymphadenectomy. Survival states and adverse events of the two treatments were compared.

Results Median follow-up time was 45 (range 11–119 months) months. In non-radical surgery group, 1 patient (1/15, 6.7%) relapsed and died, while in radical surgery group, 7 patients (7/27, 25.9%) relapsed and 5 (5/27, 18.5%) died. Significant difference was found in the mean progression-free survival between the two groups, which was 69.95%±CI 49.118–88.882) months in non-radical surgery group and 44.85%±CI 35.857–52.143) months in radical surgery group (p<0.01). There was significant difference in three-year progression-free survival (86%/vs. 71%, p<0.01). Grade 3–4 toxicity was comparable between the two groups (26.7% vs. 25.9%, p=0.938).

Conclusion For stage IB1-IIA2 cervical cancer patients with positive lymph node, primary chemoradiation after pelvic and para-aortic lymphadenectomy seems to have better survival outcomes compared with radical hysterectomy by laparoscopy plus chemoradiation in the retrospective study with limited cases. Evidence from a randomized controlled study is in need to confirm the optimal treatment for early stage node-positive cervical cancer.

Disclosures The authors declare that they have no conflicts of interest.

USP18 PROMOTES CELL PROLIFERATION AND SUPPRESSED APOPTOSIS IN CERVICAL CANCER CELLS VIA AKT SIGNALING PATHWAY

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Introduction/Background Cervical cancer is one of the most common malignancies in women worldwide. USP18 (USP43), a member of Ubiquitin-specific protease family, has been linked to several human malignancies except cervical cancer. The current study aimed to explore the expression and possible role in cervical cancer.

Methodology Real-time PCR and immunohistochemical staining was performed to analyze USP18 expression in cervical cancer tissues and normal tissues. USP18 expression was manipulated in cervical cancer cell lines, and its biological function in cell proliferation and apoptosis was assessed by Cell Counting Kit-8 assay and Annexin V/PI staining, respectively.

Results We demonstrated that USP18 expression was increased in cervical cancer specimens and cell lines. Knocking down of USP18 in cervical cancer cell lines, SiHa and Caski, inhibited cell proliferation, while induced apoptosis and the expression of cleaved caspase-3. On the contrary, USP18 overexpression showed reversed effects in Hela cells. Moreover, Gene Set Enrichment Analysis showed that USP18 expression level was correlated with PI3K/AKT signaling pathway in cervical cancer. Further, the PI3K/Akt inhibitor LY294002 blocked the effects of USP18 overexpression on cervical cancer cells.

Conclusion The current study indicates the oncogenic role of USP18 in cervical cancer, which will deepen the understanding in the pathogenesis of cervical cancer and may provide a novel target for cancer therapy.

INFLUENCE OF INITIAL VOLUME OF CERVICAL CANCER ON ACHIEVING THE RECOMMENDED BRACHYTHERAPY DOSE AT TARGET VOLUMES

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10.1136/ijgc-2020-ESGO.10

Introduction/Background 3D brachytherapy (BRT) planning, based on magnetic resonance (MR) imaging, has become a standard approach in cervical cancer radiotherapy treatment in many radiotherapy centres. T2W MR images give us precise visualization of the tumor tissue volume and tumor changes during the treatment. Adequate BRT dose coverage of the target volumes, presented through D90 and D100 dose parameters, has a primary role in achieving local control of the disease.

The goal is to estimate the initial tumor volume impact on the registered target volume dose parameters.

Methodology The curative chemoradiation was applied to 30 patients with advanced cervical cancer. Brachytherapy was performed in a high-dose rate regimen, in 4–5 weekly applications, with a dose of 7Gy per application, starting after 15 external beam fractions, endocavitary without interstitial catheters. For each patient a 3D T2W MR imaging was performed, initially prior treatment and at the time of the first and the fourth BRT application. MR images were used for tumor volume assessment and for 3D BRT planning, obtaining that way the target dose-volume parameters. Initial tumor volume influence on the registered HR-CTV dose parameters (clinically the
most important target volume dose parameter) was then investigated.

Results MR based assessment of tumor volumes initially, at the time of the first and the fourth BRT application, were as follows: (49.9±33.3 ccm, 11.3–124.2 ccm), (17.3±19.2 ccm, 1.7–78.4 ccm) and (7.0±10.9 ccm, 0.8–58.5 ccm) respectively. Registered EQD2 HR-CTV doses for the whole group of patients were D90 (107.15±22.06Gy), and D100 (80.66±14.58Gy). Initial tumor volume showed a strong negative, statistically significant correlation with registered HR-CTV D90 dose at the time of the first BRT application (rho= -0.8). ROC analysis confirmed the discriminative influence of initial tumor volume on achieving recommended HR-CTV dose, with the best initial tumor volume cut-off value of 47.87 ccm, with high sensitivity 89.4%, and specificity 90.9%. A statistically significant difference between two groups of patients (regarding the identified tumor volume cut-off value of 47.87 ccm) was found for the EQD2 HR-CTV doses: D90 (120.4±14.6Gy vs 87.33±15.4Gy, p=6.9*10^-7) and D100 (101.8±13.3Gy vs 75.85±11.9Gy, p=9*10^-5).

Conclusion The initial volume of the cervical tumor has a great influence on achieving the recommended values of HR-CTV D90 and D100 doses. Tumors with initial volume greater than 47.87 ccm cause a statistically significant lower total EQD2 dose at the HR-CTV volume, leading to poor local disease control.

Disclosures The results are part of my paper published recently in J BUON.


154 DISEASE-FREE SURVIVAL IN EARLY-STAGE CERVICAL CANCER: COMPARISON OF LAPAROSCOPIC VERSUS OPEN SURGERY IN A TERTIARY CENTRE
Amanda Veiga-Fernández, María López-Altuna, Ignacio Romero-Martínez, Elsa Mendizábal Vicente, Patricia Rincon Olubes, Santiago Lizarraga Bonelli.

Introduction/Background Over the last years, minimally invasive surgery was advancing as the preferred approach in many cancer centres for the treatment of early-stage cervical cancer, as it offers advantages against open abdominal surgery in in-hospital and short-term outcomes. However, results from a recent randomized trial suggested lower rates of disease-free survival in the follow-up of patients operated with the minimally invasive approach.

The aim of our study was to compare, in our tertiary centre, the rate of disease-free survival at 3.5 years between both surgical techniques.

Methodology Retrospective single-centre study including patients who underwent total laparoscopic radical hysterectomy (LRH) or open radical hysterectomy (ORH) due to early-stage cervical cancer (IA1-IIA1) between 2005–2017.

Results A total of 63 patients were included (39 LRH and 24 ORH). Baseline characteristics are described in table 1. Mean age was similar in both groups 47.5 ±13.3 vs. 48.3 ±12.6 (p=0.8). The prevalence of high-risk HPV was similar in both groups with a higher rate of prior conization in the LRH group 22 (56.4%) vs. 5 (20.8%) (p=0.006). There were no significant differences between both groups in terms of parametrial involvement, histologic subtypes and stage of disease. In almost half of the patients in the LRH group the uterine mobilizer was used during surgery, with 1 case of uterine perforation. There were no significant differences at 3.5 years follow-up in terms of recurrences [LRH 4 (10.3%) vs. ORH 2 (8.3%) (p=0.8)] and overall death (being secondary to their oncological process in all cases), 2 (5.1%) vs. 1 (4.2%) (p=0.87). Kaplan-Meier analysis revealed a similar rate of disease-free survival at 3.5 years in both groups: LRH 87.2% vs. 87.5% (p=0.95) (figure 1). The rate of disease-free survival in patients in which the uterine mobilizer was used was 100%.

We hypothesized that, in experienced hands and with appropriate patient selection, a minimally invasive approach via laparoscopic surgery can be as effective as conventional...
open surgery. However, the results must be interpreted with caution given the potential risk of bias derived from the relatively small sample size and the single-centre, retrospective nature of the study.

**Conclusion** In the present study, we did not find statistically significant differences between LRH and ORH for the treatment of early-stage cervical cancer in terms of disease-free survival and overall survival.

**Disclosures** Nothing to disclosure.

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**CERVICAL ONCOLOGICAL CYTOLOGIES’ (PAP TEST) EVALUATION OF THE RIVERINE WOMEN FROM RIVERS TAPAJÓS AND CUPARI (PARÁ – BRAZIL)**

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**Introduction/Background** Cervical cancer is the most prevalent in Brazil North Region. There are few studies about cervical injuries in the riverine women. The knowledge of these characteristics could improve health assistance to these women, contributing to health policies that benefit this population.

**Objective:** This paper aims to evaluate the cervical oncological cytologies of the riverine women from rivers Tapajós and Cupari (Pará - Brazil).

**Methodology** A partnership between SLMandic Medical School and the local Cities of Santarém, Aveiro and Belterra (State of Pará, Brazil) Government was established trough ‘Barco da Saúde’ (Health Boat) project. The Counties have provided a Hospital Boat named ‘Abaré’. SLMandic has provided a team made up by professors and medical students. Services in pediatrics, gynecology and obstetrics, dermatology, ophthalmology and odontology were provided. In 2019, the activities were held between July 27nd and August 5th, 206 gynecological and obstetric appointments were made and 133 cervical oncological cytologies were collected. Epidemiological data were collected from anamnesis form designed specifically for the expedition. The reading of the cytology slides was performed and de injuries classified among high grade lesions (HSIL), low grade lesions (LSIL), scaly lesions of undetermined significance (ASC-US), and glandular lesions of undetermined significance (ASC-US). Pathological agents found have also been described. The samples were classified between satisfactory and unsatisfactory. Finally, statistical analysis of data was done.

**Results** Out of 206 gynecological and obstetric appointments, 132 (64.1%) cervical cytologies were collected. Among these patients, 100 (75.75%) were screening age (25–65 years old). Median of patients age was 34.4 years old. About 128 (97%) samples were satisfactory for analysis. Cervical cancer screening was the objective of the exam in 101 (76.5%) of the cases. Related to associated microorganisms, Lactobacillus sp. were present in 68 (51.5%), Gardnerella vaginallis in 13 (9.8%), Candida sp. in 8 (6%) Trichomonas vaginallis in 2 (1.5%), in addition to others less prevalent. Inflammatory cells were present in 126 (95.5%) of the cases. The main diagnosis was benign cellular changes (122 - 92.5%) and atypical squamous cells of undetermined significance, ASC-US, 6 (4.5%). Were performed 7 (5.3%) biopsies, being 3 (42.9%) cervical polyps and 4 (57.1%) nonspecific chronic cervicitis.

**Conclusion** Despite difficulties to access health care, health indicators were better than expected. There was good cytological coverage and no high-grade lesions were found.

**Disclosures** Authors declare no conflict of interest.

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**A CLINICAL STUDY ON THE APPLICATION OF 3D-PRINTING MINIMALLY INVASIVE-GUIDED TEMPLATE IN BRACHYTHERAPY OF PATIENTS WITH LOCALLY ADVANCED CERVICAL CANCER**

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**Introduction/Background** To explore the clinical application of three-dimensional (3D)-printing minimally invasive-guided template in brachytherapy of patients with locally advanced cervical cancer.

**Methodology** From May 2016 to December 2018, 59 patients (age, 23–78 years old; median age, 57 years old) with locally advanced cervical cancer. All patients were treated with radical radiotherapy, in which external irradiation was performed, and 3D conformal and intensity-modulated radiotherapy was carried out with a radiation dose of 45 Gy in 25 fractions of 1.8 Gy per day. The included patients were randomly divided into 2 groups according to random number table method. In the template group, 29 patients assisted by 3D-printing templates to place intrauterine tubes and implant for insertion of needles. In the free implantation group, 30 patients were assisted with freehand implanted intrauterine tubes and implant needles. All patients underwent Computed Tomography (CT) to adjust the position and depth of the insertion needle, and the final CT image was transmitted to the Oncentra brachytherapy planning system, to outline the target area and organs at risk, make treatment plans, and perform treatment.

**Results** A total of 283 times of combination of intra-luminal and interstitial insertion radiotherapy were undertaken, and a total of 283 times of post-loading radiotherapy plan were formulated, including 141 times in template group and 142 times in free insertion radiotherapy. Complete Response (CR) rate in the template group (24/28;85.71%) was slightly higher than that in the free transplantation group (22/28; 78.57%). There was no significant difference in short-term efficacy between the two groups (z=-0.692, P>0.05). Importantly, D90 (90% of the target volume) of High-Risk Clinical Target Volume (HR-CTV) and Intermediate-Risk Clinical Target Volume (IR-CTV) in the template group were significantly higher than those in the free implantation group (t = 3.42, 2.13, P<0.05). D2 cm3 of bladder, rectum and sigmoid colon was significantly reduced (t = -2.59, -4.22, -2.01, P<0.05). Therefore, the incidence of grade 1, 2 and 3 acute radiation proctitis in the template group was noticeably lower than that in the free transplantation group (z = -2.112, P<0.05). However, there was no significant difference in the incidence of acute radioactive cystitis between the template group and the free implantation group (z=-1.686, P > 0.05).

**Conclusion** For large-block or eccentric cervical cancer, application of the 3D-printing minimally invasive-guided template in brachytherapy of patients with locally advanced cervical cancer.
cancer can reflect its dose-based advantages, associating with a remarkable reduction of patients’ adverse reactions and a satisfactory therapeutic effect.

Disclosures None.

203 HIGH EXPRESSION OF NANOG AND CRY1 IS INVOLVED WITH TUMOR PROGRESSION AND POOR PROGNOSIS IN PATIENTS WITH CERVICAL CANCER

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Introduction/Background Nanog is a well-known transcription factor regulating an embryonic stem cell maintenance. Recently, many evidences have been accumulated that overexpression of Nanog is intimately involved in tumorigenesis. However, the role of Nanog in cervical cancer has not been elucidated yet. Thus, we investigated the expression and clinical significance of Nanog in cervical cancer.

Methodology To evaluate the expression level of NANOG and CRY1, the immunohistochemistry on 170 cervical cancers and 263 cervical intraepithelial neoplasia (CIN) samples and the clinicopathologic variables of cervical cancer patients were compared to evaluate the significance of Nanog and CRY1 in cervical cancer. Also, in vitro assessment was performed by using Nanog knock down cervical cancer cell lines.

Results Nanog and CRY1 expression was higher in cervical cancer tissues than in CIN tissues and normal epithelial tissues (both p < 0.001). Importantly, Nanog and CRY1 overexpression was associated with poor chemoradiation response (p < 0.035, p < 0.003, respectively). Multivariate survival analysis revealed that overexpression of Nanog (hazard ratio = 0.016; 95% confidence interval [CI]: 1.25–9.27, p = 0.016) as an independent prognostic factor for overall survival. Also, the combination of high Nanog and CRY1 expression showed the highest hazard ratio (5.87; 95% CI: 2.18–15.82, p < 0.001) for overall survival. In vitro results also demonstrated the knockdown of Nanog was associated with increased cell viability (p < 0.001), migration (p<0.001) and growth (p < 0.001) supporting the oncogenic role of Nanog in cervical cancer.

Conclusion This study showed that overexpression of Nanog could be a good biomarker for the prediction of chemoradiation response. The results of survival analysis suggest a strong association between Nanog as well as CRY1 expression and poor overall survival, indicative of the potential role of this combination as a prognostic marker in clinical assessment.

Disclosures I have no conflict of interest to disclose.

204 PERFORMANCE AND DIAGNOSTIC ACCURACY OF HUMAN PAPILLOMAVIRUS TESTING ON URINE AND SELF-COLLECTED VAGINAL SAMPLES IN A REFERRAL POPULATION

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Introduction/Background Human papillomavirus (HPV) is well established as the main cause of cervical cancer. Non-invasive self-collected urine and vaginal sampling have the potential advantage of increasing patient compliance with cervical cancer screening.

Methodology Women referred for colposcopy at Korea University Guro Hospital, following abnormal cytology, were included in this study. A total of 314 paired urine, vaginal and cervical samples were collected. Primary endpoints were sensitivity for CIN2+/CIN3+ and specificity for <CIN2; secondary endpoints were the relative accuracy of hrHPV test results in vaginal and urine samples versus cervical samples.

Results For clinician-collected cervical samples, Sejong Realtime HR-S HPV test sensitivity for detecting and specificity from were similar to well-established test (Anyplex™ II HPV 28) [sensitivity for CIN3+ (n=109) 93.27% (95% confidence interval [CI], 86.62–97.25); CIN2+ (n=130) 92.74% (95% CI, 86.67–96.63); specificity for<CIN2 31.82% (95% CI, 25.01–39.25)]. All the paired differences (cervical versus urine sampling, cervix versus vaginal sampling) in sensitivity were statistically significant. However, among women with ASCUS/LSIL cytology, hrHPV sensitivity on vaginal samples was comparable to that of cervical samples for detection of CIN2+ and CIN3+ lesions. In addition, hrHPV sensitivity of Anyplex II HPV 28 assay on urine was comparable to that of cervical samples for detection of CIN3+ lesions (p=0.07) in women with ASCUS/LSIL cytology.

Conclusion HPV tests using urine and vaginal samples were still inferior to clinician-collected cervical samples in terms of detecting CIN2/3. However, these results indicate that combination of cytology with reflex hrHPV test using vaginal and urine samples may offer a reliable strategy for discriminating women at greater risk of precancerous lesion, increasing compliance of patients.

Disclosures I have no conflict of interest to disclose.

235 SUCCOR CONE: IS IT CERVICAL CONIZATION A PROTECTIVE MANEUVER

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Introduction/Background After the publication of the LACC trial, current evidence has focused on looking for the different reasons that have led to the open approach presenting better results than minimally invasive surgery (MIS). To date, no studies have considered the possible protective effect of cervical conization (CC).

Methodology Objective: The main goal of this study was to compare disease-free survival (DFS) and overall survival (OS) at 4.5 years in patients with stage IB1 cervical cancer who underwent radical hysterectomy (2013–2014) after CC versus non-CC patients. The secondary goal was to compare DFS by subgroups (tumor size and surgical approach in patients who underwent CC and those who did not) in the Propensity Matching Score (PMS) database.

Methods: Taking from 1272 patients from the European database belonging to the SUCCOR study and after applying
the different inclusion and exclusion criteria, we obtained 1156 patients, 733 CC patients and 423 non-CC patients. Subsequently, and after analyzing the first results, we decided to homogenize our database by means of a PMS analysis, by this way, we obtained a new balanced population of 374 patients (187 CC patients and 187 non-CC patients).

Results In the general population, patients with CC present a 72% reduction in the risk of relapse compared to non-CC patients (HR: 0.28 95% CI (0.17–0.46) p = 0.000) and a 90% reduction in the risk of death (HR: 0.10 95% CI (0.03–0.33) p = 0.000), these differences may be due to the fact that both populations present differences.

After homogenizing our population using the PMS, we obtained that the reduction in the risk of relapse was 65% for patients who have CC (HR: 0.35 CI 95% (0.16–0.75) p = 0.007) and 75% for the risk of death for the same cohort (HR: 0.25 95% CI (0.07–0.90) p = 0.033).

Regarding the secondary objectives, we observed that the CC seems to have a protective effect in tumours between 2–4 cm (HR: 0.33 95% CI (0.11–0.99) p = 0.049). This same protective effect is observed in patients operated on by laparoscopy (HR: 0.35 95% CI (0.14–0.89) p = 0.028). Finally, the MIS patients who have CC do not present differences compared to those operated by the open approach, whether they are conized or non-conized (Log-Rank p = 0.439 and Log-Rank p = 0.346).

Conclusion Patients undergoing CC have a significantly lower risk of relapse and death, this effect is more evident in those patients with 2–4 cm tumors or in those who are operated under MIS.

Disclosures I have nothing to disclose.

258 DESIGN AND VALIDATION OF A RECURRENT RISK PREDICTING SCORE IN EARLY STAGE CERVICAL CANCER AFTER RADICAL HYSTERECTOMY

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Introduction/Background After the LACC trial, the scientific evidence has focused on confirming and finding the cause of why the open route presents better results than minimally invasive surgery (MIS). Even though the independent factors involved in relapse has not been studied.

Methodology

Primary objective to know the independent clinical, surgical and anatomopathological factors involved in the relapse of patients with stage IB1 cervical cancer who underwent radical hysterectomy (2013–2014).

Secondary objective To create a risk predictive index (RPI) that allows us to better select and stratify patients with a higher probability of relapse.

Methods Starting from 1272 patients from the European database belonging to the SUCCOR study and after applying the different inclusion and exclusion criteria we obtained 1156 patients. We randomly divided our sample into a test group and a validation group in a proportion of 60% to 40%.

The test group was used to identify the variables independently associated with relapse and to define the relapse RPI. The RPI was applied to calculate a relapse risk score for each participant in the validation group. According to their risk of relapse, participants were classified into 3 risk groups.

Results Women who relapse are more likely to have tumours larger than 2 cm on imaging assessment (OR 2.15, 95% CI 1.33–3.5) and to undergo MIS (OR 1.61, 95% CI 1.00–2.57). On the other hand, conisation is inversely associated with the risk of relapse (OR 0.31, 95% CI 0.17–0.60).

The AUC in the validation group for RPI is (0.72; 95% CI 0.65–0.79).

Depending on their score, patients were classified at low, medium or high risk of relapse. The relapse rate observed in each group was 3.4%, 9.8% and 21.3% respectively.

With a median follow-up of 58 months, the mean DFS in the validation group for low, medium and high risk categories were 75.4 (95% CI 73.8–76.9), 75.5 (95% CI 72.4–78.5) and 64.1 (95% CI 59.4–68.9) months respectively (P < 0.001).

Conclusion Our risk predictor index proved to be valid and therefore may help to identify those patients who would benefit from adjuvant therapy and close follow-up after radical hysterectomy.

271 SURVIVAL OUTCOMES OF PATIENTS WITH CLEAR CELL CARCINOMA CERVIX: A SINGLE INSTITUTIONAL RETROSPECTIVE ANALYSIS

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Introduction/Background Cervical cancer is the most prevalent cancer and the fifth most common cause of cancer death in Indian women. Clear cell carcinoma of the cervix (CCCC) is rare, accounting for only 4% of all adenocarcinomas. CCCC can occur sporadically or in association with in-utero diethylstilbestrol (DES) exposure. There are no clear-cut treatment recommendations for the management of CCCC. Early-stage disease is usually treated by surgery and more locally advanced stages by chemoradiation followed by brachytherapy.

Methodology

Aim: This study aimed to assess the survival outcomes and patterns of failure of patients with CCCC.

Settings and Design: Retrospective study done at Regional Cancer Centre, Thiruvananthapuram, Kerala, India

Material and Methods: Case records of all the patients with CCCC who were diagnosed and treated between 1995 and 2015 were reviewed for clinical, pathological and treatment characteristics.

Statistical analysis: Disease-free survival (DFS) and overall survival (OS) were estimated using the Kaplan-Meier method.

Results The diagnosis of clear cell carcinoma of the cervix was confirmed in 15 patients. The median age was 53 years. 20% of the patients were in the International Federation of Gynaecology and Obstetrics (FIGO) stage I, 60% in stage II, 7% in Stage III and 13% in stage IVA. Stage IB and IVA patients were managed surgically, and adjuvant therapy decided based on the tumour pathology. Stage IIB and IIIIB
patients were treated with concurrent chemoradiation followed by brachytherapy. The median follow-up period was 47 months. The three-year DFS and OS were 13.3% and 13.3% respectively.

Conclusion CCCC has a poor prognosis, stage for stage compared to other histologies. The FIGO stage, tumour size, lymphovascular space invasion and pelvic node status were factors that predicted the prognosis. Adjunct radiotherapy or chemoradiotherapy have a limited role in the treatment of this rare cancer.

Disclosures The authors have no potential conflict of interest to disclose.

Introduction/Background HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri- and postmenopausal women. The objective of this sub-analysis was to evaluate the effect of the Papilocare®, a multi-ingred-ent Coriolus versicolor-based vaginal gel, on the normalization of cervical HPV-dependent atypia (ASCUS and LSIL) and associated colposcopic alterations in women older than 40 years.

Methodology Paloma clinical trial (ClinicalTrials.gov NCT004002154) was a multicenter, randomized, open-label, parallel-group, usual practice-controlled clinical trial. Unvaccinated HPV positive women aged between 30–65 with cytology of ASCUS or LSIL and concordant colposcopic image were randomized into 3 groups: A) Papilocare® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) Papilocare® 1 cannula/day for 3 months + 1 cannula/ alternate days for 3 months; C) Control group: no treatment (usual clinical practice). Primary endpoint: % of patients with normal cytology and concordant colposcopy after 6 months of treatment in the total population, high-risk HPV (16,18,31,33,35,39,45,51,52,56,58,59,68) and very high-risk HPV, respectively.

Results A total of 41 out of 84 evaluated patients included in Paloma trial were older than 40 years [mean (SD) age: 47.71 (5.56)], of which 30 and 13 were high-risk HPV and 16-18-31 HPV patients, respectively. At 6 months, normal cytology and concordant colposcopic image was observed in 92%, 90% and 75% of patients treated with Papilocare® vs 50%, 33% and 40% of patients in control group, in the total population, and high-risk and 16-18-31 subpopulations (p=0.0066; p=0.0031; p=0.2929, Fisher test) respectively.

Conclusion Papilocare® showed a robust efficacy in normalizing cervical HPV lesions in women older than 40 years old, with a statistically significant difference vs control group in the total and high-risk populations.


All other authors have declared no conflicts of interest.

Introduction/Background Real-life studies inform on the ‘effectiveness’ of a treatment what is intended to do in routine circumstances. The aim of this study is to evaluate the efficacy of Papilocare® - a multi-ingredient Coriolus versicolor-based vaginal gel- on repairing high-risk (HR) HPV-dependent low-degree cervical lesions and HR-HPV clearance in real-life practice.

Methodology Observational, multicenter, prospective, one-cohort study (PAPIL obs study ClinicalTrials.gov: NCT04199260). Currently recruiting 300 vaccinated or not HPV-positive women aged > 25y with Pap smear of ASCUS or LSIL and concordant colposcopy during routine clinical visits in Spain. Patients are treated with Papilocare® 1 cannula/ day for 21 days the first month + 1 cannula/alternate days for 5 months. After this 6-month period, patients with altered cytology and/or HPV persistency are treated for a 6-month extension treatment period with the same dosage.

Interim analysis of HR-HPV patients with normal Pap smear and concordant colposcopy image (primary endpoint) and patient with HR-HPV cleared (patients with total clearance or partial clearance together with negative Pap smear and normal colposcopy) at 6/12 months is presented. The study was approved by the ethical committee of Public University Hospital of Puerta de Hierro (Madrid). Informed consent was signed by all patients.

Results At 6 months, data of 148 and 146 patients for Pap smear/colposcopy and HR-HPV presence, respectively, were available. 67.6% of patients (100/148) had negative Pap smear and concordant colposcopy. HR-HPV clearance was observed in 58.9% of patients (86/146). Data of 46 and 44 patients included in the 6-month extension treatment period for Pap smear/colposcopy and HR-HPV presence, respectively, were available. At 12 months, 78.3% (36/46) of patients had negative Pap smear and concordant colposcopy and HR-HPV clearance was observed in 70.5% (31/44). Considering all study period, 77% (114/148) and 72.6% (106/146) of patients repaired HR-HPV-dependent cervical lesions and cleared HR-HPV, respectively.

Conclusion In this interim analysis, repairing of HR-HPV-dependent low-degree cervical lesions and clearing HR-HPV, in real life conditions, was achieved after 6-month treatment
with Papilocare® (or extending it up to 12-months if needed) in 3 out of 4 patients. These findings need to be confirmed upon study completion.

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**288 Efficacy of a Multi-Ingredient Coriolus Versicolor-Based Vaginal Gel in High-Risk HPV+ Patients: Results of Different Studies**

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**Introduction/Background** To evaluate the consistency of the efficacy of a non-hormonal multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on HPV clearance in patients infected by high-risk HPV (HR-HPV) in several studies.

**Methodology** Results at 6 months from independent observational non-comparative studies carried out in three different public centers and in one private center were compared to results from both a randomized, open, parallel and controlled clinical trial comparing the Papilocare® vs wait and see approach (The Paloma RCT) and an observational, multicenter, prospective, one-cohort study (Papilobs real-life study). Two prospective (Vigo and Bari studies) and two retrospective studies (Coruña and Hospitalet studies) have been performed.

Vigo study: HPV clearance of 25 patients infected by HPV 16 and/or 18 was evaluated as a secondary endpoint.

Bari study: HPV clearance of 98 HR-HPV patients was evaluated as primary endpoint.

Coruña study: 57 medical records of patients with HR-HPV were analyzed. HPV clearance was evaluated as primary endpoint.

Hospitalet study: Data of 91 HR-HPV patients were evaluated. Primary endpoint: composite efficacy variable (percentage of patients with normal cytology and/or HPV clearance).

Papilobs study: Interim data of 148 HR-HPV patients is presented. HR-HPV clearance was evaluated as secondary endpoint.

Paloma RCT: 66 HR-HPV patients were evaluated. Percentage of patients with HR-HPV clearance was assessed as a secondary endpoint.

**Results** After the 6-month treatment period, 48% and 57% of patients cleared HPV 16–18 and HR-HPV in Vigo and Bari studies, respectively. A reduction of 58% was observed in number of HR-HPV patients (Coruña) and 72.5% of patients negativized cytology and/or cleared HR-HPV (Hospitalet) (p=0.0001 vs baseline for all results, Chi-square). In the Paloma RCT, HR-HPV clearance was observed in 63% of patients treated with Papilocare® vs 40% in the control group. Similar rate of 59% HR-HPV clearance was observed in the interim analysis of the Papilobs study.

**Conclusion** Papilocare® has shown significant and consistent rates of HR-HPV clearance ranging from 50% to 70% in the 6 different studies. This high consistently rate of HR-HPV clearance should be further confirmed in ongoing studies.

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**306 Rationale and Evidence for Emerging Antibody-Drug Conjugates in Gynecological Cancers: Effect of Online Education on Clinician Knowledge**

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**Introduction/Background** A number of targeted antibody drug conjugates (ADCs) are emerging with the potential to become important new treatment strategies for gynecological cancers, including recurrent/resistant ovarian and cervical cancers. This study determined whether online continuing medical education could improve the knowledge of oncologists and obstetricians/gynaecologists (obs/gyns) on the rationale and evidence for emerging ADCs.

**Methodology** A 30-minute online video lecture was launched for physicians outside the USA in December 2019. Data was collected to March 2020. Educational effect assessed with repeated-pairs pre-/post-activity, where individual participants served as their own control. 3 multiple-choice, knowledge questions and 1 self-efficacy, 3-point Likert scale confidence question were analyzed. Chi-squared test assessed pre- to post-activity change (5% significance level, P <.05). Magnitude of change in total number of correct responses overall, and for each question, were determined with Cramer’s V (<.06=Modest, 0.06–0.15=Noticeable, .16–.26=Considerable, >.26=Extensive).

**Results** 49 oncologists and 154 obs/gyns completed pre- and post-activity questions. A positive educational effect was observed for oncologists (considerable effect, V=.217, P=.0002) and obs/gyns (noticeable effect, V=.097, p=.0028) with average% of correct responses increasing 40 to 62% for oncologists and 34 to 43%, for obs/gyns. Participants with 3/3 answers correct increased from pre- to post-activity (6 to 35%) for oncologists and 6 to 12%, for obs/gyns). Improvements in % of correct responses post-activity were seen for all 3 knowledge-based questions on antigen targets, and key trial data for tisotumab vedotin and mirvetuximab vedotin (88%, 39%, 45% improvements for oncologists; 70%, 15%, 16% improvements for obs/gyns). Confidence in knowledge of ADCs also improved post-activity with a total average confidence shift of 38% for oncologists and 32% for obs/gyn. 62% of oncologists’ and 44% of obs/gyns’ responses were reinforced or improved post-activity. 34% of all participants stated they would modify treatment plans as a result of participation in the activity.

**Conclusion** This on-demand, online video lecture resulted in a positive education effect for both oncologists and obs/gyns. However, persistent knowledge gaps are evident, especially amongst obs/gyns, suggesting there is a need for additional education as data on ADCs continues to emerge. Online medical education is valuable in establishing improved knowledge...
of emerging therapies, such as ADCs, as well as identifying areas of continued educational need.

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316 ‘ARE THERE LIMITS TO CURATIVE TREATMENTS?’ – THE IMPACT OF CHEMO-RADIATION IN CERVICAL CANCER PATIENTS

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Introduction/Background Cervical cancer (CC) is the second most frequent gynaecologic tumour and curative treatment often includes concomitant chemo-radiation (RT/ChT). The aim of this study was to assess the early and late impact on quality of life (QOL) of patients treated with this treatment modality.

Methodology Prospective study of patients, treated in a tertiary cancer centre, with RT/ChT (weekly cisplatin) between 2014–2016 with a median follow-up of 54.7 months. QOL was assessed using validated versions of EORTC QLQ-C30 and QLQ-Cx24 questionnaires, looking for 7 principle domains: global health, role function, physical function, social function, financial issues, sexual function and symptoms. For this evaluation two distinct moments were defined: the first one at the first day of treatment and the second one after at least 3.7 years (min-max: 3.7–5.9 years). To avoid bias in long-term questionnaires’ answers (moment two) there were excluded patients that had persistent disease after RT/ChT or recurred after complete response. Patients’ answers were converted, by linear transformation, into 0–100 score intervals. Paired Sample T-test and Wilcoxon Signed Rank Test were used to compare results.

Results 50 patients were included, with average age at diagnosis of 52 years (24–74 years) and stage disease II (FIGO 2009) in 32 (64%). First and second questionnaires were answered by 50 and 34 patients, respectively. There were no differences between the two moments concerning global health (p=.41), role function (p=.72), physical function (p=.21), social function (p=.86) and financial issues (p=.21). An emotional improvement to second evaluation (p=.03) and a decrease in cognitive function (p=.007) were observed. Related to symptoms there were no differences, except for diarrhea that was worse (p=.006) and lymphedema (p=.005) that improved later in time. Although sexual dysfunction seemed similar (p=.21), there was a progressive increase of sexual worry (p=.004).

Conclusion Careful assessment and handling of treatment toxicities is imperative to minimize long term sequelae of curative treatments. Particularly in these survivor’s cohort, focus on cognitive and sexual problems and diarrhea seems extremely important.

Disclosures The authors declare no conflicts of interest.

327 RADICAL HYSTERECTOMY IN EARLY CERVICAL CANCER: CHARACTERISTICS AND OUTCOMES OF A LARGE-CONTROLLED EUROPEAN POPULATION

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Introduction/Background Radical hysterectomy has been for years the primary treatment for early cervical cancer. Recently, a number of retrospective studies and a prospective randomized trial (LACC trial) revealed higher rates of recurrence and death in patients that underwent minimally invasive surgery.

In Europe, we did not count with large-contrasted data. We designed the SUCCOR study, a multicenter, observational cohort study with the primary goal of validating the results of the LACC trial in Europe.

In this study we try to compile all the information obtained in the Succor study to offer a comprehensive picture of the characteristics and outcomes of the surgical treatment of early cervical cancer in this large European population.

Methodology Patients were eligible if they underwent a radical hysterectomy in a European Institution for stage IB1 cervical cancer (FIGO 2009), from January 1st, 2013 to December 31st, 2014.

Results From May 15th to November 15th, 2019, we received data from a total of 1272 patients. 116 patients were excluded. The final cohort was composed of 1156 patients.

The median age of the studied population was 47.12 yo (10.8). 36.6% of patients had undergone a cone biopsy before the radical hysterectomy. The mean preoperative maximum diameter measured by magnetic resonance imaging was 19.58 mm (13.3).

633 (54%) radical hysterectomies were done by laparotomy and all the other 523 (46%) by minimally invasive surgery.

Nerve sparing technique was carry out in 61.8% of cases. Only in 224 cases (19.4%) the sentinel lymph node biopsy was performed with a rate of bilateral identification of 79.7%.

The average length of stay in the hospital was 6.72 days (4.2).

The average number pelvic nodes retrieved was 25.51, showing 12.4% of patients, nodal metastasis.

510 patients (44.1) received any type of adjuvant therapy. Standard radiation plus braquitherapy were the most frequent used modality of adjuvant treatment (54.1 and 43.3% respectively) while concomitant chemoradiation was use in 34.1% of the cases.

After a median follow up of 58 months, the 5-y disease free survival rate was 88.3% and the overall survival rate at 5-y was 94.9%.

Conclusion In this study we have collected the most extensive amount of information ever obtained on radical hysterectomy for cervical cancer in our continent. Even though it is a retrospective registry, the meticulous design of the inclusion and exclusion criteria offers a high level of accuracy when evaluating the surgical outcome of patients with cervical cancer after radical hysterectomy.

Disclosures All authors contributed to writing the manuscript and read and approved the final manuscript.

The authors declare no conflict of interest.
Introduction/Background Embryonal rhabdomyosarcoma (RMS) of the cervix is a rare entity, encountered mainly in the first two decades of life. The literature consists mainly of case reports and few small case series, and no standard treatment guidelines are available. As this is a disease of adolescence, fertility preservation in well selected cases is of paramount importance.

Methodology We report 3 cases of embryonal RMS of the cervix in adolescents, along with their clinical presentation, histopathological features, diagnosis, management tailored to individual cases.

Results To date, two of the patients have been followed for 5 years and the remaining 1 for 2 years. They all remained asymptomatic, with no evidence of recurrent disease on clinical examination and MRI.

Conclusion The embryonal type of cervical RMS is the most frequent type in this age group. Cervical RMS have good prognosis as usually they present early due to clinical features of bleeding or a mass protruding through the vagina. It should be considered as differential diagnosis for continuous vaginal bleeding in a teenager and should be investigated appropriately. The patients diagnosed with RMS should be managed by multidisciplinary team at cancer centre for best outcomes. Given the young age at diagnosis, fertility sparing treatment maintaining the oncological safety is of paramount importance and is associated with long term survival.

Disclosures Nil to disclose.

Abstract 346 Table 1 Comparison of LEEP margin positive vs. negative cases

<table>
<thead>
<tr>
<th></th>
<th>Margin positive (+)</th>
<th>Margin negative (-)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>41.4</td>
<td>40.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤40</td>
<td>39(49.4)</td>
<td>130(53.7)</td>
<td>0.5</td>
</tr>
<tr>
<td>&gt;40</td>
<td>40(50.6)</td>
<td>111(46.3)</td>
<td>0.5</td>
</tr>
<tr>
<td>Pap-smear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>21(26.6)</td>
<td>173(53.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥ASC-US</td>
<td>58(73.4)</td>
<td>118(47.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HPV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16/18</td>
<td>60(75.0)</td>
<td>105(43.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Others</td>
<td>19(24.3)</td>
<td>137(56.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lesion size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥2 cm</td>
<td>58(73.4)</td>
<td>180(74.4)</td>
<td>0.8</td>
</tr>
<tr>
<td>&gt;2 cm</td>
<td>21(26.6)</td>
<td>62(25.6)</td>
<td>0.8</td>
</tr>
<tr>
<td>Lesion size mean (cm)</td>
<td>1.99</td>
<td>1.80</td>
<td>0.06</td>
</tr>
<tr>
<td>Total</td>
<td>79</td>
<td>242</td>
<td></td>
</tr>
</tbody>
</table>

Results A total of 321 patients constituted the study group. Among the study group, 79 (24.6%) patients had margin positivity. Comparison of this group with 242 (75.4%) margin negative patients revealed that abnormal pap-smear and HPV 16 and/or 18 positivity were significantly associated with margin positivity (table 1). Pap-smear abnormality (≥ASC-US) was seen in 58 (73.4%) of margin positive cases whereas only 118 (49.0%) with margin negativity had abnormal smear (p<0.001, OR: 3.1; 95% CI: 1.7–5.6). This risk association did not differ for different Pap-smear abnormality thresholds (LSIL, HSIL etc). Being positive for HPV 16–18 was also a risk factor for margin positivity (75.9% vs. 43.4%, p<0.001, OR: 4.4; 95%CI: 2.45–7.96). However, neither age (φ=0.5) nor the lesion size (φ=0.8) was a significant factor for margin positivity. Among 79 margin positive cases, 33 (41.7%) had re-LEEP, 13 (16.5%) had cold-knife conization, 13 (16.5%) had hysterectomy, and 12 (15.1%) were just followed-up while 8 (10.2%) were lost to follow up after the LEEP procedure. Among patients who had re-LEEP or conization (n=46), 7 patients (15.2%) had still positive surgical margin after the second procedure (5 in re-LEEP (15.1%), 2 in cold knife conization (15.4%)).

Conclusion Patients with HPV 16–18 and/or Pap-smear abnormality (≥ASC-US) should be carefully evaluated before LEEP procedure for a possible margin positivity. In such cases, larger excisions may be considered to decrease the risk of margin positivity especially if the patient has no future fertility desire.

Disclosures No conflict of interest to declare.
Impact of Treatment Modality on Survival of FIGO Stage IIB Cervical Cancer: A Propensity-Score Matching Analysis Based on Surveillance, Epidemiology, and End Results Database

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Introduction/Background Concurrent chemoradiotherapy is the standard of care for FIGO stage IIB cervical cancer. However, there remains a role of surgical treatment in these patients. The aim of this study was to investigate the impact of treatment modality on survival of patients with stage IIB cervical cancer.

Methodology Patients with stage IIB cervical cancer registered in the Surveillance, Epidemiology, and End Results database between 1988 and 2015 were identified and grouped according to their treatment modalities. For patients identified as surgical group, only those receiving both hysterectomy and chemotherapy were included. For patients identified as non-surgical group, only those receiving both beam radiation and chemotherapy were included. A 1:1 propensity score matching (PSM) were performed to adjust the baseline characteristics.

Results A total of 4718 eligible patients were identified, of whom 902 were in the surgical and 3816 in the non-surgical group. Patients undergoing surgery were younger and were more likely to be married, non-Black race, non-squamous cell carcinoma, N1 stage, and have medical insurance, small tumor compared to those receiving non-surgical treatment (P=0.037 for insurance; P<0.001 for all of others). Before PSM, the surgical group showed significantly improved overall survival (OS) compared with the non-surgical group (P=0.005), while the difference in cancer-specific survival (CSS) only approached significance (P=0.084). After PSM, both the differences in OS and CSS between the two groups reached significance (P<0.001, both). In multivariate analysis, the treatment modality was found to be an independent factor for both CSS (hazard ratio [HR] =1.276, 95% confidence interval [CI] 1.084–1.502, P=0.003) and OS (HR=1.312, 95%CI 1.129–1.524, P<0.001). Other independent factors for both OS and CSS included histological type, tumor size and N-stage. Age was an independent factor for OS but not CSS. Subgroup analysis revealed that patients receiving radiotherapy prior to surgery had significantly improved CSS compared with those treated by other modalities (P<0.001), and that the omission of brachytherapy in non-surgical treatment was associated with significantly decreased CSS (P<0.001). Furthermore, for patients with squamous-cell histology, surgical and non-surgical treatments provided similar CSS (P=0.123). However, for patients with non-squamous-cell histology, surgical treatments provided significantly improved CSS compared with non-surgical (P=0.002).

Conclusion The treatment modality has significant impact on survival of patients with stage IIB cervical cancer. Surgical treatment should be preferentially considered in patients with non-squamous-cell histology. Chemoradiotherapy with completion surgery may be the most effective treatment. However,
Introduction/Background There are little data describing the economic burden among newly diagnosed and advanced cervical cancer patients, by line of therapy (L). NCCN recommends the use of systemic treatment for advanced cervical cancer patients. Therefore, this study aimed to assess healthcare costs among newly diagnosed cervical cancer patients and those newly initiating systemic treatments.

Methodology This was a retrospective observational study conducted using the Optum Clininformatics DataMart database. The first cohort consisted of cervical cancer patients newly diagnosed between January 2015 – June 2018, and continuous enrollment for 12 months prior and 6 months post diagnosis. The start of 1L was the date of the first treatment. Treatments initiated within 90 days of a surgery or the end of radiotherapy, and systemic treatment started within 28 days of any previous treatment were part of the same treatment line.

The second cohort consisted of cervical cancer patients with ≥2 claims for systemic therapy (i.e., chemo- or immunotherapy) within a 4-week period between June 2014 – October 2018, and continuously enrolled for 6 months prior and 3 months post therapy initiation. All claims for the same systemic therapy without a >90-day gap, or initiation of a new systemic therapy within 28 days of a previous treatment were attributed to the same treatment line. Claims for adjuvant systemic therapy (i.e., within ±90-days of a cervical cancer-related surgery) were excluded.

The per patient per month (PPPM) components of healthcare costs attributable to 1L and 2L were summarized for both cohorts (figures 1 and 2). Analyses for the second cohort were stratified by the presence of comorbid non-cervical cancers prior to systemic therapy initiation.

Results The first cohort included 655 patients who received at least 1L of which 162 received 2L. The mean PPPM healthcare cost from diagnosis to end of follow-up was $10,121. The mean PPPM healthcare costs (figure 1) attributable to 2L ($15,183) exceeded that of 1L ($10,929).

The second cohort included 1,229 patients who newly initiated 1L of which 357 received 2L. The mean PPPM healthcare cost from initiation of systemic therapy to end of follow-up was $15,463. The PPPM healthcare costs (figure 2) was higher during 2L versus 1L ($22,973 vs $13,044; with prior cancers: $19,822 vs $16,387). Outpatient costs accounted for >70% of total PPPM healthcare costs attributable to 1L and 2L for both cohorts.

Conclusion Moving from 1L to 2L was associated with an increase in healthcare costs which may be indicative of disease progression/recurrence.
standard CCR with weekly Cisplatin plus 3D conformal pelvic radiotherapy followed by brachytherapy (BT) and group B (received the standard CCR and BT). The primary end point: the assessment of response rate and local control. The secondary end points: assessment of the 2 years overall survival (OS) and progression free survival (PFS).

Results The median age was 54 years old and a range of 44 years old with a performance status (0, 1). The majority of patients had squamous cell carcinoma (88.24% group A vs. 94.12% group B) and most of the patients were FIGO stage IIIC, IVA and IIB (41.18%, 32.35% and 20.59% in group A vs. 32.35%, 17.65% and 17.65% in group B respectively). CT abdomen and pelvis done at time of diagnosis showed pathological enlarged lymph nodes in 64.71% and 58.82% of patients in group A and B respectively. After NAC, 97.06% of the patients achieved partial response with a reduction of tumor volume by 76.07% and only 2.94% had stable disease. Higher partial response in groups A (55.88% in group A vs. 32.35% in group B, p value 0.151) and higher overall response rate (ORR) in group A (79.41% vs.70.59%) while local control was higher in group B (91.18% vs. 97.06%, p value 0.614). The 2 years PFS was 91% in group A and 97.1% in group B and OS of 100% as all the patients remain alive till the end of the 2 years follow up.

Conclusion The addition of NAC to the standard CCR achieved a higher partial response rate and ORR with a reasonable local control of the disease. This can facilitate the CCR plane and subsequently the brachytherapy planning parameters in locally advanced cases with no inferiority of the PFS and OS compared to the standard.

Disclosures The authors of this abstract do not have any research support and no conflict of interest.

378 MUCOADHESIVE BILAYER VAGINAL TABLET AS A POTENTIAL ADJUVANT TREATMENT FOR CERVICAL CANCER

Introduction/Background Cervical cancer (CC) is described as cancer that occurs in the cells located in the cervix. Each year, more than 500,000 women are diagnosed with CC and the disease results in over 300,000 deaths across the world. Infection by high-risk oncogenic subtypes of human papilloma-virus (HPV); HPV16 and HPV18, is the cause for almost all cases of CC. In developed countries, CC incidence and mortality have more than halved over the past 30 years as they were able to establish successful national HPV screening and vaccination programs. However, this disease remains persistent and has become one of the leading causes of death among women in developing (low to middle-income) countries; mostly in African countries. Adapting to low resources, developing countries have practiced a feasible and cost-effective solutions with the screen and treat approach instead. Screening usually involves visual inspection with acetic acid (VIA) or Lugol’s iodine (VILI) that gives immediate results, facilitating instantaneous treatment strategies and prevents loss to follow-up. Treatments includes loop electrosurgical excision procedure (LEEP), cryotherapy or cold-knife conization. This research proposes the development of a self-administered chemotherapeutic vaginal tablet formulation that would complement these current treatment strategies.

Methodology The bilayer tablets were prepared one layer at a time, using a single punch direct compression machine. Tablets were then evaluated using the pharmacopeial guideline that include tablet uniformity, hardness, friability and content uniformity. Swelling test was performed by simple immersion of the tablets in dissolution medium for 24 hours, the tablet’s weight before and after were recorded. The drug release profile was evaluated by in vitro drug dissolution test using the USP paddle method in 2% aqueous sodium dodecyl sulphate (SDS) solution; maintained at 100rpm, 37±1°C and in sink conditions. All samples were measured spectroscopically. Cell viability after treatment with the drugs was determined using the MTT assay on Ca-ski cells.

Results Results showed that the tablet of this combination are uniform and durable in compliance to pharmacopeial standards, a swelling study shows promising potential for mucoadhesion and has an extended in vitro drug release profile over 72 hours. In vitro cell culture with Ca-Ski cells however, did not show a synergistic effect but only a small additive effect was observed.

Conclusion A vaginal tablet offers an easy application and direct localized access to the cervix; adjacent to the cancerous tissue. The advantages of vaginal drug delivery include (i) bypassing hepatic first pass-effect; (ii) low systemic drug exposure; and (iii) higher bioavailability. A bilayer tablet provides an opportunity to deliver two active pharmaceutical ingredients (API) simultaneously for a synergistic pharmacological effect. Additionally, the different layers physically avoid chemical incompatibilities. Chitosan and polyacrylic acid are the polymers employed for their mucoadhesive property. These polymers also provide an extended and a controlled drug release rate.

5-flourouracil (5FU) a drug developed and used for the treatment of cancer for more than 50 years was selected as the primary API. Cell studies showed the first combination formulated; 5FU and disulfiram did not show a synergistic effect. Other API will be investigated in combination with 5FU in order to achieve the synergistic effect desired.

Disclosures The authors declare no conflict of interests.

383 CHANGES IN THE PROTEOME OF CERVICOVAGINAL FLUID DURING HPV INFECTION IN HPV-VACCINATED WOMEN

Introduction/Background Cervical cancer (CC) is described as cancer that occurs in the cells located in the cervix. Each year, more than 500,000 women are diagnosed with CC and the disease results in over 300,000 deaths across the world. Infection by high-risk oncogenic subtypes of human papilloma-virus (HPV); HPV16 and HPV18, is the cause for almost all cases of CC. In developed countries, CC incidence and mortality have more than halved over the past 30 years as they were able to establish successful national HPV screening and vaccination programs. However, this disease remains persistent and has become one of the leading causes of death among women in developing (low to middle-income) countries; mostly in African countries. Adapting to low resources, developing countries have practiced a feasible and cost-effective solutions with the screen and treat approach instead. Screening usually involves visual inspection with acetic acid (VIA) or Lugol’s iodine (VILI) that gives immediate results, facilitating instantaneous treatment strategies and prevents loss to follow-up. Treatments includes loop electrosurgical excision procedure (LEEP), cryotherapy or cold-knife conization. This research proposes the development of a self-administered chemotherapeutic vaginal tablet formulation that would complement these current treatment strategies.

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5-flourouracil (5FU) a drug developed and used for the treatment of cancer for more than 50 years was selected as the primary API. Cell studies showed the first combination formulated; 5FU and disulfiram did not show a synergistic effect. Other API will be investigated in combination with 5FU in order to achieve the synergistic effect desired.

Disclosures The authors declare no conflict of interests.
The role of Ki-67, P16 and Bcl-2 in the preoperative measurement of tumor volume in cervical neoplasia

Anca Copos, Diana Mocuta, Cristina Aur, Romina Cur. County Emergency Clinical Hospital of Oradea; University of Oradea, Faculty of Medicine; Obstetrics – Gynecology

Introduction/Background Cervical cancer, a common gynecological tumor, has a high mortality and it seriously threatens the health of the women. The biomarkers of cell proliferation and apoptosis indicate the early carcinogenesis and are useful for future patient monitoring. HPV persistent infection causes overexpression of P16, but this could be also in normal tissue. P16 is important and useful for cervical cancer screening, but combined with other biomarker - Ki-67, which is a marker of cell proliferation. In normal tissues, the simultaneous expression of P16 and Ki-67 is less likely to occur. Bcl-2 is an intracellular membrane protein which prevents apoptotic cell death and it can be used as a biomarker, too.

Methodology We selected a number of 40 paraffin embedded specimens of cervical tissue from patients diagnosed with cervical pathology, who were admitted in our department from 1-st of January 2018 till 31-th of December 2019. The specimens groups were formed by L-SIL (10), H-SIL (10), scamous cervical carcinoma – SCC (10) and nontumoral cervical tissue (10) as control group. For all the specimens was performed the histopathological exam and the immunohistochemistry for Ki-67, P16 protein and Bcl-2 protein. Expression of Ki 67, P16 protein and Bcl-2 was detected and the diagnostic values were analyzed.

Results Positive rates of Ki 67 and P16 expression in H-SIL and SCC groups were significantly higher than those in L-SIL and control group. In our study the expression’s intensity of P16 and Ki-67 was positively correlated with the degree of cervical lesions. The immunostaining for Bcl-2 was highly expressed in cervical cancer tissue, compared with nontumoral cervical tissue. The difference is not well expressed compared to H-SIL and L-SIL.

Conclusion Cervical cancer is the malignant tumor with a known etiology, so that prophylactic measures could be taken. The combination of P16 and Ki-67 can identify patients with high risk of SCC and reduce the rate of misdiagnosis. This is of high value for the differential diagnosis between SCC and H-SIL. Bcl-2 is an important regulator of apoptosis. The relationships of tumor genesis with anti-apoptotic genes and pro-apoptotic genes have been confirmed. Combined with other biomarkers, Bcl-2 could be usefull in assessing the patients’ prognosis.

Disclosures I have nothing to disclose.

Preoperative measurement of tumor volume in early cervical cancer. Is it reliable?

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Introduction/Background Maximum diameter-based tumour measurement is the standard method to assess tumour size and staging pre and postoperatively. Traditionally, clinically estimation of tumour size was the preferred preoperative measuring tool.

Nowadays, thanks to the availability of advanced imaging techniques, preoperative staging could be done more precisely. Several studies have analysed the correlation between the tumour size measured with MRI and ultrasound and final pathology findings.

In this study we analyse not only the correlation of diameter-based tumour size, but also the correlation of tumour volume estimation.

Methodology A secondary analysis of the SUCCOR study was performed (European patients with FIGO 2009 stage IB1 cervical cancer that underwent radical hysterectomy from January 1st, 2013 to December 31st, 2014). Patients with previous conization were excluded. Patients with at least 3 different tumour measurements both in MRI or ultrasound and in the final pathology report were included. The 3 diameters measured to calculate the volume were defined as: craniocaudal diameter (dcc); anteroposterior diameter (dap) and the largest lateral diameter (dl).

Tumour volume estimation was calculated using the ellipsoid formula $V = \frac{4}{3} \pi \times \text{dcc} \times \text{dap} \times \text{dl} \times \pi/6$. Intraclass Correlation Coefficient (ICC) was applied to study the correlation of diameter-based tumour size and tumour volume estimation between MRI and pathology report and Ultrasound and pathology report.

Results 693 patients were included in the final analysis of SUCCOR study. 137 of them had both preoperative MRI with 3 different measures (Anteroposterior, Craniocaudal and largest lateral diameter) and pathology report. 81 patients had the 3 diameters measured preoperatively by ultrasound.

When performing a preoperative MRI, the ICC between MRI and final pathology for maximum diameter size was 0.71 (0.61–0.78) and for tumour volume 0.53 (0.38–0.64).
Preoperative ultrasound compared to final pathology report showed a ICC of 0.87 (0.8–0.91) for maximum diameter size and 0.64 (0.4–0.78) for tumour volume measurement.

Conclusions: Maximum diameter size showed a good correlation (ICC=0.75–0.9) with the pathology report when measured preoperatively by ultrasound and a moderate correlation (ICC=0.5–0.75) when measured by MRI. For tumour volume measurement both ultrasound and MRI showed a moderate correlation with the final pathology report.

Disclosures: All authors contributed to writing the manuscript and read and approved the final manuscript.

The authors declare no conflict of interest.

442 SHOULD WE REALLY ABANDON MINIMALLY INVASIVE SURGERY IN EARLY-STAGE CERVICAL CANCER? ONCOLOGICAL RESULTS OF LAPAROSCOPICALLY ASSISTED RADICAL VAGINAL Hysterectomy

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Abstract 442

Introduction: Background: Recent evidence indicates that some minimally invasive surgery (MIS) approaches, such as laparoscopic- and robotic-assisted radical hysterectomy, offer lower survival rates to patients with early-stage cervical cancer compared with open radical hysterectomy. We evaluated the oncological results of a different MIS approach, that of laparoscopically assisted radical vaginal hysterectomy (LARVH) in the treatment of patients with early-stage cervical cancer.

Methodology: From January 2001 to December 2018, patients with early-stage cervical cancer (IA1 with lymphovascular invasion, IA2, IB1, and IIA < 2 cm; FIGO 2009) were treated by LARVH. Colpotomy and initial closure of the vagina were performed following the Schauta procedure, avoiding manipulation of the tumor. Laparoscopic sentinel lymph node (SLN) biopsy was performed in all cases. Women treated between 2001 and 2011 also underwent systematic bilateral pelvic lymphadenectomy after SLN biopsy. Adjuvant radiotherapy or chemoradiotherapy was administered according to standard guidelines.

Results: One hundred fifteen patients were included. Intraoperative complications occurred in nine patients (7.8%). Adjuvant radiotherapy or chemoradiotherapy was administered to 35 (30.4%) and three (2.6%) patients, respectively. After a median follow-up of 87.8 months (range 1–216), seven women (6%) presented recurrence (three pelvic and two paraaortic recurrences, and two had distant metastases). Four women died (mortality rate 3.4%). The three and 4.5-year disease-free survival rates were 96.7% and 93.5%, respectively, and the overall survival was 97.8% and 94.8%, respectively.

Conclusion: LARVH offers excellent disease-free and overall survival in women with early stage cervical cancer and can be considered as an adequate MIS alternative to open radical hysterectomy.

Disclosures: No disclosures to declare.

445 IMPACT OF AGE ON CANCER SPECIFIC SURVIVAL IN PATIENTS WITH LOCALLY ADVANCED CERVICAL CANCER

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Abstract 445

Introduction/Background: Cervical Cancer (CC) is uncommon in very young (<35 years) and in geriatric women (> 65 years), age as a prognostic factor is still controversial. The extremes of life had certain risk factors for being diagnosed with locally advanced cervical cancer (LACC); one of them is that in young women, there is a belief that the disease does not occur; therefore, lack of knowledge of the signs, symptoms and, as an essential factor, a lack of adherence to screening is common. In women older 65 years, the screening has been suspended, explaining how this group of women tend to be diagnosed in advanced stages.

This work aims to compare sociodemographic, clinical, and pathological characteristics, response to treatment, disease-free survival, overall survival, and cancer-specific survival in patients with LACC treated with concurrent chemoradiotherapy, clustered by age.

Methodology: It is a retrospective study in patients with LACC treated at the National Cancer Institute of Mexico City from 2005 to 2014. A descriptive, comparative, and survival and cancer specific analysis was conducted.

Results: From a total of 2,091 patients with LACC, we found 125 patients (9.7%) younger than 35 years (group 1), 533 (41.35), age between 36–50 years (group 2), 444 (34.4%) between 51–65 years (group 3) and 189 (14.6%) between 66 years or older. The general characteristics are found in table 1. More than 50% of women from group 4...
were illiterate. The patients from groups 1 and 2 clinical stage IB2 was more common. Pre-treatment haemoglobin was lower in groups 1 and 2 vs. groups 3 and 4, and 58.4% of the patients in group 1 required at least one blood transfusion. Cancer-specific survival was different between groups 1 and 2 vs. 3 and 4, p=0.048 (figure 1). Multivariate analysis showed that clinical-stage, Hazard ratio (HR) 3.62 (CI 95% 1.59–8.20), pre-treatment haemoglobin HR 0.944 (CI 95% 0.89–0.99), and age HR 1.28 (CI 95% 1.02–1.64) are independent prognostic factors in patients with LACC, with lack of significance in disease free survival and overall survival.

Conclusion There are demographic, clinical, and treatment response differences between very young and young patients (under 50 years) compared to older patients (over 50 years). Cancer-specific survival, which attempts to remove the bias of advanced age in mortality, showed that women younger than 50 years had higher cancer-related mortality than those of older ages.

Disclosures The authors reports no conflicts of interest.
INTRODUCTION/BACKGROUND
At the time of diagnosis, locally advanced stages in cervical cancer is a common finding and considered the most important prognostic factor, accounting for up to 70% of cases in low-middle-income countries. Recurrence of disease is more frequent in the first two years (8 to 61% depending on the clinical stage). Late recurrence (beyond 5 years) is relatively common (0.4–7.5%). Overall survival after diagnosis of recurrence is 50.5% at two years and 22.3% at five years.

This study aims to analyse the recurrence patterns according to presentation time in patients with locally advanced cervical cancer (LACC).

METHODOLOGY
This is a retrospective study in patients with LACC who had complete response after treatment with concurrent chemoradiotherapy followed by brachytherapy treated from January 2005 to December of 2014 at the National Cancer Institute in Mexico City.

RESULTS
Of 1045 patients with LACC and complete response, 334 (32%) presented recurrence of disease. Two hundred patients (59.9%) relapsed before 2 years (group 1), 88 (26.3%) between 2–5 years (group 2), and 45 (13.5%) after 5 years (group 3). The median age was 50 years of age (range 22–75 years), with no differences between groups. Distant recurrence occurred in 81% of the patients in group 1, 75% in group 2 and 57.8% in group 3, p= 0.007. There are no differences in survival after recurrence between the groups.

Conclusion Late recurrence is a common event in LACC, these patients have less risk of having distant disease at time of diagnosis; the prognosis after the recurrence depends on the site, with statistically significant differences between local recurrence vs. locoregional and distant recurrence but not when the disease recurs. In a high-volume centre, it is important to continue follow-up of patients with LACC because of the risk of having recurrent disease after five years of treatment.

DISCLOSURES
The authors reports no conflicts of interest.

Abstract 479 Table 1

<table>
<thead>
<tr>
<th>Grade</th>
<th>Leucopenia (%)</th>
<th>Neutropenia (%)</th>
<th>Lymphopenia (%)</th>
<th>Thrombocytopenia (%)</th>
<th>Anemia (%)</th>
<th>Maximum HT(%)</th>
<th>Maximum clinical HT(%)</th>
</tr>
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<tr>
<td>0</td>
<td>3 (10%)</td>
<td>9(30%)</td>
<td>0</td>
<td>5(16.7%)</td>
<td>5(16.7%)</td>
<td>0</td>
<td>1(3.3%)</td>
</tr>
<tr>
<td>1</td>
<td>4 (13.3%)</td>
<td>6(20%)</td>
<td>0</td>
<td>15(50%)</td>
<td>13(43.3%)</td>
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<td>5(16.7%)</td>
</tr>
<tr>
<td>2</td>
<td>8 (26.7%)</td>
<td>9(30%)</td>
<td>1(3.3%)</td>
<td>7(23.3%)</td>
<td>10(33.3%)</td>
<td>0</td>
<td>9(30%)</td>
</tr>
<tr>
<td>3</td>
<td>12 (40%)</td>
<td>3(10%)</td>
<td>10(33.3%)</td>
<td>2(6.7%)</td>
<td>2(6.7%)</td>
<td>11(36.7%)</td>
<td>12(40%)</td>
</tr>
<tr>
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<td>3 (10%)</td>
<td>3(10%)</td>
<td>19(63.3%)</td>
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<td>19(63.3%)</td>
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<tr>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Maximum clinical HT includes only WBC, neutrophil and platelet gradings.
INCIDENCE OF SEXUAL DYSFUNCTION AMONG LOCAL AND SYSTEMIC CHANGES ASSOCIATED WITH THE A20

Evaluating their female sexual function will help identify the healthcare needs, but only one-third seek professional help. However, little is known about how sexual dysfunction affect their quality of life since many of them report psychosexual healthcare needs, but only one-third seek professional help. Evaluating their female sexual function will help identify the presence of sexual dysfunction among cervical cancer survivors, provide appropriate intervention and improve their quality of life.

Methodology The study used a prospective, cross-sectional survey design that employed a self-administered questionnaire using the Female Sexual Function Index (FSFI) to identify the presence of sexual dysfunction among cervical cancer patients in a tertiary medical center from June to December 2019. Descriptive statistics were reported to describe the distribution of patients in terms of the different numerical variables, whereas frequency and simple percentage were used to determine the distribution of respondents in terms of the different categorical variables.

Conclusion Significantly worse Thrombocytopenia and lymphopenia was seen compared to published data. However, there is heterogeneity in patient populations and treatments within existing studies with little data on the effects of extended field radiotherapy, lymphnode boosts or induction chemotherapy. We are therefore conducting a dosimetric analysis to investigate if bone marrow sparing VMAT could reduce the toxicity in this population of patients.

Disclosures None.

Abstract 479 Table 2 Comparison with published haematological toxicity data for cancer chemoradiotherapy with IMRT/VMAT

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reported %</th>
<th>Comparator value</th>
<th>UCLH %</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3 or more neutropenia</td>
<td>2.7-19.2% 3-12</td>
<td>10%</td>
<td>20%</td>
<td>0.073</td>
</tr>
<tr>
<td>Grade 2 or more thrombocytopenia</td>
<td>2.7-11.2% 3-11</td>
<td>8%</td>
<td>33.3%</td>
<td>0.000</td>
</tr>
<tr>
<td>Grade 3 or more lymphopenia</td>
<td>22.5% 13</td>
<td>22.5%</td>
<td>96.3%</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Introduction/Background Gynecologic cancers greatly affect a woman’s sexuality, sexual functioning, intimate relationships, and sense of self. Twenty-three to seventy percent of cervical cancer survivors report problems with their sexual functioning. However, little is known about how sexual dysfunction affect their quality of life since many of them report psychosexual healthcare needs, but only one-third seek professional help. Evaluating their female sexual function will help identify the presence of sexual dysfunction among cervical cancer survivors, provide appropriate intervention and improve their quality of life.

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Conclusion Forty-two cervical cancer patients were assessed. The mean age of the studied population was 44.85. More than half was married (59.52%), and majority was from Cebu City (66.78%). Approximately 43% (42.86%) finished college and were mostly catholics (69.05%). The mean age of diagnosis was 42.85, with an average gravidity and parity of 1. Most of the patients interviewed were diagnosed with stage 3B cervical cancer (42.86%). The mean overall Female Sexual Function Index (FSFI) score of the studied population was 6.59, which indicated that all of the patients studied had female sexual dysfunction.

Conclusion All the cervical cancer patients included in this study had female sexual dysfunction as evidenced by the low FSFI scores in each of the 6 dimensions and low overall FSFI score.

Disclosures None.

485 INCIDENCE OF SEXUAL DYSFUNCTION AMONG CERVICAL CANCER PATIENTS IN A TERTIARY MEDICAL CENTER TREATED WITH CHEMORADIATION FROM JUNE TO DECEMBER 2019

Thaila Tubungbanua, Helen Amorin. Vicente Sotto Memorial Medical Center; Obstetrics and Gynecology

10.1136/ijgc-2020-ESGO.39

Introduction/Background Gynecologic cancers greatly affect a woman’s sexuality, sexual functioning, intimate relationships, and sense of self. Twenty-three to seventy percent of cervical cancer survivors report problems with their sexual functioning. However, little is known about how sexual dysfunction affect their quality of life since many of them report psychosexual healthcare needs, but only one-third seek professional help. Evaluating their female sexual function will help identify the presence of sexual dysfunction among cervical cancer survivors, provide appropriate intervention and improve their quality of life.

Methodology The study used a prospective, cross-sectional survey design that employed a self-administered questionnaire using the Female Sexual Function Index (FSFI) to identify the presence of sexual dysfunction among cervical cancer patients in a tertiary medical center from June to December 2019. Descriptive statistics were reported to describe the distribution of patients in terms of the different numerical variables, whereas frequency and simple percentage were used to determine the distribution of respondents in terms of the different categorical variables.

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Conclusion All the cervical cancer patients included in this study had female sexual dysfunction as evidenced by the low FSFI scores in each of the 6 dimensions and low overall FSFI score.

Disclosures None.

488 LOCAL AND SYSTEMIC CHANGES ASSOCIATED WITH THE INNATE IMMUNE RESPONSE AND IMMUNOREGULATORY MECHANISMS RESPONSIBLE FOR THE ESTABLISHMENT AND PROGRESSION OF INVASIVE CERVICAL CARCINOMA

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10.1136/ijgc-2020-ESGO.40

Introduction/Background The mechanisms of innate immune response and the immune checkpoint (IC) system-governed mechanisms are the two interconnected areas currently becoming the focus of world research in view of the prospects for therapeutic reactivation of antitumor immunity. This may be especially relevant to virus-associated cancers (as, for example, most cases of cervical cancer), which are known to develop as a result of persistent infection, long-term antigen exposure and are frequently characterized by chronically inflamed environment and local and/or systemic immunosuppression. Studying the immune changes that accompany the earliest stages of tumor progression may provide insight into the mechanisms driving the onset of metastasis; and, in this respect, systemic changes observed in peripheral blood (PB) may possibly reflect local dysfunctions at the tumor site. In case of cervical cancer, these assumptions need more extensive research evidence.

Methodology To characterize the changes in the local microenvironment, we compared the transcriptomes of the early invasive squamous cell cervical cancer and its precursor high-grade
lesions by performing RNA-sequencing and bioinformatics analysis on a panel of 12 fresh tissue samples comprising HPV(+) cervical intraepithelial neoplasia 3 (CIN3) and carcinoma at FIGO IA1-IIB stages, plus normal epithelium. PB samples were obtained from women with CIN3 and stage IA cancer immediately prior to treatment; PB from healthy women was used as control. Subsets of PB lymphocytes were phenotyped using multicolor flow cytometry.

**Results**

Among the differentially expressed genes identified, there were a considerable number of genes that, according to Gene Ontology, are responsible for inflammatory and innate immune responses (including interleukin type I and II pathways) and belong to the system of self/non-self DNA/RNA recognition, with multiple anti-inflammatory factors found to be down-regulated, while a spectrum of interferon-stimulated genes, anti-viral/anti-microbial factors, pro-inflammatory cytokines, as well as markers of immune suppression were found up-regulated in invasive cancer. Accordingly, 'Influenza A' and 'Pyrimidine metabolism' KEGG pathways appeared to be significantly enriched. SPEED enrichment analysis revealed the TLR-, TNF alpha-, and IL1-dependent signalings among the top pathways lying behind the alterations of gene expression patterns observed at the initial stage of invasion. PPI network analysis confirmed close interrelation of differently expressed genes encoding molecular components of inflammatory response and virus recognition system. Among the circulating lymphocyte functional markers that may mirror the described immune alterations, the expression of CD161 in iNKT/NK-like T/NK cells (defined by CD3/CD56, Va24Ja18/Vb11-TCR, and CD4/CD8), the level of CD27 and delta2/delta1 ratio in Tgammadelta subpopulation (defined by CD3/TCRgd), and co-expression pattern of PD1/PDL1/LAG3/TIM3 in 4 subsets of CD4/CD8 T cells defined by the level of CD25/CD127, as well as in NK/NKT cells, were measured, and specific correlated differences between the control and cancer groups and between different lymphocyte populations were detected.

**Conclusion**

The findings suggest deep involvement of the inflammation-associated and IC-mediated mechanisms and coordinate contribution of various T cell subsets with innate-like properties in initiation and promotion of invasive growth of cervical carcinoma both at local and systemic levels.

**Disclosures**

The study was supported by the state assignment of the Ministry of Science and Higher Education, project No.0752-2020-0007 (AAAA-A20-12007290151-6). The authors declare no conflicts of interest.

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**THE EFFECT OF OTHER HIGH-RISK HPV TYPES ON CERVICAL INTRAEPITHELIAL NEOPLASIA AND CANCER**

Seda Sahin Aker, Frat Ortaç, Ankara University Faculty of Medicine; Gynecologic Oncology

10.1136/ijgc-2020-ESGO.41

**Introduction/Background**

Cervical cancer is the most common gynecologic cancer in worldwide with an incidence of 13,1/100.00 and has a high mortality rate of 6,9/100.000. High-risk human papilloma virus (HPV) is the main cause of cervical squamous intraepithelial lesions and invasive cervical cancer. HPV 16 and HPV 18 are the most leading types in cervical cancer and cervical neoplasms. Some studies found a significant effect of other high-risk HPV types on cervical carcinogenesis some found non-significant. The effect on cervical carcinogenesis of co-infections with other high risk HPV types remains unclear. The purpose of this study is to evaluate the influence risk of cervical carcinogenesis of the other high risk HPV types.

**Methodology**

From January 2016 to May 2020, patients who screened with cotest (pap smear and HPV DNA) and had a high risk HPV DNA positivity underwent a colposcopic analysis and biopsy enrolled the study. Patients evaluated from a Gynaecologic Oncologist or a trained fellow of Gynaecologic Oncology at department of Gynecologic Oncology of Ankara University Faculty of Medicine. Patients who have a high risk HPV positivity, age between 25–65 and non vaccinated for HPV included in the study. The exclusion criteria were pregnant patients, age <25 and >65, treated before for cervical intraepithelial neoplasia, missing medical records, radiation therapy and total hysterectomy history.

**Results**

Table 1 summarizes the demographic data of the patients. CIN2+ results are seen mostly at HPV 16 group (n=60, 36,4%) then respectively nonHPV 16/18 (n=40, 24,2%), HPV 18 ( n= 36,21,8%), non 16/18+16/18 (n=29, 17,6%) group. CIN 2+ results was found in 44,2% (n= 73), 35,8% (n=59), 12,7% (n=21), 7,3% (n=12) of patients with NILM, HSIL, ASCUS and LSIL respectively. Postmenopausal status taken as a reference; a significant difference was observed in premenopausal patients (OR= 2,688, 95% CI = 1,494–4,836 ). Gravidity and number of colposcopic biopsy...
had a statistically significant effect on CIN2+ results (OR=1.155, 95% CI=1.006–1.326, OR=1.964, 95% CI=1.531–2.519). nonHPV16/18 had taken as a reference the other HPV groups had a statistically significant effect on CIN2+ results, HPV 16 (OR = 3.099, 95% CI = 1.933–4.968), HPV 18 (OR= 4.834, 95% CI=2.715–8.608), nonHPV16/18 +HPV16/18 ( OR=3,324, 95% CI= 1,851–5,969). The most effective variable on CIN2+ results is endocervical curettage (OR= 28,571, 95% CI=17,355–47,037). The effect of cytology results ASCUS had taken as reference value, NILM and LSIL had no significant effect ( p=0,759 and p= 0,553 respectively). HSIL had a statistically significant effect on results (OR= 17,325, 95% CI=7,883–38,077). Table 2 shows HPV genotypes and association of <CIN2 and CIN2+ results.

Conclusion Almost fifty percent of HPV 18 and nonHPV16/18+HPV16/18 types are associated with CIN2+ lesions. Non16/18 HPV types are associated with a 17% percent of CIN2+ lesions. According to cytology results 44,2% of patients have negative cytology and non16/18 HPV types have 42,5% percent of negative cytology. So non16/18 HPV types are not mostly associated with high grade lesions but detected high lesions are mostly associated with negative cytology.

Disclosures The authors declare no conflicts of interest.

497 UROLOGICAL COMPLICATIONS OF CERVICAL CANCER TREATMENT: A RETROSPECTIVE ANALYSIS OF 420 PATIENTS

Introduction/Background Cervical cancer is oftentimes plagued by several urological complications during or post treatment. Early disease is mainly managed with radical hysterectomy, while more advanced disease is usually treated by chemoradiation. Although urological complications of cervical cancer treatment have declined during the past decades, owing to improvements in various therapeutic modalities, the incidence of those complications has not yet precisely defined.

Methodology Cervical cancer patients between 2009 and 2020 were retrospectively reviewed from the cancer database of our tertiary institution.

Results 420 women were diagnosed with cervical cancer of any stage in our cancer hospital. 122 (29%) of those women had early stage disease and thus were managed with radical hysterectomy (RH); the remaining 294 (71%) underwent chemoradiation, chemotherapy, or palliative therapy. 5 out of 122 RH patients (4%) experienced urological adverse events, and namely intraoperative ureteric injury, intraoperative and urinary bladder injury and postoperative ureteral necrosis. One patient (0.8%) was managed with primary end to end ureteral anastomosis, another (0.8%) with intraoperative bladder repair, one patient (0.8%) had Boari flap formation, and two (1.6%) underwent ureteral reimplantation (reoperation on the 10th and 14th postoperative day respectively). In 24 RH patients (19.6%) prophylactic cystoscopic ureteral stenting had taken place before the operation. As for the non RH group (294 patients) 10 (3.4%) had prophylactic cystoscopic stenting, while 3 patients (1%) underwent nephrostomy placement.

Conclusion Cervical cancer management –either surgical or conservative -is often accompanied by various urological complications. Prophylactic ureteral stenting, meticulous surgical technique, prompt diagnosis and management of urological adverse events are of paramount importance when dealing with cervical cancer.

Disclosures The authors declare no conflicts of interest.

525 CONCURRENT CHEMORADIOOTHERAPY FOLLOWED BY SURGERY FOR CERVICAL CANCER: A MULTICENTER RETROSPECTIVE STUDY OF 126 CASES

Introduction/Background Cervical cancer is the third leading cause of cancer death in women worldwide. Radio-
chemotherapy significantly improved overall survival rates, without recurrence, and reduced the rate of distant metastatic dissemination. The objective of this work is to describe the histological response of cervical cancer treated with concomitant radiotherapy and chemotherapy (CCRT) followed by surgery, as well as the preoperative difficulties and morbidity related to surgery

Methodology This is a retrospective study of 126 patients treated for cervical cancer by CCRT followed by surgery at the Med VI Center for Gynecologic and Breast Cancer Treatment at the UHC Ibn Rochd from January 2016 to December 2018.

Results The average age of the patients was 51, the mean total time from symptom onset to medical consultation was 7,5 months. Stage IIB was the discovery stage in 71% of the patients. Cervical biopsy results showed squamous cell carcinoma in 79%, adenocarcinoma in 16% and 5% of patients had other histological types.

All of our patients received a weekly chemotherapy of 40 mg of cisplatin, 4 cycles on average, associated with external radiotherapy sessions reaching 45 and 50 Gy supplemented by brachytherapy for 68 patients, 46% of patients were referred for surgery without additional brachytherapy most often due to lack of means. Surgical treatment, radical hysterectomy with salpingo-oophorectomy and bilateral pelvic lymphadenectomy was performed in 91.26% and 75.53% had a radical hysterectomy due to peroperative difficulties. The tumor residue was macroscopic in 29 patients. The surgical margins were positive in 8 cases. Parameters were invaded in 3 patients, 22 cases showed positive vascular emboles, Lymph node curage was positive in 14 cases.

Conclusion The overall treatment period is a main prognostic factor and second surgery following CCRT remains a great concern because of its morbidity.

Disclosures The authors declare they have no conflict of interest

## 553 Preoperative Brachytherapy Followed by Laparoscopic Hysterectomy: A New Option to Consider for Early Stages Cervical Cancer in the Light of the LACC Trial Results

Clemence Beyer, Houssein El Haji, Laurence Gonzalez, Leonel Varela, Camille Jauffret, Guillaume Blache, Laura Sabiani, Gilles Houvenaeghel, Magalie Provansal, Renaud Sabatier, Eric Lambaudie.

**Material and Methods** This retrospective study was conducted at the Marseille regional tertiary cancer center in France for patients treated for ESCC (FIGO 2018 stages IA1-IB2) between 2001 to 2012. All patients underwent a Querleu Morrow Type A hysterectomy (laparotomy and minimally invasive). The primary endpoint was the Disease Free Survival (DFS) and the secondary endpoint was the morbidity related to this radio-surgical multimodal approach.

**Results** A total of 138 patients were included. Histological analysis showed a complete response in 68 patients (49.3%) and a residual tumor < 1 cm in 36 patients (26%).

With a median follow up of 132 months (60 – 204 months), DFS was 93.5% and 9 recurrences occurred (1 local pelvic recurrence, 2 pelvic lymph node recurrences and 6 distant recurrences).

In univariate analysis, we found that a duration between the completion of brachytherapy and surgery exceeding 52 days is associated with a significant decrease in DFS (p = 0.004, OR = 8.5, 95% CI (1.5; 48.7)). Pathological complete response was found to be associated with an increased DFS (p = 0.03 OR = 6.1 95% CI (1.8; 55.3)).

The brachytherapy related rate of late complications was 17.3% (n=24) (Chassagne glossary) and the surgery related urinary tract complications rate was 6.5% (n=9), with only 2 patients (1.5%) presented grade 3 complications (Clavien Dindo classification).

**Conclusion** After a median follow up of 132 months, the multimodal radio-surgical management of ESCC (FIGO 2018 Stages IA1-IB2) consisting of POBT followed by a Querleu Morrow Type A hysterectomy appears to be a reasonable alternative to upfront open radical hysterectomy particularly in patients with high risk ESCC (<2 cm associated with negative prognostic factors or for tumors measuring between 2 and 4 cm).

This multimodal radio-surgical approach is associated with a low rate of complications and a reasonable rate of local recurrences compared to the results of the LACC trial. Further studies are necessary to confirm these results.

**Disclosures** Doctors Clémence Beyer, Houssein El Haji, Laurence Gonzalez, Leonel Varela, Camille Jauffret-Fara, Guillaume Blache, Laura Sabiani, Magalie Provansal and Renaud Sabatier have no conflicts of interest or financial ties to disclose.

Gilles Houvenaeghel and Eric Lambaudie are proctors for Intuitive Surgical.
infundibulo-pelvic pedicle stump, followed by the development of the retroperitoneal space with the identification of the umbilical artery, the iliac vessels and laterally the psoas muscle with the genito-femoral nerve. Paravesical and pararectal spaces are developed down to the pelvic floor. A radical pelvic lymphadenectomy is performed bilaterally. Once lymph node involvement is excluded, we proceed to parametrectomy.

Radical parametrectomy is started with the dissection from the posterior leaf of the broad ligament. The anterior division of the internal iliac artery (IIA) is identified and from the posterior leaf of the broad ligament. The anterior parametrectomy.

Division of the internal iliac artery (IIA) is identified and separated from the medial leaf of the peritoneum down to the ureteral tunnel below the uterine artery and to their entrance into the bladder. Aided by the vaginal probe, the bladder peritoneum is incised, and the bladder is dissected and mobilized inferiorly down to the middle third of the vagina. After dissection of the bladder pillar, the vesico-vaginal space is joined to the paravesical space, completely separating the bladder from the anterior vaginal wall. In cases of anatomical distortion or bladder adhesions, instillation of 300cc of saline solution associated with Methylene blue dye in the bladder might be required to guide the dissection. Posteriorly, the peritoneum is incised at the level of the cul-de-sac of Douglas and the rectovaginal space is developed isolating the uterosacral ligaments. The proximal parametrium and para-tumoral spaces are finally dissected as in a Type B1 Querleu Morrow radical hysterectomy.

The same procedure is performed on both sides. A circular incision is made about 3 cm below the vaginal cuff aided by upward vaginal traction.

Results When compared to Radiation therapy RP presents a lower rate of late complications, making it the preferred approach to treat younger patients. Traditionally performed via laparotomy, minimally invasive approach is now proven feasible and effective.

Conclusion This article presents a focused anatomic review and describes the surgical technique of the five-port robotic assisted radical parametrectomy.

Disclosure Eric Lambaudie and Gilles Houvenaeghle report grants and personal fees from Intuitive Surgical, outside the submitted work.

The authors have no other conflicts of interest to declare.

Enhanced Recovery after Surgery (ERAS) for Para-aortic Lymphadenectomy—a New Trend to Consider?

Isabelle Masquin, Houssein EL Hajj, Christophe Zemmour, Camille Jauffret-Fara, Guillaume Blache, Laura Sabiani, Clément Brun, Marion Faucher and Houssein El Hajj

In gynecologic malignancies, para-aortic lymphadenectomy (PAL) is indicated for either diagnostic or therapeutic finalities. Minimally invasive surgery (MIS) constitutes the cornerstone for ERAS programs.

Methods This retrospective study conducted between November 2006 and January 2018, aims to analyze the role of ERAS implementation for patients undergoing PAL. Starting in 2016, an ERAS protocol was implemented for all the patients in our institution. All patients who underwent PAL for gynecologic malignancies were included in this study. To analyze the impact of this implementation on the surgical outcomes (length of hospital stay (LOS)) and the post-operative complications, we compared the patients who underwent PAL within ERAS protocol between 2016 and 2018 ‘ERAS Group’ to the patients who underwent PAL prior to this implementation (between 2006 and 2015) ‘Prior to ERAS group’.

Results A total of 193 patients were included. ‘ERAS Group’ was associated with a significant decrease of median LOS (2 days vs. 3 days, p<0.001) and a significant increase in earlier post-operative discharges: OR=29.62 [13.58–64.64], p<0.001. Two factors were independently associated with early post-operative discharge: Implementation of the ERAS protocol (OR=25.64 [8.14–80.71], p<0.0001) and the endorsement of the extraperitoneal technique for PAL (OR=5.92 [2.10–16.68], p=0.0008). There was no difference in intra-operative complications rate between groups (p=0.497). More post-operative complications were found in the ‘ERAS group’ (23% vs 10%, p=0.017) but this difference was not significant for severe complications (p=0.277) and lymphocele rate (p=0.248).

Conclusions Implementing ERAS protocols for patients undergoing minimally invasive PAL is an independent factor improving early recovery and decreasing the LOS without increasing severe complications.

Disclosure Drs Isabelle Masquin, Mellie Heinemann, Christophe Zemmour, Camille Jauffret-Fara, Guillaume Blache, Laura Sabiani, Clément Brun, Marion Faucher and Houssein El Hajj have no conflicts of interest or financial ties to disclose. Gilles Houvenaeghle and Eric Lambaudie are proctors for Intuitive Surgical.

Diagnostics

A NEW PROPOSAL FOR THE CLINICAL CLASSIFICATION OF VULVAR LICHEN SCLEROSUS: AN OBSERVATIONAL PROSPECTIVE STUDY

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Introduction/Background Vulvar Lichen Sclerosus (VLS) is a chronic inflammatory disorder which commonly affects the female anogenital epithelium, leading to scarring, anatomical
distortions, impaired sexual function, decreased quality of life and increased vulvar cancer risk.

An agreement to measure VLS severity in a standard way is yet to be defined and, to our knowledge, no standardized clinical classification of anatomical modifications in VLS has been validated.

The purpose of this study was to prepare a clinical classification for VLS aimed at defining the morphological patterns of this condition, while stratifying them into grades. The classification is intended to provide a homogeneous and reproducible description of the different features of this disease. It also serves as an important tool for the evaluation of the course of the disease over time, response to treatment, and for comparison of clinical studies.

Methodology A board of seven specialists with expertise in vulvar pathology were asked to outline the anatomical criteria for the definition of VLS severity (phimosis of the clitoris, resorption of the labia minora, involvement of the interlabial sulcus, and narrowing of the vulvar introitus), identifying five grades to be used to build-up of a score model. The classification was validated by 13 physicians upon pictures of 137 consecutive patients. Each physician individually assigned a grade to each case, according to the abovementioned criteria. Interrater agreement among evaluators was analysed by means of ICC (Intraclass Correlation Coefficient). Intra-observer reproducibility and inter-observer concordance in vivo were analysed by means of Kappa index.

Results This study provides a new classification of VLS, based on defined anatomical criteria and graded into mutually exclusive progressive classes (table 1).

The ICC analysis showed a substantial agreement in the attribution of the grade of VLS among the 137 cases, ICC=0.89 (0.87–0.91), both in the expert and in the non-expert group (ICC=0.92 and 0.87 respectively). An ‘almost perfect’ agreement was achieved for intra-observer reproducibility and among physicians in vivo (Kappa 0.93).

Conclusion Our classification showed a high accuracy in defining morphological modifications in VLS. It is easy to use, reproducible, and can be applied by different health care providers in daily clinical practice and in all clinical settings.

Disclosure Nothing to disclose.

Diagnostic Value of HE4, CA-125, ROMA and CPH-I for Preoperative Assessment of Ovarian Tumors

Introduction/Background Among patients with adnexal masses, preoperative identification of epithelial ovarian cancer (EOC) or metastatic cancer in the ovary (MCO) is essential for surgical planning. Our aim was to assess the performance of CA125, HE4, and the probability models, Risk of Ovarian Malignancy Algorithm (ROMA) and Copenhagen Index (CPH-I), to preoperatively identify EOC or MCO.

Methodology We performed a single center retrospective study including women who underwent surgery for an ovarian tumor between January 2000 and December 2018. We defined two study groups: one group comprising women with benign pathology and borderline epithelial ovarian tumors and a second group comprising women with EOC or MCO. We computed sensitivity, specificity and predictive values of CA125, HE4, ROMA and CPH-I at different cutoff points. We performed receiver operative curve analysis for tumor markers, CPH-I and ROMA models. We performed subgroup analysis including only premenopausal, postmenopausal women, stage I EOC and women harboring ovarian tumors with inconclusive diagnosis of malignancy by ultrasound features.

Results One thousand seventy-one patients were included, 852 (79.55%) presented benign or borderline epithelial
Abstract 311 Table 1  

<table>
<thead>
<tr>
<th>Parameter (cutoff)</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>PPV (95% CI)</th>
<th>NPV (95% CI)</th>
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<tr>
<td>CA125 (100 U/mL)</td>
<td>61.85 (55.21 - 68.09)</td>
<td>92.71 (90.73 - 94.29)</td>
<td>68.91 (62.07-75.02)</td>
<td>90.89 (88.11 - 92.11)</td>
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<td>CA125 (55/65 U/mL)*</td>
<td>74.42 (68.23 - 79.81)</td>
<td>89.70 (77.81 - 91.24)</td>
<td>50.21 (44.73 - 55.64)</td>
<td>92.30 (90.22 - 94.12)</td>
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<td>CA125 (55/100 U/mL)*</td>
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<td>81.39 (78.58 - 83.90)</td>
<td>48.48 (42.86 - 54.15)</td>
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<td>61.15 (55.11 - 66.87)</td>
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<td>He4 (70/140 pmol/L)*</td>
<td>70.70 (65.95 - 76.71)</td>
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<td>ROMA (10)</td>
<td>94.24 (89.98-96.75)</td>
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<td>ROMA (15)</td>
<td>91.10 (86.21 - 94.37)</td>
<td>84.62 (81.73-87.12)</td>
<td>62.14 (56.33-67.62)</td>
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<td>ROMA (12.5/14.4)*</td>
<td>91.62 (86.83-94.78)</td>
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<td>59.32 (53.63 - 64.77)</td>
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<td>ROMA (13/12.7)*</td>
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<td>CPH-I</td>
<td>96.86 (93.32 - 98.55)</td>
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<td>94.86 (92.90-96.309)</td>
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</tbody>
</table>

PPV: positive predictive value; NPV: negative predictive value; *premenopausal/postmenopausal women

Abstract 311 Figure 1  

AUC of He4, Ca125, ROMA and CPH-I. All patients

tumors and 219 (20.45%) presented EOC or MCO. Area under the curve (AUC) for HE4 was significantly higher than AUC for CA125 (0.909 vs 0.873). No differences were seen between AUC of ROMA (0.939) and CPH-I (0.936), but they were both higher than HE4 AUC (figure 1). Subgroup analysis showed that in premenopausal women, HE4 performed better than CA125, and was equivalent to ROMA or CPH-I. Considering only ovarian tumors with inconclusive diagnosis by ultrasound, ROMA performed better than CPH-I. None of the tumor markers alone achieved a sensitivity of 90%, however HE4 was highly specific (93.5%). ROMA showed a sensitivity and specificity of 91.1% and 84.6% respectively, while CPH-I showed a sensitivity of 91.1% with 79.2% specificity (table 1).

Conclusion Both ROMA and CPH-I were more favorable than tumor markers alone for differentiating patients harboring EOC or MCO. Probability models can be helpful in order to assess the risk of malignancy of ovarian tumors, especially when expert ultrasound examination is not available or when the diagnosis by ultrasound remains inconclusive.

Disclosures The authors of this abstract have no disclosures.

Introduction/Background Sentinel lymph node (SLN) mapping is established as the standard of care for staging in selected cases of melanoma, breast and vulval cancer amongst other malignancies. Nonetheless, adapting its use in endometrial cancer (EC) and cervical cancer (CC) has been challenging. There is currently growing evidence to support its accuracy in early-stage EC and CC. One-step nucleic acid amplification (OSNA) has emerged as a rapid molecular assay for the detection of cytokeratin 19-mRNA in SLNs. The aim of the study was to ascertain the accuracy of OSNA in detecting SLN metastasis in early-stage EC and CC compared to that of histopathological ultra-staging.

Methodology A systematic search of MEDLINE, SCOPUS, ClinicalTrials.gov, and Cochrane Database was performed, spanning the period Jan 1975 to July 2020. Studies pertaining to the use of OSNA in detecting SLN metastasis in EC and CC were located. Pathologic ultra-staging was the reference standard. The quality of the included studies was assessed using the QUANDAS-2 tool. The DerSimonian-Laird random-effects model was used. Sensitivity, specificity, positive and negative likelihood ratio (LR+/LR-), diagnostic odds ratio (DOR), and the area under the curve (AUC) on SROC curve were calculated. We assessed the inter-study heterogeneity by the Higgin’s I2 index. Statistical analysis was performed using the STATA version 16.1.

ONE-STEP NUCLEIC ACID AMPLIFICATION (OSNA): A BIG ‘STEP’ TOWARDS A MORE ACCURATE INTRAOPERATIVE ASSESSMENT OF SENTINEL LYMPH NODE STATUS FOR EARLY STAGE ENDOMETRIAL AND CERVICAL CANCER?

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Results Five studies were included in the current analysis enrolling 223 women (191 with EC and 32 with CC) and 484 SLNs. The quality of the included studies was high. The number of the examined SLNs per patient ranged between one and five. The pooled sensitivity and specificity was 0.84 (95% CI 0.64 – 0.94, I²=34.59%) and 0.95 (95% 0.88 – 0.98, I²=87.58%), respectively. The pooled LR+ and LR- was 17.07 and 0.17, respectively. The pooled DOR was calculated 100.38 (95% CI 34.21 – 294.52, I²=85.24%). The SROC curve yielded an AUC of 0.95 (95% CI 0.93 – 0.97).

Conclusion The current evidence suggests that the OSNA assay is a useful and accurate technique for the intra-operative detection of SLN metastasis in early-stage EC and CC. The combined analysis using SLNs and OSNA assay is seemingly an attractive approach to tailor individualised management. The impact of micro-metastasis and isolated tumour cells on the prognosis of women with apparent early-stage EC and CC remains debatable and should be addressed in future research. As this evidence is preliminary, cross-institutional collaboration is warranted.

Disclosures Professor SK declares personal fees for consulting from Roche and Astra-Zeneca, outside the submitted work. The remaining authors certify that no party has a direct interest in the results of the research and that no benefit will be conferred to us or any organisation with which we are associated.

486 PROGNOSTIC VALUE OF PET-CT SCAN ON SURVIVAL OUTCOMES OF ADVANCED-STAGED OVARIAN CANCER PATIENTS TREATED WITH NEOADJUVANT CHEMOTHERAPY: A PROSPECTIVE STUDY

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Introduction/Background PET-CT is an imaging examination whose preoperative diagnostic value in advanced-staged ovarian cancer patients remains controversial. Main objective of this study was to answer whether performing early preoperative PET-CT scan in patients undergoing neoadjuvant chemotherapy may discriminate their response and prognosis.

Methodology A prospective observational study was performed between September 2014 and May 2016. There were exclusively included patients diagnosed with advanced-stage ovarian cancer considered as not eligible for primary debulking surgery according to laparoscopy Fagotti score. These patients were treated with four cycles of neoadjuvant chemotherapy with carboptaxolé followed by interval debulking and three additional cycles of chemotherapy. PET-CT was performed between the initiation of chemotherapy (T0), first (T1) and fourth cycle of chemotherapy (T4). Follow-up outcomes of patients were also recorded. Primary outcomes were SUVmax, MTV and TLG (Tumor Lesion Glycolysis) that were assessed by four different blinded physicians each. Total and percentage modifications of these parameters within T0-T1 and T4 were compared between patients with and without recurrence and cancer-related death, while they were also correlated with OS and DFC in a Cox regression analysis.

Results there were 10 patients recruited for this study. All patients managed to have complete excision of the disease. SUVmax, MTV and TLG did not present significant interobserver variability within physicians. SUVmax was reduced at 45.9% between T0 and T1 in patients with later cancer-related death vs. only 8.0% in survivors (P=.05), while the relative mean decrease in absolute units was 6.5 vs 1.17 (P=.06). Similarly, TLG between T0 and T1 was reduced at 76.51% vs. 33.7% (P=.04), while mean TLG decrease was 1663.8 vs 653.8 units respectively (P=.06). In contrary, patients not presenting recurrence were characterized by significantly higher TLG reduction between T1 and T4 (95.0% for non-recurrence vs 69.1% for recurrence, P=.04), while TLG mean reduction was 1088 vs. 211 units (P=.11). Furthermore, all mean values of PET-CT parameters presented a higher reduction between T1 and T4 in patients not presenting recurrence.

Conclusion PET-CT examination preoperatively in advanced-staged ovarian cancer patients may be prognostic. Further studies with larger sample size should be performed in order to assess the exact role of PET-CT scan preoperative triage of advanced-stage ovarian cancer patients.

Disclosures Authors have nothing to disclose.

Endometrial cancer

38 RISK OF ENDOMETRIAL CANCER AMONG WOMEN WITH BENIGN OVARIAN TUMORS – A DANISH NATIONWIDE COHORT STUDY

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Introduction/Background The few studies investigating a potential association between benign ovarian tumors and endometrial cancer have been inconclusive. Using data from a large Danish register-based cohort study, we assessed the overall and type-specific risk of endometrial cancer among women with a benign ovarian tumor.

Methodology We identified all Danish women diagnosed with a benign ovarian tumor during 1978–2016 in the Danish National Patient Register (n = 149,807). The study population was followed for subsequent development of endometrial cancer by linkage to the Danish Cancer Register and standardized incidence ratios (SIRs) with corresponding 95% confidence intervals (CIs) were calculated after correction for hysterectomy.

Results Women with benign ovarian tumors had a decreased incidence of endometrial cancer (SIR = 0.74, 95% CI: 0.68–0.81) compared with women in the general Danish female population. Both solid benign ovarian tumors (SIR = 0.79, 95% CI 0.70–0.88) and cystic benign ovarian tumors (SIR = 0.68, 95% CI 0.58–0.78) were associated with decreased incidences of endometrial cancer. Likewise, women with benign ovarian tumors had decreased incidences of both type I and type II endometrial cancer. The incidence of endometrial cancer was decreased to virtually the same magnitude irrespective of the age at diagnosis of a benign ovarian tumor and the
The oncologic outcome after fertility-sparing treatment for early stage endometrioid endometrial cancer

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Introduction/Background Hormonal management is an alternative treatment for preserving fertility in patients with early stage endometrioid endometrial cancer (EC). The safety and clinical outcome in longer treatment more than 9 months has controversial. This study aimed to define the oncologic outcomes after hormone therapy more than 9 months for endometrioid EC.

Methodology We retrospectively analyzed patients presumed to have stage IA, grade 1–2 endometrioid EC who underwent fertility-sparing treatment. Concurrent medroxyprogesterone (MPA) and levonorgestrel-release intrauterine devices were used for treatment. The remission rate and progression-free survival were analyzed each of the short term treatment who had treatment under 9 months and long term groups who had treatment duration over 9 months.

Results One hundred twenty patients presumed to have stage IA, grade 1 endometrioid EC had treated with hormonal medication for fertility sparing. The median age was 33.5 (range 22–43) years old and the median treatment duration was 10.7 (3–102) months. The Complete remission (CR) rate was 84.2% (101/120) and the median time interval to CR was 9.3 (2–84) months. The median follow-up time was 32.9 (1–130) months. The recurrence rate was 31.7% (38/120) and the median time to recurrence was 11 (1–92) months. The cumulative CR rate by 3, 6, 9, 12, 15, 18, 24 months was 21.7%, 36.7%, 50.8%, 61.7%, 70.8%, 74.2%, and 78.3% respectively. The CR rates in group A and B were 86.7% and 82.7% in group A and B. The recurrence rates in two group were 35.6% and 29.3% respectively.

Conclusion Fertility sparing treatment with high dose progesterin over 9 months in early stage endometrioid EC has showed high rate of CR. However, medical treatment over 9 months should counsel with patients in detail and oncologists should make careful decision.

Disclosures None.

The added value of sentinel node mapping in endometrial cancer

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Introduction/Background Endometrial cancer (EC) is the most common gynecological malignancy worldwide, with an estimated 382,069 new cases and 89,929 deaths in 2018. Lymph node involvement represents one of the most important prognostic factors and guides better planning of post-operative adjuvant treatment. Whereas lymph node assessment has been included in surgical staging since 1988, the optimal procedure for lymph node evaluation is controversial, ranging from full pelvic and para-aortic lymph node dissection (LND) to complete omission of LND. We previously evaluated the oncologic outcomes of 472 cases of EC (SLN with LND vs. LND alone) and demonstrated significantly lower likelihood of pelvic sidewall recurrences in patients who underwent SLN. These data raised the possibility that addition of SLN biopsy may not just be equivalent to conventional staging but may actually increase the detection of metastatic disease, resulting in better stratification of patients into risk groups, optimal adjuvant therapy prescription and as a result, better oncologic outcomes. In this study, we investigated the long-term oncological outcome of adding SLN to pelvic LND in patients with EC.

Methodology Retrospective study comparing survival outcomes (overall survival (OS), disease-specific survival (DSS), progression-free survival (PFS), recurrence-free survival) between endometrial cancer patients undergoing surgical staging, which included LND with or without SLN in non-overlapping contiguous eras. Hazard ratios (HR) and their respective 95% confidence intervals (95%CI) were calculated using Cox proportional hazard models.

Results 193 patients underwent LND and 250 patients had SLN mapping prior to LND. Clinical characteristics, including adjuvant therapy use, were similar between groups. During a median follow-up period of 6.9 years, addition of SLN was associated with more favorable oncological outcomes compared to LND with 6-year OS of 90% compared to 81% (p=0.009), and PFS of 85% compared to 75% (p=0.01) respectively. SLN was associated with improved OS (HR 0.5, 95% CI 0.3–0.8, p=0.004), DSS (HR 0.5, 95%CI 0.2–1.0, p=0.03) and PFS (HR 0.6, 95% CI 0.4–0.9, p=0.03) in a multivariable analysis as well, adjusted for age, ASA score, stage, grade, non-endometrioid histology, and LVS. Patients who were staged with SLN were less likely to have a recurrence in the pelvis or lymph node basins compared to patients who underwent LND only (6-year recurrence-free survival 95% vs 90%, p=0.04).

Conclusion Addition of SLN was associated with improved clinical outcomes compared to LND alone in patients with endometrial cancer undergoing surgical staging.

Disclosures We have no disclosures.

Omitting lymphadenectomy in obese endometrial cancer patients undergoing sentinel lymph node mapping: when more is less

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Introduction/Background The prevalence of obesity in the United States has tripled over the last 40 years. Obesity is a significant risk factor for endometrial cancer (EC). Sentinel lymph node (SLN) sampling has been applied for EC surgery
to minimize the rate of unnecessary LND associated morbidity. Although its use in EC is relatively new, SLN biopsy has been shown to be highly accurate for staging purpose. However, some studies reported on decreased sentinel node detection rate among obese patients. Thus, we sought to determine if SLN technique is reliable with certain factors associated with successful mapping in obese EC patients and whether omitting LND impacts oncologic outcomes.

Methodology A prospective cohort study of obese patients (BMI \(\geq 35\) kg/m\(^2\)), diagnosed with endometrial carcinoma between 2007 and 2017, comparing surgical and oncological outcomes of two patients cohorts: LND (\(\geq\) SLN) and SLN, 2-year progression-free survival (PFS), overall survival (OS), and disease-specific survival (DSS) were analyzed using life tables, Kaplan-Meier survival curves and log-rank tests.

Results Out of 223 patients with median BMI of 40.6 kg/m\(^2\), 140 patients underwent LND (with or without SLN) and 83 patients underwent SLN. The median operative time for surgical staging in SLN only group was shorter in 47.5 minutes than for patients in the LND±SLN group (190.5 minutes (108–393) vs. 238 minutes (131–440), respectively, (p < 0.001)), and they had reduced estimated blood loss (EBL) compared to the LND±SLN group (30 ml (0–300) vs. 40 ml (0–800 ml), P=0.03). At a 24 months follow-up cut-off, 98% of the patients were alive and 95.3% were free of disease, without significant differences in OS, DSS and PFS between the two groups (p=0.7, p=0.8 and p=0.4, respectively). Overall, 171 patients underwent SLN biopsy (\(\geq\)LND) and stratified by the tracer used for mapping (ICG versus blue dye). The ICG injected group had higher successful mapping and bilateral detection rates (92.8% vs 71.7%, p<0.001 and 80.2% vs 43.3%, p=0.001, respectfully).

Conclusion Omitting LND from surgical staging where SLN is performed was associated with shorter operative time and minimal bleeding without affecting survival. ICG with NIR fluorescence imaging results in higher detection than with blue dye, indicating that ICG should be the dye of choice in obese endometrial cancer patients.

Disclosures We have no disclosures.
genetic features (POLE mutation [POLEmt], microsatellite-instability high [MSI-H], homologous recombination defect [HRD], MUC16 mutation [MUC16mt]) showed significant overlap. In Kaplan-Meier survival analyses, MIS and open surgery brought similar survival outcome in patients with POLEmt, MSI-H, HRD or MUC16mt. But in POLE wild type, non MSI-H, non HRD, or MUC16 wild type patients, MIS resulted in shorter recurrence-free survival (RFS) (p=0.008, 0.015, 0.003, 0.008). Based on TCGA classification, POLE ultramutated and MSI hypermutated type had similar prognosis after two surgeries, while copy-number low type without CTNNB1 mutation and copy-number high type with TP53 mutation showed more rapid recurrence after MIS (p=0.048 and 0.037). Further analyses were done to simplify the model. In patients with ≥1 of the 4 features (POLEmt, MSI-H, HRD or MUC16mt), MIS and open surgery brought comparable overall survival and RFS (p=0.339 and 0.969); for patients with none of the features, especially those with wild type CTNNB1 or TP53 mutation, longer RFS was observed in open surgery group (p=0.001, <0.001, <0.001, respectively). All the results of Kaplan-Meier analyses were verified by Cox regressions.

Conclusion The molecular features of EC are related to patients’ prognosis after different surgical approaches. MIS should be recommended in patients with POLEmt, MSI-H, HRD or MUC16mt for similar survival outcome and less perioperative complications compared to open surgery.

Disclosures This work was supported by the National Natural Science Foundation of China (81972426, 81202041, 81672571, 81874108 and 81802607), Special Projects for Strengthening Basic Research of Peking University (BMU2018JC005), National Key Technology R&D Program of China (2019YFC1005200 and 2019YFC1005201). The authors have no potential conflict of interest to disclose.

**Abstract 165**

**AN AUDIT OF THE USE OF VAGINAL BRACHYTHERAPY IN ENDOMETRIAL CANCERS**

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10.1136/ijgc-2020-ESGO.58

Introduction/Background Vaginal Brachytherapy is an effective treatment modality to prevent local recurrence in endometrial cancers. We did an audit of the Endometrial cancer cases treated by an oncology group practice over a period of 5 years to assess the use of VBT.

Methodology The data of 106 patient data was entered and analysed. The indications of vaginal brachytherapy, number of fractions, dose per fraction, prescription points, vaginal stenosis on follow up and use of vaginal dilators were the variables collected and were entered in an excel sheet.

Results A total of 106 patient data was entered and analysed. The mean age of the patients was 60 years. The radiotherapy details were available for 84 patients. Of the 84 patients analysed, 59 patients (70%) received adjuvant Vaginal Brachytherapy, while 25(30%) did not. Of the patients who received VBT, 32 (54.2%) patients received VBT as a boost after Pelvic RT (figure 1).

VBT BOOST: Among the 32 patients who received vaginal Brachytherapy as a boost after Pelvic RT, only 4(12.5%) patients had cervix involvement. Lower uterine segment was involved in 12 patients.

The EBRT dose was 45- 50 Gy in 25 to 28 fractions.

<table>
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<th>Abstract 165 Table 1</th>
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</tbody>
</table>
The common dose fractionations for VBT were 25 Gy/5 #, 24 Gy/4# and 21 Gy/3#; weekly #s. Majority of the prescriptions were to the vaginal mucosa. There was no standard documentation of vaginal shortening. The use of vaginal dilators was scarce.

Conclusion There was a substantial percentage of women who received VBT in the low risk group. A survey among the consultants showed that poor follow up and the lack of patient awareness, as the reason behind this. Patients operated at peripheral centres ended up having VBT in the low risk group. Lower uterine segment involvement seems to be a factor tipping the decision towards VBT. The use of VBT boost after Pelvic Radiotherapy, has been seen in about 88% of the patients without the involvement of cervix, warranting a national consensus guideline for these tumours.

Disclosures We disclose no conflict of interest.

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**Introduction/Background** The European Society of Gynaecological Oncology (ESGO) and The British Gynaecological Cancer Society (BGCS) recommend laparoscopic surgery for treatment of endometrial cancer. Conversion rates to open can be high when performing surgical staging, particularly in patients with high BMI. The Royal Surrey in Guildford has been performing laparoscopic surgery for endometrial cancer since 2002 and introduced robotic assistance in January 2010. Since then >1400 gynaecological oncology robotic procedures have been performed: the greatest experience in the UK.

**Objective** Assess surgical outcomes and survival for endometrial cancer since robotic surgery was introduced.

**Methodology** Retrospective cohort study of surgical treatment for corpus cancer using data collected prospectively on a dedicated database between 1st January 2010 and 31st December 2019. Conversion rate to laparotomy (%), estimated blood loss in ml (EBL), mean and median length of stay (LOS) and 30-day mortality rate (n, %) were calculated.

**Results** 952 patients received primary surgery for corpus cancer between 2010–2019

Robotics: 734 operations, conversion rate 0.54% Median EBL 50 ml, Median LOS 1 day, 30-day Mortality 1/734 (0.14%) Open: 164 operations, Median EBL 500 ml, Median LOS 6 days, 30-day Mortality 5/164 (3.05%).

In 2019 115/126 (91%) of all operations performed for corpus cancer were performed using the Da Vinci Robot with 9 open. Between 2008 and 2019 the median length of stay for patients with corpus cancer fell, from 6 days to 1 day. The rate performed by minimal access surgery (MAS) increased from 33% to 93% despite an increasingly obese population.

**Conclusion** In 2019, 93% of women treated in Guildford for endometrial cancer, received MAS. Since 2008 our conversion rate to open has fallen from 18% to 1.7%; median EBL from 300 ml to 50 ml and our median LOS from 6 days to 1 night. In our experience, Robotic surgery is extremely well tolerated, safe and predictable. Increasingly, we are performing palliative procedures for women with advanced endometrial cancer with minimal negative impact. Robotic surgery is particularly well suited to high BMI patients; allowing surgical staging to be performed without undue difficulty or surgical compromise. This study demonstrates the lowest 30-day mortality (0.14%) within our robotic cohort. Introduction of the Da Vinci robot in our Centre has led to a revolutionary change in practice with significant patient benefit. Many cases previously thought not fit for surgery at all, are now recommended robotic surgery.

**Disclosures** Anil Tailor: Proctor for Intuitive Surgical

Jayanta Chatterjee: paid-lectures on behalf of pharmaceutical companies

Agnieszka Michael: Educational-grants: Clovis, GSK, Ipsen, Novartis, Pfizer, and Tesaro

Simon Butler-Manuel: Proctor for Intuitive Surgical, Plasma Surgical & Ethicon
BRCA1/2 MUTATIONS PREDICT BETTER SURVIVAL IN HIGH-GRADE ENDOMETRIOID ENDOMETRIAL CANCER

Yibo Dai, Jingyuan Wang, Luyang Zhao, Zhiqi Wang, Jianliu Wang. Peking University People's Hospital

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Introduction/Background Recent studies and clinical trials demonstrated the vital significance of BRCA mutational status in ovarian cancer treatment, but related evidence in endometrial cancer (EC) is still limited. This study aims to investigate the role of BRCA mutations in predicting EC patients' survival.

Methodology 510 eligible cases from the Cancer Genome Atlas database were retrospectively analysed. Clinicopathological characteristics of patients with different BRCA1/2 mutational status were compared. To analyse the survival influence of BRCA1/2 mutation, Kaplan-Meier survival analyses and Cox regressions were conducted. In order to control confounding bias between groups, propensity score matching method was used.

Results Among the eligible patients, 11 (2.2%) harboured BRCA1 mutations, 43 (8.4%) harboured BRCA2 mutations, and 36 (7.1%) harboured both. Body mass index, rates of hypertension history, proportion of non-endometrioid histology and rates of positive peritoneal cytology were lower in BRCA1/2 mutant patients compared with the wild-type counterpart ($p = 0.020, 0.048, 0.001$ and $0.012$, respectively). Patients with BRCA1/2 mutations showed longer overall (OS) and recurrence-free survival (RFS) (in Kaplan-Meier analyses, $p < 0.001$ and $p = 0.004$, respectively; in Cox regressions, $p = 0.001$ and $0.007$, respectively). Further analyses indicated that the survival influence of BRCA1/2 mutations was only significant in high-grade endometrioid EC patients. Based on the cohorts generated after propensity score matching, in high-grade endometrioid EC patients, the influence of BRCA1/2 mutations remained significant on OS, but not on RFS ($p = 0.003$ and $0.057$ in Kaplan-Meier analyses, $p = 0.020$ and $0.071$ in Cox regressions).

Conclusion BRCA1/2 mutations could predict better survival outcome in high-grade endometrioid EC patients, indicating the value of BRCA testing in EC clinical management.

Disclosures This work was supported by the National Natural Science Foundation of China (81972426 and 81874108), Special Projects for Strengthening Basic Research of Peking University (BMU2018JC005), National Key Technology R&D Program of China (2019YFC1005200 and 2019YFC1005201). The authors have no potential conflict of interest to disclose.

WHICH DIETARY AND EVERYDAY LIFE HABITS AFFECT ENDOMETRIAL CANCER RECURRENCE? THE MACHINE GIVES THE ANSWER

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10.1136/ijgc-2020-ESGO.61

Introduction/Background The increased life expectancy and westernization of the lifestyle are considered the major contributors to a sustainable rise in endometrial cancer (EC) rates. The factors predicting EC recurrence include patient age and tumour characteristics, such as type, differentiation, and depth of invasion. At the same time, recent studies testify the impact of meal and exercises on the course of various diseases. What are the food preferences and activities that could influence the ultimate risk of EC relapse and death?

Methodology The study included 481 women who previously underwent a hysterectomy due to EC at Karolinska University Hospital. The participants filled an extensive questionnaire on their dietary habits and everyday routines. Related clinical data was obtained through the National e-health system. It resulted in a large dataset with more than 180 variables, which was processed using the Random Survival Forest (RSF) approach. The latter is applied to a right-censored data and uses a collection of decision trees to rank the variables by their importance for the occurrence of an event. The top-ranked variables were further investigated with the Cox proportional hazards model. Analyses were performed using the RandomForestSRC package for Python.

Results The consumption of the fried potatoes significantly increased the risk of EC relapse and death [HR=8.62 (2.22–33.56), $p=0.002$; HR=6.00 (1.06–34.01), $p=0.043$, respectively], the latter persisted after adjustment for body mass index, age and smoking status. Besides, each additional serving of sweetened soda drinks increased the risk of death [3.262 (1.834–5.800), $p=0.0001$]. In contrast, physical activity was beneficial with each additional Metabolic Equivalent per day decreasing the risk of death by 7.3% [HR=0.927 (0.892–0.964), $p<0.0001$].

Conclusion We hypothesise that the fried potatoes' detrimental effect may be related to the acrylamide, which is formed in starch-rich foods under high-temperature conditions. It acts as a carcinogen and endocrine disruptor, causing the endometrial hyperplasia and EC in animal studies. Sweetened beverages cause a rise in insulin, which in turn inhibits sex-hormone binding protein. This results in higher levels of circulating free oestrogens. Also, insulin has mitogenic and anti-apoptotic properties, further inducing the endometrium proliferation. The favorable influence of regular physical activity on EC relapse and death is in accordance with previous studies, including recent meta-analysis.

Therefore, we encourage women treated for EC to consider reducing sweetened beverages and fried potatoes consumption and increasing physical activity.

Disclosures The authors have nothing to disclose.

USE OF PREOPERATIVE AND INTRAOPERATIVE PARAMETERS FOR DECISION MAKING IN OVARIAN PRESERVATION IN ENDOMETRIAL ADENOCARCINOMA

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10.1136/ijgc-2020-ESGO.62

Introduction/Background Oophorectomy which is the integral part of surgery in endometrial adenocarcinoma leads to some adverse effects in premenopausal patients. Therefore, ovarian preservation concept has recently emerged especially in early stage disease. Several studies have shown that such approach does not adversely impact oncologic prognosis. This study
aimed to retrospectively investigate the characteristics of endometrial adenocarcinoma patients with ovarian metastasis and to define criteria for ovarian preservation by using preoperative and intraoperative parameters.

**Methodology**
Patients with endometrial adenocarcinoma who were operated at Hacettepe University Faculty of Medicine, Department of Obstetrics and Gynecology were identified. The clinical and pathological characteristics of these patients were reviewed. Following univariate and multivariate analysis to determine factors associated with ovarian spread, different sets of criteria were analyzed to determine the subgroup of patients with no or negligible risk of ovarian metastasis.

**Results**
The study group consisted of 725 patients and ovarian metastasis was detected in only 66 (9.1%) of the patients. Univariate analysis showed tumor diameter, grade, histological type, myometrial invasion, peritoneal cytology, lymphovascular space invasion (LVSI), cervical invasion, omental and lymph node metastasis are significantly associated with ovarian metastasis while only LVSI, cervical invasion, omental and lymphatic involvement were significant on multivariate analysis. By using preoperative and intraoperative parameters only, no risk of ovarian metastasis was seen in patients of all ages with endometrioid tumor of any grade without myometrial invasion and risk was negligible (0.7%) among 142 patients (19.6% of study population) of any age with grade 1, endometrioid type tumors without deep myometrial invasion.

**Conclusion**
Oophorectomy is not always necessary in endometrial adenocarcinoma. Preoperative and intraoperative uterus-related factors may be used to define patients in whom ovarian preservation is safe similar to the approach used to determine surgical extent. Thus, ovaries may safely be preserved in almost 20% of patients with endometriod adenocarcinoma.

**Disclosures** No potential conflict of interest to declare.

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**Introduction/Background**
Guidelines recommend surgery as primary therapy for endometrial cancer patients. Subsequent treatments can include radiation with/without systemic therapy depending on patients’ prognosis. However, there is little data describing real-world treatment patterns and economic burden among newly diagnosed endometrial cancer patients. Therefore, this study aimed to assess real-world treatment patterns and healthcare costs by line of therapy (LOT) among newly diagnosed endometrial cancer patients.

**Methodology**
Endometrial cancer patients newly diagnosed between January 2015 – June 2018 with continuous medical enrollment for 12 months prior and 6 months post diagnosis were identified in the Optum Clinformatics DataMart database. Treatments associated with endometrial cancer, including surgeries (bilateral salpingo-oophorectomy, hysterectomy and lymphadenectomy), radiotherapy (external beam radiotherapy and brachytherapy) and systemic therapies (chemotherapies, immunotherapies and hormonal therapies) were identified and described by LOT. The first treatment received post diagnosis was classified as LOT1. Treatments initiated within ±90 days of surgical procedures, 30 days of the end of a radiotherapy, and 28 days of the start of a systemic therapy were considered to be a part of the same LOT. Study outcomes included time to treatment initiation, most frequently received treatments in LOT1 and LOT2, and per patient per month (PPPM) costs attributable to LOT1 and LOT2.

**Results**
Among 5,006 newly diagnosed endometrial cancer patients, 3,574 (71%) received at least LOT1 and 771 (15.4%) received LOT2. The median time from diagnosis to LOT1 initiation was 1.0 (1.0 – 2.0) month. Hysterectomy (98.9%) was the most common treatment in LOT1. Majority of patients received radiation therapy (65%) in LOT2. Treatments received in LOT1 and LOT2 are summarized in table 1. The mean total healthcare cost from diagnosis to end of follow-up was $6,088 PPPM. The PPPM costs attributable to each LOT are presented in figure 1. The total healthcare costs during LOT2 exceeded those incurred during LOT1 with outpatient costs being the biggest driver.

**Conclusion**
Newly diagnosed endometrial cancer patients received treatments consistent with guidelines with hysterectomy being the most common LOT1 treatment. Outpatient costs accounted for 70%-80% of total healthcare costs attributable to LOT1 and LOT2. Moving from LOT1 to subsequent LOTs was associated with an increase in healthcare costs attributable to LOT1 and LOT2.

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**Table 1**

<table>
<thead>
<tr>
<th>Treatments</th>
<th>First Line of Therapy</th>
<th>Second Line of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>N=3,309</td>
<td>N=476</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>3,274 (98.9%)</td>
<td>41 (87.2%)</td>
</tr>
<tr>
<td>Lymphadenectomy</td>
<td>1,389 (47.7%)</td>
<td>20 (63.5%)</td>
</tr>
<tr>
<td>Bilateral salpingo-oophorectomy</td>
<td>830 (25.0%)</td>
<td>11 (34.6%)</td>
</tr>
<tr>
<td>Radiation</td>
<td>N=884</td>
<td>N=501</td>
</tr>
<tr>
<td>Radiation only</td>
<td>55 (6.2%)</td>
<td>331 (65.8%)</td>
</tr>
<tr>
<td>Radiation + systemic</td>
<td>298 (6.5%)</td>
<td>163 (32.5%)</td>
</tr>
<tr>
<td>Radiation + surgery</td>
<td>604 (63.3%)</td>
<td>4 (0.8%)</td>
</tr>
<tr>
<td>Radiation + surgery + systemic</td>
<td>167 (18.8%)</td>
<td>4 (0.3%)</td>
</tr>
<tr>
<td>Systemic only</td>
<td>N=152</td>
<td>N=232</td>
</tr>
<tr>
<td>Carboplatin</td>
<td>49 (32.3%)</td>
<td>116 (50.2%)</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>42 (27.6%)</td>
<td>80 (34.2%)</td>
</tr>
<tr>
<td>Megeostrol acetate</td>
<td>35 (23.3%)</td>
<td>12 (5.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>88 (57.8%)</td>
<td>144 (62.3%)</td>
</tr>
</tbody>
</table>

**Abstract 291**

**Figure 1**
Mean per patient per month healthcare costs by line of therapy among newly diagnosed endometrial cancer patients.
costs which may be indicative of disease progression/recurrence.

Disclosures This study was funded by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Chizoba Nwankwo is an employee of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Anuj Shah, Ruchit Shah, Shelby Corman, and Nehemiah Kebede are employees of Pharmerit, which received consulting fees related to this study.

Introduction/Background NCCN guidelines recommend the use of systemic therapy for women with advanced endometrial cancer. However, there are no data examining real-world treatment patterns and economic burden in this population. Therefore, this analysis described treatment patterns, and costs in a real-world cohort of endometrial cancer patients initiating systemic treatment.

Methodology Endometrial cancer patients with ≥2 claims for a systemic therapy (i.e., chemo-, immuno- or hormonal therapies) within a 4-week period or a claim for an intrauterine device between June 2014 – September 2018 and having continuous medical enrollment for 6 months prior and 3 months post therapy initiation were identified in the Optum Clinformatics DataMart database. Patients with endometrial cancer-related surgery performed within ±90 days of systemic therapy initiation were not included to exclude adjuvant use. All claims for the same systemic therapy without a >90-day gap or a new systemic treatment initiated within 28 days were a part of the same line of therapy (LOT). We reported the most frequently used treatments and associated costs in LOT1 and LOT2. All analyses were stratified by the presence of non-endometrial cancers prior to systemic therapy initiation.

Results 2,659 women with endometrial cancer newly initiated systemic therapy (i.e., LOT1), 877 (32.98%) received a LOT2, and 350 (13.16%) had a LOT3. Most patients had a non-endometrial cancer (88.9%) prior to initiating systemic therapy. The treatments received and associated costs in LOT1 and LOT2 are described in table 1 and figure 1, respectively. The median durations of LOT1 and LOT2 were 3.5 and 3.1 months, respectively. The proportions of patients receiving monoclonal antibody therapy in LOT1 and LOT2 were 55.3% and 54.4%, respectively. The mean PPPM total healthcare expenditure over the entire follow-up was $11,109 and outpatient costs ($8,073) accounted for ~75% of this burden. Healthcare expenditure increased as patients moved from LOT1 to LOT2.

Conclusion Both taxanes and platinum-based therapies were used as the primary systemic treatments in this population. The use of targeted and immunotherapies was not common perhaps because the approval of these treatments was recent and not adequately captured in the data. Delaying progression to subsequent LOTs may help reduce the economic burden in this population.
study aims to determine prognostic factors for survival in UCS.

Methodology Obsertational retrospective study of pts with UCS treated in a Cancer Centre between 2000–2018. Clinical data was retrieved from records. Prognostic variables were tested by multivariate analysis using Cox’s proportional hazards regression model, and Kaplan-Meier survival curves were generated.

Results A total of 73 women with early or locally advanced UCS were identified, with median age 68.0 yrs (46–89). Most pts had Performance Status (PS) 0–1 (n=59, 80.8%). Regarding predisposing factors, 8 had used tamoxifen and 5 had undergone pelvic radiotherapy. FIGO stage distribution as follows: 26 (35.5%) stage I; 13 (17.7%) stage II; 30 (41.0%) stage III; and 4 (5.8%) stage IVA.

Initial treatment was surgery for 70 pts. All pts underwent total hysterectomy and bilateral anexectomy, 22 (31.4%) pts pelvic and lomboaortic lymph node dissection (LND), and 19 (27.1%) pts isolated pelvic LND. Residual disease was present in 15 pts (20.5%). Adjuvant treatment was as prescribed as follows: isolated radiotherapy (RT) for 22 pts (30.1%) (of which 13 received additional brachytherapy), chemotherapy followed by RT for 17 pts (23.3%) and isolated chemotherapy for 11 pts (15.1%). Isolated adjuvant RT was prescribed mostly before 2010, and afterwards the use of adjuvant chemotherapy became more common.

After a median follow up of 29.7 months (95% CI [22.1–37.4]), 51 pts (69.9%) died. Relapse occurred in 40 pts (54.8%), mostly with a pattern of distant failure (33 pts). Local recurrence occurred in 18 pts. Median overall survival (OS) and disease free survival (DFS) were 18.3 (95% CI 13.3–23.3) and 11.3 (95% CI 7.5–15) months, respectively.

In multivariate analysis, PS (HR 3.93, 95% CI [1.16–13.27], p=0.028), residual disease (HR 12.21, 95% CI [2.13–70.02], p=0.005), adjuvant RT (HR 0.27, 95% CI [0.09–0.83], p=0.022) and adjuvant brachytherapy (HR 0.31, 95% CI [0.09–0.99], p=0.048) were independent prognostic factors for OS. No prognostic factors for DFS were found.

Conclusion In concordance with previous studies, UCS presented a high rate of recurrence and mortality. This study identified PS, residual disease, and adjuvant radiotherapy and brachytherapy as prognostic factors for OS. Despite relapse occurring mostly at distance, adjuvant chemotherapy did not impact survival.

Disclosures The authors have no disclosures.

299 SENTINEL LYMPH-NODE MAPPING WITH INDOCYANINE GREEN IN ENDOMETRIAL CANCER: DETECTION RATE AND ANATOMICAL SITES

Migle Gedgaudaite, Arturas Sukovas, Arnoldas Bartusevicius, Saulius Paskauskas, Daiva Vatliene, Ruta Jolanta Nadzsiukiene, Adrijus Gaulnikas. Lithuanian University of Health Sciences; Obstetrics and Gynaecology

Introduction/Background Lymph-node status is one of the prognostic factors related to the survival of patients with endometrial cancer (EC). However, systemic pelvic lymphadenectomy (PLN) is related to increased perioperative morbidity. A number of studies using different techniques have demonstrated the sentinel lymph-node biopsy (SLB) could be a better alternative to PLN in different patient groups. With evidence still lacking, SLB is considered an experimental method by major professional organisations like European Society of Gynaecologic Oncology. The aim of this study was to evaluate the adherence of the SLB procedure in a center with no previous experience of SLB in EC.

Methodology Prospective interventional study was performed in Lithuanian University of Health Sciences Hospital, Centre of Oncogynaecology in the period of 2018 March and 2020 July. 96 patients with histologically confirmed endometrioid endometrial carcinoma were included into the study. Indocyanine green (ICG) dye was used to map sentinel lymph-nodes using previously described technique. PLN was performed after SLB procedure for intermediate and high-risk patients.

Results Detection rate, timing and anatomical sites

The overall SL detection rate was 87.5% (bilateral in 63.5% (61/96), unilateral in additional 24.0% (23/96) of patients). The median time for the detection of the 1st SL was 35 minutes after injection of ICG (range 13–140 min), and 45 minutes (range 25–115 min) for the 2nd (contralateral) one. The median number of SL removed was 2 (range 1–8). The most frequent sites for SLs were right external iliac area (31.0%), left external iliac area (24.2%), right internal iliac area (11.9%) and left obturator fossa (11.3%). 4.8% of SL mapped in paraaortic region.

SL metastasis rate Lymph node metastasis were found in 6 (6.3%) patients and 4 (4.4%) of them were detected by SLB. The sensitivity of SLB was 66.7% and negative predictive value 97.4%. SLB has moderate – strong agreement with PLN (kappa coefficient 0.787, p < 0.001).

SL mapping failures SL mapping failed in 12.5% (12/96) of the patients. The factors that might be associated with mapping failure was age (73 vs. 64.5 vs. 62.8, p=0.005) and present extragenital pathology (100% vs. 60.9% vs. 57.4%, p=0.019).

Conclusion With the overall detection rate of 87.2% (63.5% bilateral and 24.0% - unilateral) we find SLB ICG procedure feasible. Most frequently SLs were detected in the external iliac region. Age and extragenital pathology are the statistically significant factors associated with the failure of SLB procedure.

309 ROLE OF THREE-DIMENSIONAL TRANSVAGINAL ULTRASOUND AND DIFFUSION-WEIGHTED MAGNETIC RESONANCE IMAGING FOR ASSESSMENT OF MYOMETRIAL INVASION IN PATIENTS WITH LOW-RISK ENDOMETRIAL CANCER

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Introduction/Background In patients with early-stage, grade 1–2, endometrioid endometrial cancer, preoperative assessment of myometrial invasion is essential to define the need of pelvic and paraaortic lymph node dissection. Our aim was to evaluate the role of three-dimensional transvaginal ultrasound (3D-TVUS) and diffusion-weighted magnetic resonance imaging (DW-RMI) for the assessment of myometrial invasion in patients with low-risk endometrial cancer.
Results One hundred and fifty-three patients were included, 120 (78.43%) patients presented myometrial invasion <50% in postoperative analysis of surgical specimen and 33 (21.57%) patients presented deep myometrial invasion. Sensitivity and specificity of 3D-TVUS for diagnosis of deep myometrial invasion was 68.8% and 80.5% respectively, while DW-RMI showed a sensitivity and specificity of 76.2% and 84.4%. When combining both techniques (we considered that a patient had deep myometrial invasion when 3D-TVUS or DW-RMI – or both of them – showed deep myometrial invasion), sensitivity was 93.1% and specificity was 68.4%. The proportion of patients with uterine fibroids was higher in the group of patients with false negative (60%) or false positive (39.13%) result in 3D-TVUS, although these results did not reach statistical significance. Regarding the intraoperative frozen section pathological study of surgical specimen, it showed a sensitivity of 75% with specificity of 96.4% for diagnosis of deep myometrial invasion.

Conclusion The combination of 3D-TVUS and DW-RMI offers a better sensitivity, higher than intraoperative frozen section pathological study of the surgical specimen, for the diagnosis of deep myometrial invasion in patients with early-stage, grade 1–2, endometrioid endometrial cancer. Such information may be useful in selecting patients who require lymph node dissection.

Disclosures The authors of this abstract have no disclosures.
A threshold of 5 mm can reveal 14/15 cancers in asymptomatic patients, while this figure is 12/15 for a 10 mm threshold and 6/15 for a threshold of 20 (figure 1). A threshold for 10 mm is reasonable for asymptomatic patients, missing 3 cancer patients (1 low grade, 2 high grade). In symptomatic patients, these figures were 46/49 for 5 mm threshold (3 missed cancer), 37/49 for a 10 mm threshold (12 missed cancer) and 21/49 for a 20 mm threshold (28 missed cancer).

Conclusion Endometrial biopsy should be performed routinely in patients with postmenopausal bleeding due to high numbers of missed cancers. However, in asymptomatic patients, a biopsy can safely be ignored in patients with endometrial thickness of less than 5 mm. A biopsy may also be reserved for patients with an endometrial thickness > 10 mm (Cancer detection rate is 1.4% vs. 7.8%).

Disclosures Nothing to declare.

PHASE-SPECIFIC AND LIFETIME COSTS OF CERVICAL AND ENDOMETRIAL CANCER AMONG COMMERCIALLY INSURED PATIENTS IN THE UNITED STATES

1Ruchithbai Shah, 1Nehemiah Kebede, 1Anuj Shah, 2Shelby Corman, 3Chizoba Nwankwo.

1Pharmerit – an Open Health Company; Pharmerit International, Bethesda, MD, USA; 2Pharmerit; Pharmerit – an Open Health Company; USA; 3Merck and Co., Inc

Introduction/Background There are little data describing the economic burden of cervical/endometrial cancers. Therefore, this study aimed to estimate the incremental lifetime economic burden among newly diagnosed cervical and endometrial cancer patients versus non-cancer controls using a phase-based costing approach.

Methodology Cervical and endometrial cancer patients newly diagnosed between January 2015 – June 2018, with continuous enrollment for 12 months prior and 6 months post diagnosis were identified in the Optum Clininformatics DataMart database. Non-cancer controls included patients who did not have any cancer diagnosis and had at least 18 months of continuous enrollment in the data. The index date was the date of the first diagnosis for cancer cases and the first claim date after 12 months of continuous enrollment for non-cancer controls. Both cases and controls were followed until death/loss of enrollment/end of data availability. Cancer patients were matched with non-cancer controls on the propensity of receiving a cervical/endometrial cancer diagnosis, index year, and year of last follow-up.

Per patient per month (PPPM) costs (outpatient, inpatient, ER, pharmacy) attributable to cervical and endometrial cancer were calculated for the following 4 phases: pre-diagnosis (3 months prior to diagnosis), initial (6 months post-diagnosis), terminal (6 months pre-death), and continuation (any remaining time between initial and terminal phases). Survival data were obtained (cases: Surveillance, Epidemiology, and End Results registry; controls: United States life tables) to determine the monthly proportion of patients in each phase of care. Total survival adjusted monthly cost were obtained by multiplying the proportion of patients in each phase by the total cost incurred during that month (figures 1 and 2). Generalized linear models were used to assess phase-specific incremental costs attributable to cervical and endometrial cancer.
Results The analytic cohort included 1,002 cervical cancer patients and 4,005 matched non-cancer controls, and 5,003 endometrial cancer patients matched with 19,999 non-cancer controls. The incremental total PPPM phase-specific costs attributable to cervical and endometrial cancer were: pre-diagnosis (cervical: $1,057; endometrial: $3,315), initial (cervical: $12,084; endometrial: $8,618), continuation (cervical: $2,732; endometrial: $1,147), and terminal (cervical: $2,702; endometrial: $5,442). Incremental costs were significantly higher for cancer patients versus non-cancer controls across all phases of care (except terminal phase costs for cervical cancer). Outpatient costs were the major driver of costs across all post-diagnosis phases (figure 1 and 2).

Conclusion The mean phase-specific costs followed the following order: Terminal > Initial > Continuation > Pre-diagnosis. This study highlights the substantial cost burden associated with cervical/endometrial cancer, and cost variation by phases of care.

Disclosures This study was funded by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Chizoba Nwankwo is an employee of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, Anuj Shah, Ruchit Shah, Shelby Corman, and Nehemiah Kebede are employees of Pharmerit International, which received consulting fees related to this study.
SAFETY AND ANTITUMOR ACTIVITY OF DOSTARLIMAB IN PATIENTS (PTS) WITH ADVANCED OR RECURRENT DNA MISMATCH REPAIR DEFICIENT (dMMR) OR PROFICIENT (mMMR) ENDOMETRIAL CANCER (EC): RESULTS FROM THE GARNET STUDY

Ana Oaknin, Lucy Gilbert, Anna V Tinker, Renaud Sabatier, Valentina Boni, David O’Malley, Shaied Ghamande, Wei Guo, Ellie Im, Bhaviana Pothuri. Vall D’Hebron University Hospital, Vall D’Hebron Institute of Oncology (Vhio); McGill University Health Centre-Ri; BC Cancer; Institut Paoli Calmettes, Aix-Marseille University; Department of Medical Oncology; Centro Integral Oncológico Clara Campal, Hospital Universitario HM Sanchinarro; The Ohio State University – James CCC; Georgia Cancer Center, Augusta University; Glaxosmithkline; New York University; Department of Obstetrics and Gynecology

10.1136/ijgc-2020-ESGO.71

Introduction/Background
Dostarlimab is a humanised programmed death (PD)-1 receptor monoclonal antibody that blocks interaction with the PD-1 ligands, PD-L1 and –L2. GARNET is a phase I study assessing antitumour activity and safety of dostarlimab monotherapy in patients with advanced solid tumours.

Methodology
This multicentre, open-label, single-arm study is being conducted in 2 parts, dose escalation and expansion. Here we report on 2 independent expansion cohorts of patients with recurrent or advanced endometrial cancer (EC) that progressed on or after a platinum-based chemotherapy regimen. Assignment to cohort A1 (mismatch mutation repair deficient [dMMR] EC) or cohort A2 (mismatch mutation repair proficient [mMMR] EC) was determined by

<table>
<thead>
<tr>
<th>Variable</th>
<th>dMMR EC, n=103</th>
<th>MMRP EC, n=142</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective response rate*, n (%, 95% CI)</td>
<td>46 (44.7%, 34.9–54.8)</td>
<td>19 (13.4%, 8.3–20.1)</td>
</tr>
<tr>
<td>Complete response, n (%)</td>
<td>11 (10.7)</td>
<td>3 (2.1)</td>
</tr>
<tr>
<td>Partial response, n (%)</td>
<td>35 (34.0)</td>
<td>16 (11.3)</td>
</tr>
<tr>
<td>Stable disease, n (%)</td>
<td>13 (12.6)</td>
<td>31 (21.8)</td>
</tr>
<tr>
<td>Progressive disease, n (%)</td>
<td>39 (37.9)</td>
<td>77 (54.2)</td>
</tr>
<tr>
<td>Not evaluable, n (%)</td>
<td>3 (2.9)</td>
<td>0</td>
</tr>
<tr>
<td>Not done, n (%)</td>
<td>2 (1.9)</td>
<td>15 (10.6)</td>
</tr>
<tr>
<td>Disease control rate†, n (%, 95% CI)</td>
<td>59 (57.3%, 47.2–67.0)</td>
<td>50 (35.2%, 27.4–43.7)</td>
</tr>
<tr>
<td>Response ongoing, n (%)</td>
<td>41 (69.1)</td>
<td>12 (63.2)</td>
</tr>
</tbody>
</table>

Abstract 385 Table 1 Antitumour activity

Abstract 385 Table 2 Most common adverse events

<table>
<thead>
<tr>
<th>MedDRA preferred term, n (%)</th>
<th>dMMR EC N=126</th>
<th>MMRP EC N=145</th>
<th>Overall N=271</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any grade TRAEs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>17 (13.5)</td>
<td>30 (20.7)</td>
<td>47 (17.3)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>20 (15.9)</td>
<td>19 (13.1)</td>
<td>39 (14.4)</td>
</tr>
<tr>
<td>Nausea</td>
<td>16 (12.7)</td>
<td>21 (14.5)</td>
<td>37 (13.7)</td>
</tr>
<tr>
<td>Grade ≥3 TRAEs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaemia</td>
<td>5 (4.0)</td>
<td>2 (1.4)</td>
<td>7 (2.6)</td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>2 (1.6)</td>
<td>2 (1.4)</td>
<td>4 (1.5)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>2 (1.6)</td>
<td>2 (1.4)</td>
<td>4 (1.5)</td>
</tr>
<tr>
<td>TRAEs leading to discontinuation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>1 (0.8)</td>
<td>2 (1.4)</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Aspartate aminotransferase increased</td>
<td>1 (0.8)</td>
<td>1 (0.7)</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Transaminases increased</td>
<td>2 (1.6)</td>
<td>0</td>
<td>2 (0.7)</td>
</tr>
</tbody>
</table>

dMMR, mismatch mutation repair deficient; EC, endometrial cancer; MMRP, mismatch mutation repair proficient; TRAE, treatment-related adverse event.

Int J Gynecol Cancer 2020;30(Suppl 4):A1–A141
immunohistochemistry (IHC) testing. Patients received 500 mg dostarlimab intravenously once every 3 weeks for 4 cycles, then 1000 mg once every 6 weeks until disease progression, discontinuation or withdrawal. The primary endpoints are objective response rate (ORR) and duration of response (DOR) by blinded independent central review using RECIST version 1.1.

Results In total, 126 dMMR and 145 MMRp pts identified by IHC were enrolled and dosed. Of these, 103 dMMR and 142 MMRp pts had measurable disease as baseline and sufficient follow-up time (6 months) for efficacy analyses, respectively. Patients that progressed prior to 6 months were included in the evaluable population. ORR for dMMR EC was 44.7%; ORR for MMRp EC was 13.4% (table 1). Median DOR and OS were not reached in either cohort. Overall, 15 pts (5.5%) discontinued treatment due to a TRAE (5 dMMR, 10 MMRp). Safety by cohort and overall are shown in table 2. There were no deaths attributed to dostarlimab.

Conclusion Dostarlimab demonstrated durable antitumour activity in both dMMR and MMRp advanced/recurrent EC. dMMR status by IHC was associated with a higher response rate. Dostarlimab demonstrated a notable disease control rate (35.2%; 2.1% complete response, 11.3% partial response, 21.8% stable disease) in patients with MMRp EC, which comprised a higher percentage of patients with Type II EC and is historically associated with a worse prognosis. No new safety signals were detected. These cohorts are the largest prospective evaluation of a PD-(L)1 therapy in EC to date.

Disclosures Clinical trial registration: NCT02715284

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Dr. Pothuri reports grants, personal fees and non-financial support from GSK; Advisory Board fees from AstraZeneca and Clovis Oncology.

Dr. Boni has nothing to disclose.

Dr. Guo and Im are employees of GlaxoSmithKline.

Abstracts

386 PATIENT-REPORTED OUTCOMES (PROS) IN THE GARNET TRIAL IN PATIENTS (PTS) WITH ADVANCED OR RECURRENT MISMATCH REPAIR DEFICIENT/ MICROSATELITE INSTABILITY-HIGH (dMMR/MSI-H) ENDOMETRIAL CANCER (EC) TREATED WITH DOSTARLIMAB

1Rebecca Kristeleit, 2Cara Mathews, 3Andrés Redondo, 4Joyce Huang, 5Laurie Eliason, 6Ellie Im, 7Julie Brown, 8Guy’s and St. Thomas Hospitals, NHS Foundation Trust; 9Women and Infants Hospital of Rhode Island; 10Hospital Universitario La Paz – Idiarpaz; 11Glaxosmithkline; 12Levine Institute, Atrium Health

Introduction/Background PROs enable direct measurement of the experiences of pts with cancer related to an intervention. Regulators increasingly use PROs to inform the risks and benefits of new drug candidates, focusing on 3 core concepts: physical functioning (PF), disease-related symptoms (DRS), and symptomatic adverse events (AEs).

Dostarlimab is an investigational anti-programmed death-1 monoclonal antibody that has shown activity in pts with advanced dMMR EC (objective response rate, 42%; disease control rate, 58%) and an acceptable safety profile. Here, we report on PROs in pts treated with dostarlimab in the single-arm GARNET trial.

Methodology Pts with recurrent or advanced dMMR/MSI-H EC that progressed on a platinum regimen received 500 mg Q3W*4 of dostarlimab, then 1000 mg Q6W until disease progression or discontinuation (DC). PRO assessment, an exploratory endpoint, was measured using the EORTC-QLQ-C30. PROs were collected at baseline (BL), each dose cycle, and after DC. For PF and DRS (pain and fatigue), we conducted multi-item descriptive analyses, including change from BL. For symptomatic AEs and tolerability (nausea, vomiting, constipation, diarrhoea, tiredness/fatigue), we conducted item-level analyses to understand response distribution and change in response categories from BL: improved, stable, and 1-, 2-, or 3-category worsening.

Results PRO data were available for 66/104 pts who received ≥1 dose of dostarlimab. Questionnaire compliance was consistent across domains, ranging from 100% at BL to 45% at cycle 7. Pain, fatigue, and PF were maintained above BL starting at cycles 1, 3, and 4, respectively. Symptomatic AEs were experienced by a minority of pts, with <25% and <6% of pts having 1- or ≥2-category worsening, respectively. Improved scores were reported by 6% to 37% of pts.

Conclusions PROs from the GARNET trial showed that dostarlimab was generally well tolerated and disease-related symptoms were improved or maintained while on treatment. These data, along with the efficacy and safety profile of dostarlimab, support use of dostarlimab in pts with dMMR/MSI-H advanced EC.

Disclosures Clinical trial registration: NCT02715284

Funding: GlaxoSmithKline, Waltham, MA, USA

Encore statement: This data is presented on behalf of the original authors with their permission. Presented at European Society for Medical Oncology (ESMO) annual meeting, September 19–21, 2020, Virtual.

Dr. Kristeleit reports personal fees from Tesaro.

Dr. Mathews reports institutional grants from Tesaro.

Dr. Redondo reports institutional research funding from PharmaMar, Roche, and Eisai; and advisory roles at PharmaMar, AstraZeneca, Tesaro, Roche, and Eisai.
Dr. Brown reports honoraria from Olympus; consulting or advisory role at Caris, Tesaro, Clovis, AstraZeneca, and Genentech; and speakers' bureau at Clovis.

Drs. Huang, Eliason, and Im are employees of GlaxoSmithKline.

Introduction/Background ARK1-USC, a highly annotated USC-derived cell line with a clinically relevant mutation spectrum,1 is employed in vitro and in vivo for translational studies of novel USC therapies.2 In ovarian cancer, stemness and malignancy-supporting collagen microenvironment coinide. Both promote resistance to therapy. Considering the shared histological and molecular characteristics of USC and OSC, we hypothesized that USC cells likewise display ovarian markers for stemness and collagen regulators of stemness. We tested this prediction in ARK1-USC.

Methodology Profiling of the time-dependent transcriptome, with flow cytometric analysis of select protein markers. Results ARK1-USC expressed the repertoire of cancer stem cell (CSC) markers of ovarian malignancies, such as CD44, CD117, CD144, CD133, ROR1, and ALDH1A1. Relative to 12 h after plating, at 48 h expression was decreased (CD117 and ROR1 by half, FDR adjusted p-value [q] £ 0.003); increased (ALDH1A1 and CD144 2.5- and 2.1-fold (q=0.027 and q=0.000, resp.); or unchanged (CD44 and CD133).

Conclusion ARK1-USC classify as CSCs with neuronoid properties. This conceptual framework, which captures the current clinical experience with USC treatment, is worthy of further study as it envisions a previously unnoted cytological sanctuary that still holds promising novel mechanistic targets for interdicting cancer cell entry and persistence.

Disclosures The authors have nothing to disclose.
reduces the number of contralateral pelvic lymphadenectomies. The TUMIR technique allows detection of para-aortic SNs in more than 30% of patients, much higher than that obtained with other techniques.

Disclosures
No disclosures.

**Introduction/Background**
Approximately 10% of patients with intraoperative diagnosis of low risk Endometrial Cancer (EC) will suffer an upstage after the definitive histological evaluation of the piece of hysterectomy and bilateral adnexectomy. We aim to explore the results associated with the performance of pelvic and para-aortic lymphadenectomy as restaging these patients that will require a second surgery, and to compare those with and without Sentinel Node Biopsy (SNB) in the first procedure.

**Methodology**
Retrospective cohort study involving 27 patients diagnosed with low-risk EC (ESMO-ESGO-ESTRO criteria) with surgical restaging due to upstage in the final histological result at the Hospital Universitario Donostia from April 2013 to September 2018. Surgical and oncological results were compared between patients who underwent hysterectomy and
double adnexectomy without any additional procedure (SNB-) n=17 and those who also had a pelvic and aortic SNB (SNB+) n=10. The main outcome evaluated in the study was intraoperative complications. Secondary outcomes were mean operative time, length of hospital stay, number of nodes obtained, Progression-Free Survival (PFS) and Overall Survival (OS).

**Results** The median duration of restaging surgery was 240 minutes (Q25 - Q75: 180 – 300) in the SNB(-) group, and 300 (Q25 - Q75: 247.5 – 330) minutes in the SNB(+) group, this difference being statistically significant (one-side t-student test, p=0.0295). With regard to intraoperative complications, there were 17.65% vs 40% respectively, all of them vascular, this difference being not significant. There were no statistical differences in length of hospital stay and number of pelvic nodes obtained. PFS and OS in both groups were the same.

**Conclusion** Women with EC who require lymph node restaging due to upstage and have previously undergone sentinel lymph node biopsy have greater surgical difficulty with longer duration of the procedure. The risk of complications is increased. We advise against performing a second re-staging surgery in patients sentinel node biopsy.

**Disclosures** No disclosures.

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**492 ENDOMETRIAL CANCER: THE ROLE OF PROGNOSTIC FACTORS AND THEIR IMPACT ON RECURRENCE PATTERN**

1. Giulia Parpinel, 1Luca Fusco, 1Maria Elena Laudani, 1Annalisa Carapezi, 2Enrico Badellino, 2Nicoletta Petronio, 2Marisa Ribotta, 1Martina Barboni, 2Annamaria Ferrero, 2Paolo Zola, 1San’Anna Hospital; Department of Surgical Sciences; 1Mauriziano Hospital; Department of Surgical Sciences; 2Aou Città Della Salute e Della Scienza; Department of Pathological Anatomy

**Introduction/Background** The rate of recurrence of endometrial cancer is 11–19%. It is related to different prognostic factors which define specific risk classes in order to decide for an adjuvant treatment. The objective of this study is to evaluate how prognostic factors influence the probability and pattern of recurrence.

**Methodology** This multicentric observational retrospective study was conducted on 552 patients treated for endometrial cancer between February 2011–2019. The considered parameters were: age, BMI (Body Mass Index), surgery, stage, LVS (Lymphovascular Space Involvement), myometrial infiltration, histological grade, lymph node involvement, adjuvant therapy, relapse. DFS (Disease Free Survival) and OS (Overall Survival) were stratified by the presence or absence of prognostic factors.

**Results** The rate of recurrence was 14.7%. Median time to recurrence was 15 months and 5-years OS was 84%. We observed an increase from 6 to 30% in the distance metastasis rate associated with positive LVS. Monovariate analysis showed a correlation between DFS and advanced stage (O.R. II 6.7; III-IV 9.2 p=0.0001), positive lymph nodes (O.R. 3.7; p=0.04), myometrial infiltration (O.R. 3.9 p=0.0001) and LVS (O.R. 3.5 p=0.005). Similar results were observed considering OS and grading (p=0.002). We conducted a Cox multivariate analysis on the ESGO/ESMO/ESTRO risk classification results and were statistically significant for both DFS (p=0.003) and OS (p=0.0001).

**Conclusion** Almost all the considered prognostic factors influence the presence of recurrence, but the stage is the most important factor while LVS correlates with distance metastasis. The definition of the risk factors must be considered to develop targeted therapeutic pathways.

**Disclosures** The authors declare that the research was conducted in the absence of any commercial or financial relationship that could be construed as a potential conflict of interest.
METFORMIN AS A PREVENTIVE AND THERAPEUTIC MODALITY IN ENDOMETRIAL CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROL TRIALS

Anastasia Prodromidou, Sofia Lekka, Alexandros Fotiou, Victoria Proumiadou, Dimitrios Giamnoupoloulous, Cristos R Iavazzo, Metaxa Memorial Cancer Hospital; Metaxa Memorial Cancer Hospital of Piraeus; Gynecologic Oncology

10.1136/ijgc-2020-ESGO.78

Introduction/Background Endometrial cancer (EC) is the most commonly diagnosed gynecological malignancy in the developed countries. Obesity, diabetes mellitus and infertility are some of the contributory factors. Some patients with EC wish to preserve their fertility or others have several comorbidities that contraindicate surgery. These groups of patients could benefit from a conservative treatment strategy such as the use of metformin. This agent is an option in women with increased EC risk as well as in those with atypical endometrial hyperplasia.

Methodology We evaluated the protective effects of metformin in EC patients, its preventive role in breast cancer and obese patients and its effectiveness, safety and efficacy in addition to progesterone monotherapy in treatment of fertility sparing candidates. We reviewed the literature and then conducted a meta-analysis of the relevant parameters. A total of 6 studies was included in the meta-analysis.

Results Comparing the pre-surgical treatment with metformin versus placebo, meta-analysis of mean difference in Ki-67 after treatment among two groups, revealed no difference (MD - 7.10, 95% CI -23.31 to 9.11, p=0.39). Meta-analysis of fertility sparing EC management with a combination of megestrol acetate (MA) and metformin (500 mg three times a day) in comparison with monotherapy with 160 mg daily MA revealed no difference in either complete response or partial response rates (166 patients OR 2.94, 95% CI 0.85 to 10.15, p=0.09 and 166 patients OR 0.76, 95% CI 0.34 to 1.66, p=0.49, respectively). Regarding breast cancer survivors under tamoxifen, metformin was related with significantly reduced median endometrial thickness after 52 weeks of evaluation when compared to women in placebo group (2.3 mm vs 3.0 mm, p=0.05).

Conclusion Metformin neither was found to have a preventative role against the development of endometrial cancer nor a beneficial one in addition to the progesterone monotherapy for EC fertility sparing candidates. However, metformin was found to be protective in breast cancer survivors under tamoxifen.

Disclosures Nothing to disclose.

COMBITEC: MULTICENTRIC RETROSPECTIVE STUDY ON SENTINEL LYMPH NODE DETECTION BY COMBINED ICG + 99MTC VERSUS EXCLUSIVE ICG IN ENDOMETRIAL CANCER

1Vicente Bebia Corea, 2Marc Barahona, 2Cristina Almansa, 2Pablo Padilla Iserbe, 2Lola Marti, 2Ponce Sebastià Ponce, 2Alvaro Tejerizo, 3Santiago Domingo, 4Antonio Gil-Moreno, 5Silvia Cabrera Diaz, 1Hospital Universitari Vall D’Hebron; Gynecologic Oncology; 2Hospital Universitarios Bellvitge; Gynecologic Oncology; 3Hospital Universitario 12 de Octubre; Gynecology; 4Hospital Universitario La Fe; Gynecologic Oncology; 5Fundación Vall Hebron; Institut de Recerca; Gynecologic Oncology; 6Hospital Universitari Vall D’Hebron; Gynecoloy; Gynecologic Oncology

10.1136/ijgc-2020-ESGO.79

Introduction/Background Despite its extended use, there is scarce evidence about the combined use of 99mTc-albumin nanocolloid (99mTc) and indocyanine green (ICG) for the detection of sentinel lymph node (SLN) in endometrial cancer, when compared to ICG alone. The aim of this study is to compare the detection parameters of both methods.

Methodology Multicentric retrospective study (November 2015-June 2020) including patients diagnosed with endometrial atypical hyperplasia or initial preoperative stage endometrial carcinoma (FIGO I-II) who underwent SLN biopsy by cervical injection of: a) ICG intraoperatively, or b) 99mTc preoperatively, and ICG intraoperatively (ICG+99mTc).

Results A total of 180 patients were included, 51% (n=92) in the ICG group and 49% (n=88) in the ICG+99mTc group. 86.7% of the patients presented endometrioid histology, and 58.7% were preoperatively classified as low risk, according to the ESMO/ESGO/ESTRO criteria. The vast majority of the procedures (99.4%) were performed by a minimally invasive approach. Both groups were comparable according to their basal characteristics, except for a higher body mass index (27.6 vs. 30.3 kg/m2, p=0.014) in the ICG+99mTc group and a bigger proportion of robotic-assisted procedures (54.4 vs 29.6%, p=0.001) in the ICG group.

Global detection rate was 92.8% (IC 95%: 88.0–95.7), without statistically significant differences among groups (ICG:94.6% vs ICG+99mTc:90.9%, p=0.344). No significant differences were observed in the pelvic bilateral mapping rate (71.6%, ICG:70.7% vs ICG+99mTc:71.6%, p=0.890) or the aortic mapping rate (5.6%, ICG:8.7% vs ICG+99mTc:2.3%, p=0.058).

When ICG+99mTc was used, surgical procedures were 30 minutes longer when compared to ICG (150 vs 180 min, p=0.003). In 12 patients (6.7%) at least one positive SLN was found (ICG:9.8% vs ICG+99mTc:3.4%, p=0.164).

No significant differences were observed regarding the empty node packets rate or the number of SLNs retrieved per patient. There were no patients with a positive lymphadenectomy specimen and a negative SLN, thus sensitivity was 100%.

Conclusion Combining preoperative 99mTc to intraoperative ICG did not improve SLN detection in endometrial cancer, but resulted in longer procedures.

Disclosures Nothing to disclose.
study was to evaluate the role of radiomic analysis of pelvic adipose tissue at CT in predicting the incidence of post-operative complications of L.

**Methodology** Consecutive patients who underwent surgical treatment of endometrial cancer at Careggi University Hospital between January 2016 and December 2019 were enrolled. Only patients underwent to pelvic lymphadenectomy were enrolled. Exclusion criteria were bulky nodes at the preoperative imaging. Staging CT images were used for the radiomic analysis; pelvic adipose tissue was identified and segmented, so the images were imported to the 3D Slicer software. Subsequently, the extractions of the three radiomics features (busyness, flatness, elongation) of the rea of interest were carried out.

**Results** Twenty seven patients were enrolled. Five patients developed post-operative complications. The value of Busyness, Flatness and elongation correlated with postoperative complications (p= 0.04, p= 0.021, p=0.03, respectively).

**Conclusion** Our preliminary study shows that radiomic might be useful to predict whether a patient will develop any complications associated with the lymphadenectomy. Consequently pre-operative imaging might be used also to select which patient benefit the most from sentinel node study instead of L.

**Disclosures** The authors have no conflicts of interest to declare.
patient. SLNs were most commonly identified in the external iliac basins (78.2%), followed by the obturator fossa (10.3%), internal iliac basins (5.9%), common iliac basins (3.73%), presacral (0.93%) and para-aortic region (0.93%), respectively. Lymph node metastasis was detected in 25 women (14.5%). There was no statistical correlation between the SLN detection and the age, BMI, grade and histology, respectively. The bilateral SLN detection was adversely correlated with grade 3 (\( p = -0.29 \), \( p\text{-value} = 0.0001 \) and high-risk histology (\( p = -0.3 \), \( p\text{-value} = 0.0001 \)). In multivariate analysis, both grade (\( OR = 0.21 \), \( p\text{-value} = 0.005 \)) and high-risk histology (\( OR = 0.39 \), \( p\text{-value} = 0.04 \)) remained significant. Only three cases of Grade 1 lower extremity lymphoedema were reported.

Conclusion Intra-operative SLN mapping using fluorescence imaging with ICG in EC patients is feasible, yields high detection rates and reduces the lymphadenectomy-associated morbidity. Further studies are warranted to evaluate its accuracy in high-risk EC.

Disclosures We certify that no party has a direct interest in the results of the research and that no benefit will be conferred to us or any organisation with which we are associated.

Fertility pregnancy

| 227 | FERTILITY-SPARING TREATMENT IN ADVANCED BORDERLINE OVARIAN TUMORS. AN ANALYSIS FROM THE MITO14 STUDY DATABASE |
| 1Francesca Falcone, 1Stefano Greggi, 1Pierandrea De Iaco, 2Gabriella Ferrandina, 4Gennaro Cimmino, 5Violante Di Donato, 6Maria Mangili, 5Francesca Raspagliesi, 5Mario Malzoni, 5Enrico Breda. 1Istituto Nazionale Tumori, IRCCS “Bellini”; 2Sanità University; 3Department of Obstetrics and Gynecology, University of Palermo; 4Department of Obstetrics and Gynaecology, University of Naples “Federico II”; 5Center for Advanced Endoscopic Gynecological Surgery; 6Endoscopica Malzoni. |

Introduction/Background For advanced borderline ovarian tumors (BOTs), data concerning the efficacy and safety of fertility-sparing surgery (FSS) are very limited. The MITO14 is a multi-institutional retrospective study conducted among MITO Centres with the aim of systematically collecting data from consecutive BOT patients. In the present analysis, data are presented on women with advanced BOT registered into the MITO14 database and conservatively treated between January 1995 and December 2019.

Methodology The objectives were: i) to evaluate the recurrence rate and to determine predictors of recurrence; ii) to assess the impact of a FSS on disease-free survival (DFS) and disease-specific survival (DSS); iii) to evaluate pregnancy and live birth rates following treatment.

Only patients undergoing FSS and with histologically proven FIGO2014 stage II – III BOTs at final pathology were included. Cases submitted to bilateral salpingo-oophorectomy with uterine preservation were eligible. The following exclusion criteria were considered: i) age >43 years; ii) presence of second tumor(s) requiring therapy interfering with the treatment of BOT.

Results A total of 101 patients were recruited. The median follow-up time from primary cytoreduction was 124 months (IQR range 80–177.5). Fifty-five patients (54.5%) experienced at least one recurrence (median time to first relapse 21 months, IQR range 9–53), 53 of whom (96.3%) undergoing secondary surgery (further FSS in 34). At univariate analysis, significant predictors of relapse were: size of largest extraovarian lesion, peritoneal cancer index, completeness of cytoreduction, type of implants. After multivariable analysis, the size of extra-ovarian lesions and the presence of invasive implants resulted as the only independent predictors of recurrence (Tab. 1). Median DFS and DSS were respectively 96 months (95% CI, 17.5–174.4) and 290.4 months (95% CI, 280.8–299.9) (figure 1). Thirty-one patients attempted to conceive: 23 (74.2%) achieved at least one pregnancy and 20 (64.5%) gave birth to a healthy child. At the end of the observation period, 96 patients (95%) showed no evidence of implantation.
disease, 2 (2%) were alive with disease, and 3 patients (3%) died from BOT.

Conclusions Despite the recurrence high rate, the survivals and pregnancy outcomes indicate that FSS could be considered in advanced BOTs. Among predictors of recurrence, oophorectomy (vs. cystectomy) has resulted not significant as in early-stage BOTs likely due to the advanced-stage setting. Size of extra-ovarian lesions and presence of invasive implants were the only significant predictors. Completeness of cytoreduction was lacking significance likely because of low number of patients with residual disease.

Disclosures All authors declare no financial support or relationships that may pose conflict of interest.

Introduction/Background The maternal diagnosis of cancer complicates approximately 0.1% of all pregnancies. The most frequently diagnosed malignancies are breast cancer, cervical cancer, lymphoma, ovarian cancer and melanoma. Although chemotherapy can be administered during pregnancy, its effects on obstetric and neonatal outcomes are still largely unknown. The aim of this study is to assess the oncologic management as well as the obstetric and perinatal outcomes in a consecutive series of patients diagnosed with cancer during pregnancy.

Methodology Retrospective cohort study including 47 pregnant women diagnosed with primary invasive cancer during pregnancy between 2010 and 2019 at IRCCS Policlinico di Milano and Istituto Europeo Di Oncologia (Milan, Italy). All the included patients have been treated with chemotherapy during pregnancy. Oncologic, obstetric and neonatal data have been collected and compared. Linear regression analysis was used to assess the correlation between the therapy and perinatal outcomes. All the analysis were performed with Stat Direct 2,7,9 (StatsDirect Ltd, Altrincham).

Results The most common malignancies diagnosed in our cohort of 47 women were: breast cancer as the most common type (87.2%), followed by lymphomas (6.4%). All the maternal characteristics are listed in table 1.

All the patients were treated with chemotherapy during pregnancy consisting of different number of cycles according to the gestational age at diagnosis (1–12). Maternal chemotherapy-related toxicity was generally lower than expected, maximum grade 1 according to National Cancer Institute – Common toxicity Criteria (NCI-CTC).

All pregnancies ended with a livebirth fetus, at a mean gestational age of 36.7 weeks. The delivery was planned at least 3 weeks after the last administration of chemotherapy: 21 patients had a vaginal delivery, 23 an elective caesarean section and 2 an emergency caesarean section.

Table 2 shows the results of the correlation between maternal chemotherapy and perinatal outcomes: neonatal birthweight percentile, Apgar score and blood count parameters. No correlation has been demonstrated neither for the number of cycles or the gestational age at diagnosis and any of the outcome considered.

Conclusion Our results show that administration of chemotherapy during pregnancy is not associated with perinatal complications. Neonatal birth weight, Apgar score and neonatal hematologic indices are not affected by the number of chemotherapy cycles and the gestational age at the beginning of the treatment.

Disclosures Nothing to disclose.

459 EVALUATION OF THE EFFECT OF INTRAUTERINE INJECTION OF PLATELET-RICH PLASMA ON THE PREGNANCY RATE OF PATIENTS WITH A HISTORY OF IMPLANTATION FAILURE IN THE IN VITRO FERTILIZATION CYCLE

Marzieh Ghasemi. Zahedan University of Medical Sciences

10.1136/ijgc-2020-ESGO.86

Introduction/Background Implantation failure is a major problem in reproductive medicine, and despite the various methods described for treatment, there is little consensus on the
most effective method. Therefore, this study was conducted to investigate the effect of intrauterine injection of platelet-rich plasma (PRP) on the pregnancy rate of patients with a history of implantation failure in the in vitro fertilization (IVF) cycle.

Methodology In this clinical trial study, women attending the infertility clinic of Ali ibn Abitaleb Hospital in Zahedan (Iran) in 2019, who had a history of implantation failure and were candidates for frozen embryo transfer (FET), were examined. After receiving informed consent, the patients were divided into two groups of PRP recipients and the control group. IVF was performed routinely, and in the PRP receiving group, intrauterine injection was performed 48 hours before embryo transfer (ET). Then, demographic factors such as age, body mass index (BMI) and endometrial thickness were investigated in the two groups. The number of gestational sacs, the rate of implantation, the frequency of chemical and clinical pregnancies, as well as the frequency of abortion were compared in two groups.

Results In this study, 90 patients with a history of implantation failure participated the study and finally the information of 85 patients was studied. The mean age of the patients as well as the BMI did not differ between the two groups. The frequency of chemical pregnancy was 40% in the experimental group, 27% in the control group, and regarding clinical pregnancy 33% in the experimental group, and 24% in the control group, but there was no significant difference between the two groups. The rate of implantation, the mean thickness of the endometrium and the frequency of abortion did not differ significantly between the two groups.

Conclusion In general, the results of this study showed that in patients with endometrial thickness greater than 8 mm with a history of recurrent implantation failure, intrauterine injection of PRP had no effect on fertility outcome.

Disclosures None.
Among 35 (79.6%) patients who retained their childbearing potential: 17 (48.6%) had a second conization; 2 (5.7%) relapsed and underwent definitive treatment. After a median follow-up of 51 (range 1–184) months no deaths were reported. Twenty-two (66.7%) women attempted to conceive. There were 13 natural pregnancies among 12 (54.5%) women who got pregnant. Live birth rate was 76.9%: nine (69.2%) term and one (7.7%) preterm (at 32w) deliveries. Two (15.4%) miscarriage (1st and 2nd trimester) and one (7.7%) termination of pregnancy for medical reasons were recorded.

**Conclusion** Conization plus laparoscopic nodal evaluation is an ultraconservative but feasible option in the setting of fertility-sparing treatment for early-stage cervical cancer patients.

**Disclosures** The authors declare that there are no conflicts of interest.

No funding sources supported this investigation.

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**OUTCOME OF FERTILITY SPARING SURGERY IN CERVICAL CANCER, A NATIONAL STUDY IN SPAIN: CEFER STUDY**

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**Introduction/Background** The aim of this study was to analyze fertility sparing surgery (FSS) data in Spain and to evaluate its oncological results in patients with early cervical cancer (CC).

**Methodology** Retrospective, multicenter, comparative cohort study carried out in 13 Spanish referral hospitals between 2000 and 2018, which included women with early CC (IA1 with lymphovascular invasion to IB1 FIGO 2009) who underwent FSS (group FSS) or conventional radical surgery (control group).

**Results** A total of 222 patients were included in the study: 111 in the FSS group and 111 in the control group. No differences were found between both groups regarding baseline characteristics (table 1). In the FSS group, the chosen surgical approach was mainly vaginal (64.9%), followed by laparoscopic (29.7%) and laparoscopic robot-assisted (5.4%).

There were more intraoperative complications but fewer late complications (≥ III-IV Clavien-Dindo) in the FSS group than in the control group (5.4% vs. 2.7% and 0% vs. 6.3%, respectively; both p<0.05).

After a median follow-up of 54 months (range 1–173 months), 16 relapses were observed, 11 (9.9%) in the FSS group and 5 (4.5%) in the control group. However, disease-free survival (DFS) was similar in both groups (p=0.17; figure 1). There were two disease-related deaths, one in each group.

When focussing on the FSS group, 6 out of 11 (54%) relapsed patients had adenocarcinoma histology and 54% (6/11) of relapses corresponded to patients with tumors >2 cm. Univariate analysis of DFS in the FSS group did not show association with any of the tested variables (FIGO stage p=0.13, histology p=0.24; lymph node assessment p=0.79, and lymphovascular space invasion p=0.25), with the exception for tumor size (> vs ≤ 2 cm, p=0.008).

**Conclusion** FSS is rarely performed in patients with early CC in our country with an acceptable rate of intraoperative complications. Regarding oncological results, no differences were observed between FSS and conventional surgery. However, patients managed with FSS presented a higher recurrence rate in adenocarcinoma histologies and for tumors larger than 2 cm (statistically significant) a finding in accordance with the size established as a limit in current European guidelines.

**Disclosures** The authors declare no disclosures.

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**Abstract 564 Table 1** Baseline characteristics

<table>
<thead>
<tr>
<th>FIGO Classification</th>
<th>Total</th>
<th>FSS group</th>
<th>Control group</th>
</tr>
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<tbody>
<tr>
<td>IA</td>
<td>22</td>
<td>9 (40.9%)</td>
<td>13 (59.1%)</td>
</tr>
<tr>
<td>IB+</td>
<td>25</td>
<td>23 (92.0%)</td>
<td>2 (8.0%)</td>
</tr>
<tr>
<td>IA+</td>
<td>111</td>
<td>111 (100%)</td>
<td>0 (0%)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Histology</th>
<th>Total</th>
<th>FSS group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenocarcinoma</td>
<td>81</td>
<td>79 (97.5%)</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Adenocarcinoma + Cc</td>
<td>1</td>
<td>1 (100%)</td>
<td>0 (0%)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Lymphovascular space invasion (LVS)</th>
<th>Total</th>
<th>FSS group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>20</td>
<td>19 (95.0%)</td>
<td>1 (5.0%)</td>
</tr>
<tr>
<td>Negative</td>
<td>101</td>
<td>101 (100%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

**Abstract 564 Figure 1** Disease-free survival (DFS)
Introduction/Background The objective of this study was to examine the clinical utility of the American College of Surgeons (ACS) surgical risk calculator, developed as part of the National Surgical Quality Improvement Programme (NSQIP), in predicting perioperative morbidity in gyna-oncology patients, primarily, as a prediction model and secondly, as a tool to identify patients who are at increased risk of developing complications.

Methodology A retrospective review of 142 patients who underwent major surgery under the gynae-oncology team between 06/08/2018–16/04/2019 at the University Hospital of Wales. Pre-operative factors combined with a procedure-specific code generated the predicted risk of 13 post-operative complications for each patient. Brier scores assessed calibration and receiver operated curves (AUC) evaluated the discriminative power of NSQIP.

Results Complications were experienced by 35.2% (50/142) patients. The calculator displayed adequate calibration when used to predict serious complications (Brier = 0.070), readmission (Brier = 0.058), return to OR (Brier = 0.000) and UTI (Brier = 0.001). It had the greatest discriminative power when predicting the risk of serious complications (AUC = 0.672; 95% CI, 0.481–0.863). The calculator successfully identified a majority of patients who had a complication as being of ‘above average risk’ for all complications, apart from return to OR, based on their pre-operative factors.

Conclusion NSQIP has previously been demonstrated to be a useful pre-operative tool for evaluating the risk of post-operative complications in colorectal surgery. This study suggests that in the setting of gyna-oncology surgery the calculator does not have adequate discriminatory power to be an absolute predictor of all complications, however, it may be useful in identifying patients who are likely to develop serious complications and those at above average risk of complications.

Disclosures Inés Murray – I can confirm that I have no conflict of interest with reference to this work.

Kenneth Lim – I can confirm that I have no conflict of interest with reference to this work.

Robert Howells – I can confirm that I have no conflict of interest with reference to this work.

Rhidian Jones – I can confirm that I have no conflict of interest with reference to this work.

Aarti Sharma – I can confirm that I have no conflict of interest with reference to this work.

Sadie Jones - I can confirm that I have no conflict of interest with reference to this work.

Int J Gynecol Cancer 2020;30(Suppl 4):A1–A141
Results 1,811 tweeters used #goASCO20/#ASCO20 in 11,530 tweets. These tweets received 27,962 retweets. 12.4% (224) of tweeters received 80% of all retweets, while 34.2% (619) received no retweets. 7,644 accounts tweeted/retweeted using #ASCO20 hashtag, producing 11,455 tweets and 27,888 retweets. 11.1% of accounts (850) only tweeted, 76.3% (5,833) just retweeted, and 12.6% (961) both tweeted and retweeted.

#goASCO20 was used in 200 tweets and generated 262 retweets. This activity stemmed from 38 accounts that tweeted/retweeted using #goASCO20. Of these accounts 13% (5) just tweeted, 74% (28) just retweeted and 13% (5) both tweeted and retweeted.

Top hashtags used during ASCO 2020 are shown in table 1. Figure 1 compares Gynaecology related hashtags used during the conference. #goASCO20 hashtag was number 13 by tweets and 27th by retweets during the conference period.

Conclusion ‘#goASCO20’, a unique Gynaecological Oncology hashtag was created to disseminate Gynaecological Oncology information from ASCO 2020 virtual event. #goASCO20 was one of several gynaecological oncology hashtags used. Each of these were used by relatively small groups of individuals. Discussions were fragmented resulting in an overall lower profile for Gynaecological Oncology related tweets compared to general tweeting during ASCO 2020. The use of Twitter in academia is increasing. Its use during such conferences facilitates the spread of clinical knowledge; arguably more than any other academic platform. Gynaecological oncology tweeting needs coordination and agreement on a common hashtag to organise content at virtual events and between meetings.

Disclosures Esra Bihir: Member of Communication and Social Media Committee at The European Network of Young Gynae Oncologists (ENYGO) since May 2020.

Introduction/Background The ovaries are a frequent site of metastasis and tumors metastatic to the ovaries account for 5–6% of all ovarian tumors. In most cases, the primary tumor originates from gastrointestinal tract, breast, and gynaecologic organs including endometrium and cervix. The diagnosis is often made on final pathology since many metastatic tumors mimics primary ovarian carcinoma and most patients present with pelvic mass. Therefore, surgery is the mainstay of management. The prognosis of patients with ovarian metastasis is generally poor. However, survival rates are even worse in patients with non-gynaecologic primaries.

Methodology Patients with pelvic mass who were operated at Hacettepe University Faculty of Medicine, Department of Obstetrics and Gynaecology for a five-year period were identified. Among them, the clinical and pathological characteristics of patients with tumors metastatic to the ovaries were retrospectively reviewed. Survival analysis was done as well with a particular focus on the origin of the primary tumor.

Results Tumors metastatic to the ovaries accounted for 16.2% of all ovarian malignancies and 79 cases with ovarian metastases constituted the study group. Mean age of the patients was 56.3 years. Primary tumor non-gynaecologic in 65.8% of cases and colon cancer was the most common non-gynaecologic primary followed by stomach and breast cancer. All remaining patients (34.2%) had primary endometrial cancer metastatic to the ovaries. Patients with gynaecologic primaries were significantly older, but the levels of tumor markers were similar. Patients with non-gynaecologic primaries most-commonly presented with abnormal imaging results and pain while abnormal bleeding was the most common symptom in those with gynaecologic primaries. Staging surgery and total abdominal hysterectomy with bilateral salpingo-oophorectomy were the most common surgeries performed. Bilateral ovarian involvement was detected in 62.0% of cases. Mean diameter of the tumor was 6.5 cm. Adjuvant treatment was given in 96.2% of patients. Of patients, 43.0% died of disease. Median survival was 19.7 months, but this was significantly longer in patients with non-gynaecologic primaries (10.0 months vs 32.6 months, p=0.05). Longest survival was detected in patients with colon cancer. Extent of surgery or the type of adjuvant therapy given did not affect median survival.

Conclusion Tumors metastatic to the ovaries account for a significant proportion of all ovarian cancers. Most of these tumors are diagnosed in elderly patients and prognosis is
relatively poor regardless of the surgical procedures performed and adjuvant therapies given.

Disclosures No potential conflict of interest to declare.

A SYSTEMATIC REVIEW TO IDENTIFY AND ASSESS THE MENTAL HEALTH SEQUALAE AMONGST WOMEN WITH ENDOMETRIOSIS WITH OR WITHOUT CHRONIC PELVIC PAIN (THE ELEMI PROJECT)

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Introduction/Background Endometriosis is a complex, chronic gynaecological condition impacting approximately 176 million women globally. It is associated with symptoms such as chronic pelvic pain (CPP), dysmenorrhoea, menorrhagia, sexual dysfunction and infertility. During several points in the lifecycle of this chronic disease, women bear the consequent burden of mental health (MH) difficulties, due to the complex symptomatology and comorbidities of endometriosis. For example, delayed diagnosis (the average time to diagnose being 7–8 years), undergoing often repeated excision surgeries, and difficulties with subfertility and sexual activities, and suffering with long-term CPP and analgesic use, can all negatively influence MH and can have significant impact on the psychological, sexual, relationship and social functioning of affected women. Therefore, a systematic review was conducted as part of the evidence synthesis phase of the ELEMI project to identify and assess this complex relationship with a view to report on any knowledge and clinical practice gaps.

Methodology The systematic protocol was published in PROSPERO (CRD42020181495). MeSH terms developed include Endometriosis, Depression, Anxiety, Low mood, Psychiatry comorbidity, Women’s health and CPP. All studies and material published between January 1980 to June 2020 in English and participants were included.

Results Out of 28 studies included in the systematic review, 17 were included in the meta-analysis (anxiety: 6, chronic pelvic pain: 3, depression: 11, and dyspareunia: 3) which described the prevalence and extent of MH symptoms in endometriosis and/or CPP. The pooled prevalence for anxiety was found to be 31.8% (95% CI: 26.5% - 37.1%), whilst for depression 28.9% (95%CI: 8.6%-49.2%). Pooled prevalence for CPP was high at 57.2% (95%CI: 7.0%, 107.4%) and pooled estimate of mean SF-MPQ for chronic pain to be 13.09 (95%CI: 7.13, 19.05). Computed prevalence for dyspareunia was also identified to be high (prevalence: 54.9%, 95%CI: 43.9%, 65.9%). The narrative analysis showed depression and anxiety to be the most commonly reported MH symptoms. None of the papers indicated if these had received a clinical diagnosis or were...
being treated. Generic MH assessments were used in all samples. Thus, whilst it is vital to identify the reporting of these symptoms, their clinical significance is yet to be comprehensively ascertained, and further exploratory evidence is required (figure 1).

Conclusion Limited research is currently available to evaluate the MH sequelae of endometriosis. Further comprehensive research is required to fully assess and treat the MH associated endometriosis patient reported outcomes.

Disclosures Nothing to declare

370 SAFETY OF ONCOLOGIC SURGERY WITHOUT PREOPERATIVE COVID-19 TESTING IN ASYMPTOMATIC PATIENTS

Nazlı Orhan, Utku Akgor, Nejat Özgul, Mehmet Coskun Salman, Murat Gütekın. Hacettepe University Faculty of Medicine; Department of Obstetrics and Gynaecology; Hacettepe University Faculty of Medicine; Department of Gynaecological Oncology; Department of Obstetrics and Gynaecology

Introduction/Background Novel Coronavirus Disease (COVID-19) pandemic has a significant impact on healthcare services. Non-emergent surgeries are being restricted since medical facilities are mostly occupied by or reserved for COVID-19 patients. However, postponing oncologic surgeries may have significant effects on survival. Also, many reports were published regarding the safety of oncologic surgeries during the pandemic. In this study, we aimed to evaluate the safety of oncologic surgeries without preoperative COVID-19 testing in asymptomatic patients with gynaecological cancers when preoperative COVID-19 testing was not mandatory.

Methodology Patients with gynaecological cancers who were operated between March 11 to June 11 without preoperative COVID-19 testing at Hacettepe University Faculty of Medicine, Department of Obstetrics and Gynaecology were identified. These patients were followed up 6 weeks after surgery to evaluate COVID-19 related morbidity or mortality.

Results The study group consisted of 30 patients. Of these, 17 had endometrial cancer, 9 had ovarian cancer, 3 had cervical, and 1 had vulvar cancer. Mean age of patients was 58 years. Twenty-two patients (73.3%) had co-morbidities and among those 3 (10.0%) had pulmonary disease. Five patients (16.7%) were followed up in the intensive care unit postoperatively based on decision of attending anesthesiologists. Despite venous thromboembolism prophylaxis, one patient (3.3%) with ovarian cancer developed pulmonary embolism who was tested negative for COVID-19. This patient developed acute abdomen on 20th postoperative day and was subjected to re-laparotomy, but she died of cardiac arrest 3 days later. No significant morbidity or mortality was observed in remaining 29 patients (96.7%).

Conclusion During the COVID-19 pandemic, risk of surgical morbidity or mortality is not increased and oncologic surgeries may safely be performed without routine COVID-19 testing in asymptomatic cases even if they have co-morbidities. However, adequate infrastructure is crucial since postoperative intensive care unit admission is required for a significant proportion of patients.

Disclosures No potential conflict of interest to declare.
RACIAL DISPARITIES IN PATIENTS WITH COVID-19 INFECTION AND GYNECOLOGIC MALIGNANCY

Olivia Lara, 1Maria Smith, 2Yuyan Wang, 2Resin O’carthail, 3Stephanie Blank, 4Anne Krissely, 5Jennifer Mochon, 6Lisa Gabor, 7Eloise Chapman-Davis, 8Justin Lee, 9Sara Isani, 1Mengling Liu, 2Jason Wright, 3Bhavana Pothuri, 4Nyu Langone Health; Obstetrics and Gynecology, 5NYU Langone Health, New York, United States; 6Nyu Langone Health; Population Health; 7Memorial Sloan Kettering Cancer Center; Weill Cornell Medical College; Medical Oncology; 8Icahn School of Medicine at Mount Sinai; Obstetrics, Gynecologic and Reproductive Science; 9College of Physicians and Surgeons, Columbia University; Obstetrics and Gynecology; 1State University of New York Downstate Medical Center; Obstetrics and Gynecology; 2Montefiore Medical Center and Albert Einstein College of Medicine; Obstetrics and Gynecology and Women’s Health; 3Cornell University; Obstetrics and Gynecology

Diagnostic accuracy of serum insulin-like growth factor binding protein-2 for ovarian cancer

Pande Kadek Aditya Prayudi, 1Nyoman Gede Budiana, Ketut Suwiyoga. Division of Gynecologic Oncology, Department of Obstetrics and Gynecology Faculty of Medicine Udayana University/Sanglah General Hospital

Introduction/Background Insulin-like growth factor binding protein-2 (IGFBP2) have been shown to play important roles in the pathogenesis of ovarian cancer. It also serves as a potential biomarker for prognosis of ovarian cancer. However, its role in the diagnosis of ovarian cancer has never been studied. This study is aimed to determine the diagnostic accuracy of serum IGFBP2 in differentiating between malignant and benign ovarian lesion.

Methodology Preoperative IGFBP2 level was determined from the serum of 76 patients with adnexal mass who underwent exploratory laparotomy and subsequent histopathology examination at Sanglah General Hospital, Denpasar, Bali, Indonesia. Diagnostic accuracy of IGFBP2 level was determined from the receiver operating characteristics curve (ROC).

Results Of the 76 patients, 46 patients were diagnosed with ovarian cancer and 30 patients were diagnosed with benign ovarian lesions. Serum IGFBP2 level was significantly higher in patients with ovarian cancer, as compared to those with benign ovarian lesions (median: 945.9 vs. 401.5 g/ml, p<0.001). Using a cut off value of 551.6 ng/ml, the area under the ROC (AUC) for diagnosing ovarian cancer was 0.815 (95% CI 0.721–0.910, p<0.001), sensitivity was 76.1%, specificity was 80%, and diagnostic odd ratio (DOR) was 12.7 (95% CI 4.1–39.0, p<0.001). The diagnostic performance of IGFBP2 was enhanced in postmenopausal women [AUC 0.893 (95% CI 0.771–1.000, p=0.002), sensitivity 85%, specificity 85.7%, DOR 34 (95% CI 2.9–392.8), p=0.001] and in advanced stage [AUC 0.904 (95% CI 0.806–1.000, p<0.001), sensitivity 87.5%, specificity 80%, DOR 28 (95% CI 6.2–126), p<0.001].

Conclusion IGFBP2 is a potential biomarker for diagnosis of ovarian cancer. Disclosures Pande Kadek Aditya Prayudi discloses no potential conflict of interest. Nyoman Gede Budiana discloses no potential conflict of interest. Ketut Suwiyoga discloses no potential conflict of interest.
RISK FACTORS FOR LYMPH NODE METASTASIS OF OVARIAN CANCER

INTRODUCTION/BACKGROUND

Conditional relative survival (CRS) considers changes in prognosis over time and thus, may offer more useful estimates for survivors and clinicians. We aimed to investigate the CRS among patients with ovarian cancer with comprehensive stratification by various factors that influence survival probabilities.

METHODOLOGY

This nationwide retrospective cohort study used data from the Korean Central Cancer Registry. We included 78,606 patients diagnosed with cervical cancer as their first cancer between January 1, 1997 and December 31, 2016. CRS and the conditional probabilities of death for the following 5 years were calculated stratified by age at diagnosis, histology, stage at diagnosis, year of diagnosis, and social deprivation index.

RESULTS

The 5-year relative survival rate at the time of diagnosis was 61.1% for all cases. The probability of surviving an additional 5 years conditioned on having already survived 1, 2, 3, 4, and 5 years after diagnosis was 65.0%, 69.5%, 74.6%, 79.3%, and 83.9%. Patients with poorer initial survival estimates (older, advanced stage) generally showed the
Abstracts

EVALUATION OF SURVIVAL OUTCOMES FROM DELAYED CYTOREDUCTION SURGERY FOLLOWING NEOADJUVANT CHEMOTHERAPY IN ADVANCED EPITHELIAL OVARIAN CANCER

1Shih-Ern Yao, 2James Nicklin. 1Queensland Centre for Gynaecological Cancer; Level 6, Ned Hanlon Building; Royal Brisbane and Women’s Hospital; 2Queensland Centre for Gynaecological Cancer

Introduction/Background Optimal timing of cytoreductive surgery following neoadjuvant chemotherapy (NACT) has not been established in the treatment paradigm of advanced epithelial ovarian (EOC) cancer. Traditionally, interval cytoreduction surgery (ICS) is undertaken following 3 cycles of treatment, however in a proportion of patients, surgery is delayed for reasons including incomplete disease response, poor surgical candidacy and anticipated suboptimal tumour resectability.

We looked to investigate survival outcomes in advanced epithelial ovarian cancer (EOC) patients with the intention of maximal cytoreduction following neoadjuvant chemotherapy (NACT) with respect to timing of surgery and degree of cytoreduction.

Methodology A retrospective review was conducted of 572 patients with EOC treated with NACT with the intention of interval cytoreduction surgery (ICS) between 2008 and 2017. Overall survival (OS) and progression-free survival (PFS) outcomes were analysed and compared with patients who only received chemotherapy. Outcome measures were correlated with the number of NACT cycles and amount of residual disease following surgery.

Results There was no difference in the proportion of patients in whom complete cytoreduction was achieved based on number of cycles of NACT. Median 5-year OS and PFS for patients undergoing cytoreduction after NACT was 38 and 24 months respectively with no significant difference in OS between standard and delayed timing of surgery. Significant OS advantage was associated with patients who had undergone complete cytoreduction compared with those with any macroscopic residual disease (<1 cm residual: HR 1.68; ≥1 cm residual: HR 2.77).

Conclusion From this study, survival outcomes do not appear to be worse for patients with EOC treated with NACT if cytoreduction surgery is delayed beyond three cycles. In EOC patients, the imperative to achieve complete surgical cytoreduction remains gold standard, irrespective of surgical timing, for best survival benefit.

Disclosures This work was supported by a research grant from Gynaecological Cancer Research Education and Development Society.

Neither author disclose any conflict of interest

PREOPERATIVE EVALUATION OF LIPID MARKERS OF MALIGNANT EPITHELIAL OVARIAN TUMORS

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Introduction/Background The venous blood is repleted with abundant tumor-promoting factors and lipids, that play an essential role in ovarian high-grade serous carcinoma (HGSC). A comprehensive picture of mediators impacting HGSC progression is, however, not available.

Research question to determine the value of the serum lipid profile in HGSC for diagnosis.

Methodology This study was approved by the Institute Research Medical Ethics Committee. Analysis of blood serum lipids of healthy volunteers (n = 13, control group) and patients with verified HGSOC (I-IV stages, n = 28, main group): I-II stages (n=5), III-IV stages (n=23)) has been performed. Patients with HGSOC managed in the Department of Innovative Oncology and Gynecology (National Medical Research Center for Obstetrics, Gynecology and Perinatology named after Academician V.I. Kulakov) were comparable in age, body mass index, grade and FIGO stages. Lipids were analysed by high performance mass spectrometry liquid chromatography (HPLC-MS). The Orthogonal Projections to Latent Structures Discriminant Analysis (OPLS-DA) multifactor analysis method and non-parametric t-test, have been applied for statistical data processing. Random forest model was used to evaluate predictive performance of potential biomarkers based on leave-one-out cross-validation in terms of area under the receiver operating characteristic (ROC). The predictive accuracy of the predictive lipids was performed using the logistic regression modeling with AUC value.

Results In main group the levels of 128 of 345 studied lipids differed significantly compared to the control group (p<0.05), the parameters of the OPLS-DA model were: R2 = 0.87, Q2 = 0.80; AUC=0.99. ROC curve sensitivity = 96% and specificity =1%, the AUC value of these metabolite combinations for predicting HGOC recurrence was 1. Lipid profile changes significantly differed between the groups: control group vs I-II stages (p≤0.05), control group vs III-IV stages (p≤0.05).

11 patients who developed the disease relapse or progression had significant preoperative increase of oxidized lysophosphatidylcholine (OxLPC) and phosphatidylethanolamine (PE) in contrast to 17 patients who showed no evidence of recurrence after at least 14 months of follow up.

Disclosures I have no conflicts of interest.

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111

A56

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Conclusion Lipid profile changes in HGSC may have considerable prognostic value for the disease after treatment. The signatures defined by our work may provide a basis for the development of prognostic tools and may predict the clinical course of HGSC patients.

This work was supported by RSF grant № 20-65-46014.

Disclosures Nothing to disclose.
role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. The authors declare that they have no competing interests.

230 PRELIMINARY RESULTS OF ANLOTINIB AND NIRAPARIB DUAL THERAPY EVALUATION IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER (ANNIE): A MULTICENTER, SINGLE-ARM, PHASE 2 TRIAL

1Guochen Liu, 1Jihong Liu, 3Bingna Xian, 3Yanling Feng, 3Qidan Huang, 5Sun Yat-Sen University Cancer Center; Department of Gynecologic Oncology; 5Sun Yat-Sen University Cancer Center; 2Department of Gynecologic Oncology

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Introduction/Background Patients with platinum-resistant ovarian cancer have a poor prognosis. Effective treatment options for these patients are limited. In this study (ANNIE), we evaluate the activity of niraparib combined with anlotinib in patients with platinum resistant recurrent ovarian carcinoma.

Methodology The ANNIE trial was a multicentre, single-arm, phase 2 study that evaluated the safety and activity of niraparib combined with anlotinib in patients (≥18 & ≤70 years) with recurrent ovarian epithelial, fallopian tube, or primary peritoneal cancer whose disease recurred in less than 6 months after the last administered platinum therapy. Patients received oral niraparib 300 mg/200 mg once daily continuously and anlotinib 12 mg on day 1–14 of each 21-day cycle thereafter until disease progression or intolerable toxicity. The primary objective was to assess objective response rate (ORR; complete plus partial responses). 40 cases are planned to be enrolled.

Results Between May 22, 2020 and August 3, 2020, we enrolled 9 patients (median age, 54 years [range, 44–64 years]). Patients had received a median of five (range, 2–8) previous lines of therapy. All but one (voluntarily withdrew) of the patients were still on treatment, the longest has been taking medication for more than 4 cycles. Three patients underwent imaging evaluation, including 1 confirmed complete responses, 1 with confirmed partial responses, 1 with stable disease. No drug-related grade 3 or worse treatment-emergent adverse events were detected, the most common treatment emergent adverse events were hypertension (5 of 9 patients), hand-foot skin reaction (4 of 9 patients), hoarseness (4 of 9 patients). Enrollment was ongoing so far.

Conclusion It seems niraparib in combination with anlotinib is tolerable, with promising antitumor activity for patients with platinum resistant recurrent ovarian cancer. Besides, we observed unusual safety signals in the combination (more hoarseness and less haematological toxicities). The conclusion can be clarified after the research is completed.

Disclosures Trial registration ClinicalTrials.gov identifier: NCT04376073, Funding: Zai Lab, The authors declare no conflicts of interest.

247 OPTIMISING PREDICTION ACCURACY OF COMPLETE CYTOREDUCTION FOR HIGH GRADE SEROUS ADVANCED OVARIAN CANCER PATIENTS USING NEAREST-NEIGHBOR MODELS

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10.1136/ijgc-2020-ESGO.106

Introduction/Background The foundation of modern ovarian cancer care is cytoreductive surgery to remove all macroscopic disease (R0). Identification of R0 resection patients may help individualise treatment. Machine learning and AI have been shown to be effective systems for classification and prediction. For a disease as heterogenous as ovarian cancer, they could potentially outperform conventional predictive algorithms for routine clinical use. We investigated the performance of an AI system, the k-nearest neighbor (k-NN) classifier to predict R0, comparing it with logistic regression.

Methodology A cohort of patients diagnosed with high grade serous advanced ovarian, tubal and primary peritoneal cancer (HGSOC), undergoing surgical cytoreduction from 2015–2019, was selected from the ovarian database. Performance for these patients are limited. In this study (ANNIE), we evaluated the safety and activity of niraparib combined with anlotinib in patients with platinum resistant recurrent ovarian carcinoma.

Methodology The ANNIE trial was a multicentre, single-arm, phase 2 study that evaluated the safety and activity of niraparib combined with anlotinib in patients (≥18 & ≤70 years) with recurrent ovarian epithelial, fallopian tube, or primary peritoneal cancer whose disease recurred in less than 6 months after the last administered platinum therapy. Patients received oral niraparib 300 mg/200 mg once daily continuously and anlotinib 12 mg on day 1–14 of each 21-day cycle thereafter until disease progression or intolerable toxicity. The primary objective was to assess objective response rate (ORR; complete plus partial responses). 40 cases are planned to be enrolled.

Results Between May 22, 2020 and August 3, 2020, we enrolled 9 patients (median age, 54 years [range, 44–64 years]). Patients had received a median of five (range, 2–8) previous lines of therapy. All but one (voluntarily withdrew) of the patients were still on treatment, the longest has been taking medication for more than 4 cycles. Three patients underwent imaging evaluation, including 1 confirmed complete responses, 1 with confirmed partial responses, 1 with stable disease. No drug-related grade 3 or worse treatment-emergent adverse events were detected, the most common treatment emergent adverse events were hypertension (5 of 9 patients), hand-foot skin reaction (4 of 9 patients), hoarseness (4 of 9 patients). Enrollment was ongoing so far.

Conclusion It seems niraparib in combination with anlotinib is tolerable, with promising antitumor activity for patients with platinum resistant recurrent ovarian cancer. Besides, we observed unusual safety signals in the combination (more hoarseness and less haematological toxicities). The conclusion can be clarified after the research is completed.

Disclosures Trial registration ClinicalTrials.gov identifier: NCT04376073, Funding: Zai Lab, The authors declare no conflicts of interest.
predicted by a k-NN model that included age and CCI (figure 1).

Conclusion The k-NN algorithm is a versatile and promising tool for R0 resection in HGSOC patients, which outperforms logistic regression. The model, which is very much reflective of ‘previous clinical experience’ can be directly available to clinicians and is expected to improve accuracy with data expansion.

Disclosures No disclosures.

250 SURVIVAL IMPLICATION OF PRE-TREATMENT IMAGING TUMOR DISSEMINATION PATTERN IN PATIENTS SURGICALLY TREATED FOR ADVANCED HIGH GRADE SEROUS OVARIAN CANCER

Alexandros Laits, Yong Tan, Angelika Kaufmann, Mohamed Otify, Richard Hutson, Amudha Thangavelu, George Theophilou, David Nugent, Diederick Dejong. St James’s University Hospital; Leeds Teaching Hospitals; Gynaecologic Oncology

Introduction/Background Clarity and precision about the anatomical extent of disease in cancer is essential for prognostication, research, and cancer-control activities. To select effective therapeutic approaches for advanced high-grade serous ovarian cancer (HGSOC), yet the most prevalent and lethal form, it is important to identify stratification factors that could accurately predict prognosis before initial intervention. We hypothesized that women with different tumor dissemination patterns at pre-treatment imaging would have different prognosis.

Methodology This was a retrospective analysis of 209 FIGO stage III-IV HGSOC women, who were scheduled for cytoreductive surgery in SJUH Leeds between Jan 2015 to Dec 2018 with curative or life-prolonging intent. CT scans were reported by an MDT radiologist. Three pre-treatment imaging dissemination patterns were identified and verified by final histology. A Cox proportional hazard analysis was used to test the effect of imaging dissemination patterns, age, performance status (PS), timing of surgery (upfront vs delayed cytoreduction), surgical complexity score (SCS), residual disease (RD), disease score, and type of chemotherapy on survival. Kaplan-Meier survival curves were produced using SPSS® 26.

Results There were no statistical differences in the cytoreduction rates amongst the three groups (figure 1). The mean progression-free survival (PFS) for patients grouped as intraperitoneal (n=137), intraperitoneal and lymphatic (n=56), and intraperitoneal and haematogenous (n = 16) was 26.5 (95% CI 23.4–29.6), 21.3 (95% CI 18.3–24.4) and 19.1 months (95% CI 15.1–22.9), respectively. The mean overall survival (OS) was 45.8 (95% CI 41.5–50.2), 34.8 (95% CI 29.2–40.3) and 30.7 months (95% CI 24.5–36.9), respectively (p=0.05) (figure 2). The mean PFS and OS for the entire cohort was 25 months (95% CI 22.6–27.3) and 41.8 (95% CI 38.3–45.2), respectively. For PFS, Cox regression analysis identified PS (HR 1.23, 95% CI 1.1–1.5, p=0.04), RD (HR 0.69, 95% CI 0.46–0.98, p=0.05) as statistically significant. For OS, Cox regression analysis identified PS (HR 1.47, 95% CI 1.14–1.89, p=0.03), dissemination pattern (HR 1.36, 95% CI 1.02–1.86, p=0.05) as statistically significant.

Conclusion For HGSOC prognosis, one should consider not only the patient’s disease burden but also their overall medical status and ability to undergo extensive surgery. Prolonged survival rates were found predominantly in those patients with intraperitoneal only pre-treatment imaging dissemination pattern. Baseline tumor dissemination pattern can be a prognostic factor for overall survival. Classification of such patterns can help counsel patients initially on their prognosis and identify those who might benefit from intraperitoneal chemotherapy.

Disclosures No disclosures.

257 CONTRASTING CLINICAL CHARACTERISTICS AND TREATMENT PATTERNS IN WOMEN WITH NEWLY DIAGNOSED ADVANCED-STAGE OVARIAN CANCER IN AUSTRALIA, SOUTH KOREA AND TAIWAN

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Introduction/Background Epithelial ovarian cancer (EOC) is often associated with diagnosis at an advanced stage, poor prognosis and high mortality. Limited data exist on the clinical management of ovarian cancer (OC) patients in the Asia-Pacific region. We evaluated secondary databases from Australia, South Korea and Taiwan to review the current standard of care in a real world setting prior to the introduction of poly-(adenosine diphosphate-ribose) polymerase inhibitor (PARPi) maintenance after first-line chemotherapy.

Methodology Data from medical records of nearly 1,000 women diagnosed with advanced-stage EOC in a 5 year period, between January 2014 and December 2018 were obtained from clinic- (Taiwan, South Korea) and cohort-based...
Conclusion Although there were differences in demographics and treatment patterns, advanced-stage EOC had poor prognosis and relatively short progression-free intervals across Asia-Pacific countries with well-developed healthcare systems, highlighting the need to develop novel approaches to improve patient outcomes. Variation in the germline BRCA1/2 mutation rates across three datasets is probably due to differences in the composition of the contributing registries (clinic or cohort-based).

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Soo Young Jeong, Hung-Hsueh Chou, Chih-Long Chang, Heng-Chen Hsu and Wen-Fang Cheng have no conflict of interests to be declared.
Introduction/Background PARP inhibitors (PARPi) maintenance after Platinum (Pt) based chemotherapy (CT) significantly improves progression-free survival (PARPi-PFS) and PFS after subsequent (ssq) CT (PARPi-PFS2) in relapsed high grade serous ovarian cancer (HGSOC). Data regarding ssq CT is scarce, and PARPi/Pt crossed mechanisms of resistance may impact on outcome of ssq Pt. We provide Real-world-data on this issue.

Methodology We included HGSOC patients treated with ssq CT after progression to maintenance PARPi until 15th Jul 2020 in 3 hospitals. Endpoints were related to this ssq CT: objective response rate (ORR), median(m) progression-free survival (PFS) and overall survival (OS). Multivariate Cox and logistic regression models were adjusted by BRCA status and Pt-free interval (PFI) (6–12 months vs ≥12 mo). Adjusted hazard ratios (aHR) and odds ratios (aOR) of the risk of progression/death and ORR, respectively, were reported with 95% confidence intervals (CI).

Results 56 patients were identified (32 BRCAmut; 1p BRIP1mut). 4 patients (7.1%) received PARPi after 1st line CT, 26 (46.4%) after 2nd line and 26 (46.4%) after ≥3rd line. 34 patients (60.7%) received olaparib and 22 (39.3%) niraparib. m-PARPi-PFS in the recurrent setting was 7.5 mo (longer in BRCAmut: 10.1 vs 5.5 mo, p = 0.03). m-PARPi-PFS2 was 15.8 mo (longer in BRCAmut: 20.9 vs 15.4 mo, p = 0.07).

Endpoints regarding ssq CT are shown in table 1. ORR to ssq Pt was 33.3% and progression disease without any response 28.6%. ORR in p who received ssq Pt-free CT, ssq Pt with PFI 6–12 mo, and ssq Pt with PFI ≥12 mo were 33.3%, 23.8% and 42.8%, respectively. Five complete responses occurred among BRCAmut patients that had received PARPi in the recurrent setting. mPFS and mOS were significantly longer in the PFI ≥12 subgroup vs the others (figure 1).

Focusing in p receiving ssq Pt, when adjusting by BRCA status: aOR of ORR in p with PFI ≥12 vs 6–12 mo was 0.56 (95% CI: 0.13–2.30), aHR of mPFS between these two subgroups was 0.61 (95% CI: 0.30–1.20; p = 0.16), and aHR of mOS was 0.20 (95% CI: 0.7–0.61; p = 0.005). Results did not change when excluding the 4p who received PARPi as 1st line.

Conclusion A trend towards higher benefit from ssq Pt after PARPi was observed in the PFI ≥12 subgroup. Benefit from ssq Pt after PARPi in the PFI 6–12 subgroup was similar to benefit from CT in the non-Pt subgroup. The role of ssq Pt after PARPi in the PFI 6–12 subgroup warrants further research.

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Iris Teruel, Anna Esteve and Andrea Gonzalez have nothing to disclose.
**Introduction/Background** Malignant sex cord stroma cell tumours (SCST) account for less than eight percent of ovarian malignancies. The Arbeitsgemeinschaft für Gynäkologische Onkologie (AGO) has established a clinicopathological (Current Ovarian geRm cell and SExor coid stromal Tumour Treatment strategies, CORSETT) database for a better documentation and understanding of this rare disease. Here, we present the first clinicopathological descriptive analysis for patients with independently confirmed SCST from the CORSETT database.

**Methodology** 20 German centres entered mixed retro- and prospective data of SCST patients with tumour specimens available treated between 2000 to 2014 into the CORSETT database. An independent CORSETT pathology reference panel checked the primary histological diagnosis.

We conducted a descriptive analysis of the treatment strategies and created Kaplan-Meier curves and cox regression analyses for the survival analysis.

**Results** The reference pathology panel diagnosed 143 patients with granulosa cell (GCT, FIGO stage I= 120, 87.0%) and 14 patients with Sertoli-Leydig cell (SLCT, FIGO stage I = 11, 91.7%) tumours (others = 5). The median age of patients with GCT was 57.6 years (SLCT: 47.2 years). 87 of GCT (61.7%) and eight SLCT (57.1%) patients were treated with laparoscopy and the tumour ruptured intraoperatively in 22% (SLCT: 7.7%) of the cases. 57 GCT (45%) and eight SLCT (57%) patients received fertility-sparing surgery. 19 of GCT (15%) and two SLCT (15.4%) patients received adjuvant chemotherapy. 59 of GCT (45%) and two of SLCT (14.3%) patients experienced a disease recurrence. The median progression-free survival (PFS) for all SCST patients was 80.4 months, (overall survival not reached). Advanced FIGO stage was associated with decreased PFS (p < 0.05).

Adjuvant chemotherapy had no statistically significant beneficial effect on PFS (all regimens p > 0.05).

**Conclusion** In this analysis, almost every fourth SCST patient treated surgically experienced an intraoperative cyst rupture that had however no impact on disease recurrence. One in five SCST patient received adjuvant chemotherapy that had no PFS improvement.

**Disclosures**

290 **TARGETING AKT AND DNA-PK AS A THERAPEUTIC STRATEGY IN PLATINUM RESISTANT HIGH-GRADE SEROUS OVARIAN CANCER**

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**Introduction/Background** High-grade serous ovarian cancer (HGSOC) is the most lethal form of gynaecological malignancy. Despite initial sensitivity to platinum chemotherapy, the majority of patients develop resistance to treatment and eventually die. Current treatment options for platinum-resistant patients are limited.

The role of the PI3K/AKT/mTOR pathway has been described in chemo-resistant HGSOC, in particular through activation of AKT by DNA-PK in response to platinum treatment. As increasing numbers of AKT and DNA-PK inhibitors advance to clinical trials, determining mechanism of action and efficacy is crucial.

This project aims to evaluate inhibition of AKT or DNA-PK as a therapeutic strategy to target platinum resistance in HGSOC, and identify proteomic signatures confirming mechanism of action and target inhibition.

**Methodology** A panel of seven AKT and DNA-PK inhibitors were tested in combination with cisplatin chemotherapy in immortalised HGSOC cell lines and primary tumour cells cultured from HGSOC tumour/ascites samples. Clonogenic assays were performed to establish effect of inhibitor treatment in combination with cisplatin chemotherapy on the ability of cells to form colonies. Isobologram assays were performed to establish synergy/antagonism between inhibitors and cisplatin chemotherapy. Proteomic Reverse Phase Protein Array (RPPA) was performed to determine the mechanism of action of inhibitors, and results were confirmed with immunoblotting.

**Results** Treatment with AKT or DNA-PK inhibitors in combination with cisplatin led to significantly enhanced apoptotic responses in immortalised platinum-resistant HGSOC cell lines (n=5), and in primary cells derived from ascites or tumour (n=4, p < 0.01, p < 0.05), compared to cisplatin treatment alone. In platinum-resistant HGSOC cell lines, fewer cell colonies were observed with increasing concentrations of AKT or DNA-PK inhibitors in combination with cisplatin (n=3) in comparison with cisplatin alone. Varying synergistic effects were observed across the panel of inhibitors when combined with cisplatin; Uprosertib (AKT inhibitor) in particular displayed strong synergy with cisplatin (Loewe analysis). Proteomic analysis of inhibitor treatment in HGSOC platinum-resistant cells demonstrated the mechanism of action of Uprosertib in targeting the PI3K/AKT pathway.

**Conclusion** In platinum-resistant HGSOC cells, AKT or DNA-PK inhibition functioned synergistically with cisplatin and reduced cell growth and proliferation. In both immortalised and primary HGSOC cell lines tested, AKT or DNA-PK inhibition significantly enhanced the apoptotic response to cisplatin demonstrating the efficacy of AKT or DNA-PK as potential therapeutic targets in chemoresistant HGSOC. By improving patient response to treatment, AKT and DNA-PK inhibitors could expand the therapeutic options for patients with platinum-resistant HGSOC, improving overall survival.

**Disclosures** CF: advisory boards and honoraria from Roche, Tesaro, Sequana, Olympus, Astra Zeneca. Other authors have no conflict of interest.

293 **TREATMENT STRATEGIES AND SURVIVAL OF WOMEN WITH MALIGNANT OVARIAN GERM CELL TUMOURS – AN ANALYSIS OF THE AGO-CORSETT DATABASE**

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**Introduction/Background** Malignant ovarian germ cell tumours (OGCT) account for about five percent of all ovarian malignancies in Western countries. The Arbeitsgemeinschaft fuer
PATIENT-REPORTED OUTCOMES (PROS) IN PATIENTS (PTS) RECEIVING NIRAPARIB IN THE PRIMA/ENGOT-OV26/GOG-3012 TRIAL

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Background Niraparib is a poly(ADP-ribose) polymerase (PARP) inhibitor that is approved for use in heavily pretreated pts and as maintenance treatment of pts with newly diagnosed or recurrent ovarian cancer following a response to platinum-based chemotherapy (CT). Here we report PROs in pts receiving niraparib and placebo (PBO) in the PRIMA/ENGOT-OV26/GOG-3012 trial.

Methods This double-blind, PBO-controlled, phase 3 study randomised 733 pts with newly diagnosed advanced ovarian, primary peritoneal, or fallopian tube cancer with a complete or partial response (CR or PR) to first-line (1L) platinum-based CT. Pts received niraparib or PBO once daily for 36 months or until disease progression. The primary endpoint was progression-free survival (PFS) assessed by blinded independent central review. PROs, a secondary endpoint, were collected every 8 weeks for 56 weeks, then every 12 weeks thereafter while treatment was ongoing. Once a pt discontinued treatment, PRO evaluations were performed at the time of treatment discontinuation and then at 4, 8, 12, and 24 weeks (±1 week for each time point) after the end of treatment, regardless of the status of subsequent treatment. The validated PRO instruments utilised were FOSI, EQ-5D-5L, EORTC-QLQ-C30, and EORTC-QLQ-OV28.

Results Compliance rates were high for all of the PRO instruments used in the study. PRO analysis of the EORTC-QLQ-C30 and EORTC-QLQ-OV28 did not indicate a difference in health-related quality of life scores of pts treated with niraparib vs placebo. Mean scores between niraparib and placebo arms were similar at each time point. Overall, the health utility index showed a slight improvement trend in pts who received niraparib vs placebo.

Conclusion Consistent with PRO results in the NOVA study, pts receiving niraparib in the PRIMA trial did not experience a decrease in quality of life compared with those receiving placebo.

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NON-SURGICAL MANAGEMENT OF MALIGNANT BOWEL OBSTRUCTION IN ADVANCED OVARIAN CANCER PATIENTS – A SYSTEMATIC REVIEW AND META-ANALYSIS

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Introduction/Background Ovarian cancer is the most lethal gynaecological malignancy and the 6th most common cancer among women globally. The incidence of malignant bowel obstruction (MBO) in patients with advanced disease is up to 51%. It presents a very distressing scenario for patients, their families and clinicians.

Management of MBO can be divided into surgical and medical management. Surgical management can involve direct resection, bypass surgery or stoma formation. Medical management includes endoscopic procedures, nasogastric tubes for decompression, bowel rest, parenteral feeding and symptom control such as chemotherapy, steroids, antisecretory drugs, analgesia and anti-emetics.

The rationale in choosing between surgical or medical management strategies is not well defined. High perioperative morbidity (up to 90%) and mortality (up to 40%) can make surgery a risky choice and there is increasing evidence that non-surgical management can significantly improve symptoms and quality of life.

The objective of this study was to evaluate the outcomes of patients with advanced ovarian cancer who undergo non-surgical management of malignant bowel obstruction and conduct a meta-analysis to estimate median survival.

Methodology A literature search was carried out using the Pubmed, Embase and Medline online libraries up until November 2019. We also searched abstracts of scientific meetings, reference lists of included studies and contacted experts in the field. Relevant studies that met the inclusion criteria were independently selected by two of the co-authors and the data extracted and analysed separately.

Results In total 24 studies were found to be relevant for the systematic review and 9 met the eligibility criteria for the meta-analysis, a total of 2236 patients were included. Median survival for patients managed medically for bowel obstruction was 44 days (95% CI 38–49 days, I² = 0%, P = 0.128).

Conclusion The quality of the included studies was relatively low, however the evidence shows that non-surgical management of bowel obstruction in advanced ovarian cancer patients results in a short survival period, but with controlled symp-
toms. Where quality of life is the main concern, this may be a feasible and effective strategy.

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LEAP-005: EVALUATING THE SAFETY AND EFFICACY OF LENVATINIB AND PEMBROLIZUMAB IN PATIENTS PREVIOUSLY TREATED FOR OVARIAN CANCER, A MULTI-COHORT PHASE 2 STUDY

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Introduction/Background Lenvatinib, an antiangiogenic multiple receptor tyrosine kinase inhibitor, plus pembrolizumab, a programmed death-1 immune checkpoint inhibitor, demonstrated promising clinical benefit in a previous phase I/II trial across several cancer types (ClinicalTrials.gov, NCT02501096). We assessed clinical outcomes with lenvatinib plus pembrolizumab in patients with ovarian cancer in the ongoing, open-label, multicohort, phase II LEAP-005 study (ClinicalTrials.gov, NCT03797326).

Abstract 296 Figure 1
Methodology 

Female patients aged ≥18 years with histologically/cytologically confirmed metastatic/unresectable ovarian cancer, measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST v1.1), Eastern Cooperative Oncology Group (ECOG) performance status 0/1, and 3 prior lines of therapy were enrolled. Patients received lenvatinib 20 mg daily plus pembrolizumab 200 mg every 3 weeks for 35 cycles, or until confirmed disease progression or unacceptable toxicity. Primary endpoints were objective response rate (ORR); response assessed every 9 weeks for 54 weeks, then every 12 weeks, by blinded independent central review per RECIST v1.1) and safety. Secondary endpoints included disease control rate, duration of response, and progression-free survival.

Results 31 patients with ovarian cancer received ≥1 dose of lenvatinib plus pembrolizumab in LEAP-005 (median age 62 years [range 40–76]); median study follow-up was 7.8 months (range, 4.6–12.4) as of April 10, 2020. ORR was 32% (95% confidence interval, 17–51); other efficacy endpoints were also favorable (table 1). Treatment-related adverse events occurred in 29 (94%) patients (table 1).

Conclusion Lenvatinib plus pembrolizumab demonstrated encouraging efficacy and manageable safety in patients with heavily pretreated ovarian cancer, including those with prior platinum failure and those with previous bevacizumab exposure.

Disclosures 

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Abstract 297 Table 1

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<th>Levetiracetam + Pembrolizumab (n=31)</th>
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<tr>
<td><strong>Efficacy</strong></td>
<td></td>
</tr>
<tr>
<td>Confirmed ORR, % (95% CI)</td>
<td>30 (17–51)</td>
</tr>
<tr>
<td>Disease control rate, % (95% CI)</td>
<td>74 (55–88)</td>
</tr>
<tr>
<td>Duration of response, median (range) months</td>
<td>NR (1.5+ to 7.9+)</td>
</tr>
<tr>
<td>Progression-free survival, median (95% CI) months</td>
<td>14.6 (10.6–21.5)</td>
</tr>
<tr>
<td><strong>Respones by prior therapy, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Platinum refractory/resistant (n=25)</td>
<td>6 (24)</td>
</tr>
<tr>
<td>Bevacizumab exposed (n=19)</td>
<td>4 (21)</td>
</tr>
<tr>
<td>Treatment-related AEs in (%)</td>
<td>29 (94)</td>
</tr>
<tr>
<td>Grade 3–5 treatment-related AEs</td>
<td>21 (68)</td>
</tr>
<tr>
<td>Treatment-related AEs leading to death</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Treatment-related AEs resulting in treatment discontinuation</td>
<td>4 (13)</td>
</tr>
<tr>
<td>Treatment-related AEs occurring in ≥10 patients</td>
<td></td>
</tr>
<tr>
<td>Any Grade</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>17 (55)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>19 (62)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>9 (29)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12 (39)</td>
</tr>
<tr>
<td>Protrusio</td>
<td>10 (32)</td>
</tr>
</tbody>
</table>

- Defined as best overall response of complete or partial response, or stable disease.
- Percentages are based on the total number of patients in each prior therapy subgroup. 0% patient had a serious AE of hypovolemic shock that led to death. Among treatment-related AEs occurring in ≥10 patients, none were grade 4–5. AE: adverse event; NR, not reached; ORR, objective response rate.

Abstracts

THE EVOLVING ROLE OF PARP INHIBITORS IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER: THE EFFECT OF ONLINE EDUCATION ON CLINICIAN KNOWLEDGE, COMPETENCE AND CONFIDENCE

1Geoff Fisher, 1Amy Furedy, 1Juliette Vandenbergroucq, 1Bradley Monk. 1Medscape Global Education, New York, United States; 2University of Arizona College of Medicine, Phoenix, United States

Introduction/Background The treatment of newly diagnosed advanced ovarian cancer is changing rapidly with the expanded use of PARP inhibitors. This study determined whether online continuing medical education could improve the knowledge, competence and confidence of oncologists and obstetricians/gynaecologists (ob/Gyns) with regard to the application of PARP inhibitors in this setting.

Methodology A 30-minute online video panel discussion with synchronized slides was launched for physicians outside the USA in November 2019. Data was collected to January 2020. Educational effect was assessed with repeated-pairs pre-/post-activity, where individual participants served as their own control. 3 multiple-choice, knowledge questions and 1 self-efficacy, 5-point Likert scale confidence question were analyzed. Chi-squared test assessed pre- to post-activity change (% significance level, P <.05). Magnitude of change in total number of correct responses overall, and for each question, were determined with Cramer’s V (<.06=Modest, 0.06–0.15=Noticeable, .16–.26=Considerable, .26=Extensive).

Results 157 oncologists and 152 ob/Gyns completed pre- and post-activity questions. A positive educational effect was
observed for both oncologists (considerable effect, V=.159, P<.0001; with average% of correct responses increasing from 59 to 74%) and obs/gyns (noticeable effect, V=.101, P<.01; average% of correct responses increasing from 48 to 58%). Participants with 3/3 correct answers increased from pre- to post-activity (16 to 44% for oncologists and 11 to 32% for obs/gyns). Improvements in% of correct responses post-activity were seen for questions on identifying data from PRIMA trial of niraparib (oncologists: 18 to 48%; obs/gyns 16 to 41%) and the PAOLA trial data for olaparib (oncologists: 68 to 80%; obs/gyns 53 to 59%). Participants had a good baseline understanding of the correct treatment approach for a patient presenting with HRD +ve advanced ovarian cancer (90% oncologists, 74% obs/gyns with the correct answer), although no increases were observed post-activity. Confidence in the ability to integrate PARP inhibitors into practice improved post-activity (total average confidence shift: 14% for oncologists and 29% for obs/gyns). 47% of all participants stated they would modify treatment plans as a result of participation in the activity.

Conclusion This on-demand, online video panel discussion resulted in a positive educational impact. However, education gaps remain evident, especially amongst obs/gyns. Online medical education, increasingly important during the COVID-19 pandemic, is valuable in supporting implementation of new treatment strategies and identifying areas of continued educational need.

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314 CLINICAL CHARACTERISTICS AND PROGNOSIS OF OVARIAN CLEAR CELL CARCINOMA: A 10-YEAR RETROSPECTIVE STUDY

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10.1136/ijgc-2020-ESGO.118

Introduction/Background Ovarian clear cell carcinoma (OCCC) is a special subtype of epithelial ovarian carcinoma with unique characteristics and no specific tumour markers. Due to the inherent chemoresistance, there are no effective chemotherapy regimen for OCCC, resulting in the extremely poor prognosis of patients, especially at advanced stage. Therefore, the purpose of our research is to investigate the clinical characteristics and outcomes of ovarian clear cell carcinoma (OCCC) and to provide additional supporting evidence to aid in the clinical diagnosis and management.

Methodology This was a retrospective study investigating the clinical characteristics and survival outcomes of 87 patients with OCCC treated at The First Affiliated Hospital of University of Science and Technology of China (USTC), between January 2010 and March 2020. Survival analysis was also performed on 179 patients with OCCC diagnosed between 1975 and 2017, obtained from the Surveillance, Epidemiology and End Results (SEER) cancer registry database.

Results The median age of study participants was 49.28 ± 9.8 years old, with 74.71% diagnosed at an early stage. Median CA125 level was 607.26 IU/mL, with 23.94% having a normal CA125 level. 16 patients (18.39%) had co-existing endometriosis and 8 patients (9.2%) had a preoperative history or developed postoperative complications of venous thromboembolism (VTE). Surgical staging procedures were performed on 65 patients and cytoreduction was performed on 22 patients, among whom 17 patients received optimal cytoreduction. 67 patients (77.01%) underwent lymphadenectomy, and only 3 (4.48%) were found to have positive lymph nodes. Positive HNF1ß, and negative WT-1, ER, and PR are reliable immunohistochemical indicators of OCCC. Patients diagnosed at an early stage had higher 3-year overall survival (OS) (89.47%) vs. 44.44%) and progression-free survival (PFS) rates (78.95% vs. 22.22%) than those with advanced stage OCCC at diagnosis. CA199 (P = 0.025) and ascites (P = 0.001) were significantly associated with OS, while HE4 (P = 0.027) and ascites (P = 0.001) were significantly associated with PFS. Analysis of data from the SEER database showed that the presence of positive lymph nodes is also an independent prognostic factor for OS (P = 0.001).

Conclusion OCCC often presents at an early stage and young age with a mild elevation in CA125 level. CA199, HE4, massive ascites and positive lymph node are independent prognostic factors for overall survival in OCCC.

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320 CHARLSON COMORBIDITY INDEX AS A FACTOR IMPACTING SURVIVAL AMONG OVARIAN CANCER PATIENTS – RESULTS FROM A SYSTEMATIC REVIEW

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Introduction/Background There are a few scattered primary level studies from various regions of the globe proving impact of co-morbidities on survival in ovarian cancer patients. In last 20 years, there has been improvement in survival among ovarian cancer patients. Radical surgical approaches and advancements in chemotherapeutic agents have primarily contributed for same. Pre-existing uncontrolled co-morbidities impact ovarian cancer survival directly and indirectly. This affects the performance status of the patient leading to delay in treatment or aversion from radical surgical approaches thereby not achieving the goal of optimal treatment. It may also lead to a less aggressive chemotherapeutic modifications of using lower doses or single agent chemotherapy. The objective of this study was to systematically review the literature and summarize prevalence of various comorbidities with evaluation of impact of the Charlson Co-morbidity Index (CCI) on survival in ovarian cancer patients.
Methodology Primary studies were identified by following a defined search strategy on the prevalence of co-morbidity and survival pattern among ovarian cancer patients. This study has been conducted in accordance with PRISMA guidelines for systematic review. Co-morbidity assessment in the included studies had been done through the Charlson Co-morbidity Index (CCI) tool. Qualitative summarization of data from included studies for prevalence of various co-morbidities and influence of CCI score on survival in ovarian cancer patients has been performed.

Results Common co-morbidities prevalent in ovarian cancer patients were hypertension (11% to 26%), cardiovascular disease (4.5% to 12%) and diabetes (2.5% to 8.3%). Less commonly occurring co-morbidities were liver disease, renal disease, neurological problems and collagen vascular disease. Majority of ovarian cancer patients lie in CCI score 0 (68% - 76%). The range for one year% survival for CCI score 0 was 73 to 80%, for CCI score 1–2 : 58 to 71% and CCI score 2 + : 43 to 53%. The range five year% survival for CCI score 0 was 37 to 43%, for CCI score 1–2 : 24 to 30% and CCI score 2 + : 12 to 23%.

Conclusion Co-morbidities plays an important role in survival outcomes among ovarian cancer patients. Overall one year% and five year% survival decreases with increase in the CCI index score.

Disclosures The authors have no conflict of interest.

Results Patients with a complete surgical cytoreduction had longer OS compared to those with an optimal or sub-optimal cytoreduction (48 vs 31 months, p=0.0001). PS and CRS were independent predictors for PFS, irrespective of BRCA status (p=0.00001 and 0.00006). There was no significant difference between BRCA mutation carriers and non-carriers for mean PFS and OS (19 vs 18 months, and 50 vs 42 months, p=0.69 and 0.39, respectively). BRCA mutation carriers had no better chemo response or less extended surgery to achieve a complete surgical cytoreduction following neoadjuvant chemotherapy compared to non-carriers (p=0.67 and 0.5, respectively). In the subgroup of patients with a CRS of 3, BRCA mutation carriers had longer PFS and OS than non-carriers (RR 12.5 and 20.8, 95% CI 3.32-47.6 and 4.8-88.8, p=0.00 and 0.00, respectively).

Conclusion Complete surgical cytoreduction remains pivotal in achieving better survival outcomes in AOC women, irrespective of BRCA status. A survival benefit is unlikely for patients with poor PS, and those receiving single-agent chemotherapy. A favourable response to neoadjuvant chemotherapy or less extended surgery to achieve a complete surgical cytoreduction in patients with a BRCA 1/2 germline mutation could not be confirmed.

Disclosures No Conflict of interest or any disclosure to make.
were considered in the negative class. The study was restricted to the most common prognostic variables and focused on predictive model comparisons. Dataset was split into training and test cohorts with repeated random sampling until there was no significant difference ($p=0.20$) between the two cohorts with respect to all variables.

**Results** 172 out of 209 patients with fully curated data were eligible for 2-year prognosis prediction analysis. 104/172 (60%) and 55/172 (32%) patients had disease recurrence or died of disease within two years, respectively. The variable importance for the 2-year progression free survival (PFS) and overall survival (OS) is shown in figure 1. A combination of good performance status, upfront cytoreduction and increased surgical complexity score best predicted 2-year PFS with an accuracy of 63% and 62.1% for the SVM and K-NN classifiers, respectively. SVM best predicted 2-year OS by a combination of Carboplatin/Taxol chemotherapy, low disease score, no residual disease, increased surgical complexity score, and upfront cytoreduction with an accuracy of 71.6% (AU-ROC: 0.66) (figure 2).

**Conclusion** ML appears to be promising for accurate estimation of HGSOC prognosis. We provide evidence as to what combination of prognosticators leads to the largest impact on the HGSOC two-year prognosis. The cohort is currently expanding to further examine the short term vs long term contribution of the clinical variables from the comparative models.

**Disclosures** No disclosures.

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**THE EFFECT OF ENDOMETRIOSIS ON THE PROGNOSIS OF OVARIAN CLEAR CELL CARCINOMA: THE JURY IS STILL OUT**

1Felicia Elena Buruiana, 1Anastasios Tranoulis, 2Bindiya Gupta, 1Janos Balega, 1Kavita Singh. 1Panbirmingham Gynaecological Cancer Centre, Birmingham City Hospital; Gynaecological Oncology; 2The Pan-Birmingham Gynaecological Oncology Centre, City Hospital, Panbirmingham Gynaecological Cancer Centre, Birmingham City Hospital; Gynaecological Oncology

**Introduction/Background** Women with endometriosis carry an increased risk for ovarian clear cell ovarian carcinoma (OCCC), also referred to as ‘endometriosis-associated ovarian carcinoma’. Considered as the precursor lesion of a subset of OCCC, the prognostic role of endometriosis amongst women with OCCC remains a field of contention. Few studies have evaluated the prognostic significance of the concurrent endometriosis with conflicting results. The aim of this study was to ascertain the effect of endometriosis on the prognosis of OCCC.

**Methodology** This was a retrospective cohort study, from 2000 to 2019. Population-based prospectively collected data on OCCC with or without concurrent endometriosis were retrieved via the Pan-Birmingham Gynaecological Oncology database. Ninety-four women with a primary diagnosis of OCCC have been divided into groups based upon the detection of cancer arising from ovarian endometriosis (n=48,
51.1%) or not (n = 46, 48.9%) according to Samson and Scott criteria. Chi-squared test, t-test, and univariate/multivariate Cox regression were used. Survival curves were plotted via the Kaplan-Meier method, whilst survival differences were examined via the log-rank test for categorical variables or Cox regression for continuous variables. All reported p-values were two-tailed. Statistical significance was set at p-value <0.05. The statistical analysis was performed using Stata version 16.1 (Stata Corporation, TX, USA).

Results Women with OCCC arising from endometriosis had significantly lower levels of pre-operative CA-125 (434.63 ± 1135.57 Vs 867.30 ± 1609.67, p-value=0.02) and significantly lower incidence of post-operative residual disease (RD) (p-value=0.02). Age, post-menopausal status, FIGO stage and incidence of capsule rupture were not statistically significant. The mean overall survival (OS) and overall progression free survival (PFS) were 86.35 (95% CI 69.47 – 103.22) and 115.97 (95% CI 98.77 – 133.17) months, respectively. The presence of endometriosis did not affect neither the OS (87.99 Vs 75.30, p-value=0.25) nor the PFS (111.13 Vs 117.42, p-value=0.48). In univariate analysis, the FIGO stage II-IV and RD were correlated with poorer OS, whilst capsule rupture (CR) with poorer PFS. In multivariate analysis, FIGO stage [HR=2.86 (95% CI 1.47 – 5.55), p-value=0.002] and RD [HR=2.52 (95% CI 1.48 – 4.94, p-value=0.007) were found independent predictors for OS, whilst CR [HR=0.3 (95% CI 0.11 – 0.82), p-value=0.02] for PFS, respectively. No factors affected OS after stratification by stage.

Conclusion In this cohort concurrent endometriosis was not a predictive factor for the survival of OCCC women. Further studies are warranted to ascertain whether OCCC with or without coexisting endometriosis develop via distinct pathogenic pathways.

Disclosures Nil to disclose.

Abstract 347 Table 1

<table>
<thead>
<tr>
<th>Safety population</th>
<th>Niraparib</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>&lt;65 yo n=294</td>
<td>≥65 yo n=190</td>
</tr>
<tr>
<td>Any-grade TEAE, n (%)</td>
<td>187 (64)</td>
<td>134 (71)</td>
</tr>
<tr>
<td>Thrombocytopenia event&lt;sup&gt;a&lt;/sup&gt;</td>
<td>185 (63)</td>
<td>126 (66)</td>
</tr>
<tr>
<td>Anemia event&lt;sup&gt;b&lt;/sup&gt;</td>
<td>126 (43)</td>
<td>79 (42)</td>
</tr>
<tr>
<td>Neutropenia event&lt;sup&gt;c&lt;/sup&gt;</td>
<td>101 (34)</td>
<td>87 (46)</td>
</tr>
<tr>
<td>Grade ≥3 TEAE, n (%)</td>
<td>98 (33)</td>
<td>52 (27)</td>
</tr>
<tr>
<td>Thrombocytopenia event&lt;sup&gt;a&lt;/sup&gt;</td>
<td>60 (20)</td>
<td>40 (21)</td>
</tr>
<tr>
<td>Anemia event&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenia event&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Includes thrombocytopenia and platelet count decreased.

<sup>b</sup>Includes anemia, hemoglobin decreased, and anemia macrocytic.

<sup>c</sup>Includes neutropenia, neutrophil count decreased, and febrile neutropenia.

TEAE=treatment-emergent adverse event; yo=years old.

Introduction/Background The PRIMA/ENGOT-OV26/GOG-3012 (PRIMA) trial showed that niraparib significantly improves progression-free survival (PFS) in pts with newly diagnosed advanced OC that responded to first-line platinum-based chemotherapy (CT) (hazard ratio [HR] 0.62; 95% CI 0.50–0.76). Here we discuss the impact of age on efficacy and safety of niraparib.

Methodology This double-blind, placebo (PBO)-controlled phase 3 trial evaluated niraparib in pts with newly diagnosed, advanced, high-grade serous or endometrioid ovarian, primary peritoneal, or fallopian tube cancer with a complete or partial response to first-line platinum-based CT. Pts were randomised 2:1 to receive either a fixed starting dose (FSD) of 300 mg niraparib or PBO QD. A protocol amendment introduced an individualised starting dose (ISD): 200 mg QD in pts with bodyweight <77 kg or platelet count <150,000/µL or 300 mg QD for all others. Pts were dichotomized by age group <65 vs ≥65 years old (yo) to analyse efficacy and
safety of niraparib vs PBO in older patients. The primary endpoint was PFS assessed by blinded independent central review.

**Results** Of 733 enrolled pts, 444 were <65 yo (297 niraparib, 147 PBO), and 289 were ≥65 yo (190 niraparib, 99 PBO). Efficacy was comparable in pts <65 yo (HR 0.61; 95% CI 0.47–0.81) and ≥65 yo (HR 0.53; 95% CI 0.39–0.74) who received niraparib compared with PBO. Any-grade and grade ≥3 treatment emergent adverse events were similar across age groups (table 1). Grade ≥3 thrombocytopenia events in pts <65 yo were reported in 43% of pts receiving a FSD and 18% of pts receiving ISD. In pts ≥65 yo, the values were 57% and 26%, respectively. Patient reported outcomes (PROs) and quality of life (QOL) were similar in both age groups as assessed by FOSI and EQ-5D-5L.

**Conclusion** Niraparib efficacy, safety, and QOL were similar in compared age groups. Implementation of an ISD regimen improved rates of grade ≥3 thrombocytopenia events in older pts.

**Disclosures** Funding: GlaxoSmithKline

**NCT number:** NCT02655016

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Drs Li and Gupta are employees of GlaxoSmithKline.
Conclusion Niraparib improved PFS when utilised as maintenance therapy after front-line treatment of OC in patients with BRCAwt tumours, including in the most difficult to treat subgroup of patients with BRCAwt and HRp tumours.

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Dr. Monk reports consulting and advisory role at Merck, GSK, Roche/Genentech, AstraZeneca, Advaxix, Cerulean Pharma, Amgen, Immunogen, NuCana BioMed, Clovis Oncology, Pfizer, Mateon Therapeutics, Precision Oncology, Perthera, Abbvie, Myriad Pharmaceuticals, Incyte, VBL Therapeutics, Takeda, Samumed, Oncomed, OncoSec, ChemoID, Geistlich Pharma, Eisai and Chemocare; and Speakers’ bureau at Roche/Genentech, AstraZeneca, Janssen, Clovis Oncology and GSK; Honoraria from Merck, GSK, Roche/Genentech, AstraZeneca, Advaxis, Immunogen, NuCana BioMed, Clovis Oncology, Pfizer, Mateon Therapeutics, Precision Oncology, Perthera, Abbvie, Myriad Pharmaceuticals, Incyte, Janssen, Amgen, Genmab, Samumed, Takeda, VBL Therapeutics, Puma Biotechnology, Immunomedics, Conjupuro Biotherapeutics, Agenus, OncoQuest, ChemoID, Geistlich Pharma, Eisai and Chemocare; and Research funding from Novartis, Amgen, Genentech, Lilly, Janssen, Array BioPharma, GSK, Morphotek, Pfizer, Advaxis, AstraZeneca, Immunogen, Regeneron, and Nucana.

Drs. Honhon and Fabbro have nothing to disclose.

Dr. Gupta is an employee of GlaxoSmithKline.

Introduction/Background Although randomised controlled trials (RCTs) have demonstrated the benefit of PARP inhibitors and bevacizumab as monotherapies and combination therapies, there is limited direct head-to-head evidence of their relative clinical efficacy.

In the PRIMA study, niraparib demonstrated a clinically significant improvement in progression-free survival (PFS) compared with placebo, as a first-line (1L) ovarian cancer (OC) maintenance therapy.

The objectives of the study were to assess feasibility of an indirect treatment comparison (ITC) and a population-adjusted indirect treatment comparison (PAIC) for estimating the relative efficacy of niraparib compared with olaparib, olaparib plus bevacizumab, and bevacizumab as maintenance following 1L chemotherapy in OC. The study focused on fully powered statistical cohorts.

Methodology Trials included in the ITC analysis were based on a systematic literature review conducted in February 2020.

Guidelines from the Cochrane Handbook for Systematic Reviews of Interventions were used to assess the level of heterogeneity across the studies in terms of designs, population characteristics, treatment arms and outcome measures.
The feasibility of PAIC for the PRIMA and PAOLA-1 trials was assessed based on assumptions outlined in the guidance by the Decision Support Unit in NICE DSU Technical Support Document 18; PFS was the outcome for the analysis. **Results** All 12 RCTs assessed for ITC feasibility were excluded based on various factors including: the lack of a common comparator with PRIMA within the network (ICON-7, GOG-0218, PAOLA-1, VELIA/GOG-3005); differing measurement of PFS and overall survival starting timepoint due to trial design (ICON-7, GOG-0218, VELIA/GOG-3005); inclusion of stage III patients with no visible residual disease following debulking surgery (PAOLA-1, SOLO-1, VELIA/GOG-3005); disparity between disease biomarker (SOLO-1).

For the PAIC, three fundamental differences between the PRIMA and PAOLA trials were identified; inclusion criterion related to residual disease was wider in PAOLA meaning that the ‘conditional constancy of absolute effects’ was violated; receipt of neoadjuvant chemotherapy was identified as a confounding factor that would bias a PAIC; discrepancies in the assessment of type and frequency of measurement of the PFS outcome.

**Conclusions** Based on the evidence currently available, neither an ITC nor PAIC would meet current guidelines, such as those outlined by the International Society for Pharmacoeconomics and Outcomes Research, for these analyses. Their results would not be considered appropriate evidence for use in clinical decision making or reimbursement decisions. The extent of imbalance caused by differences in the patient inclusion/exclusion criteria for intended comparisons is unknown and a recognised limitation of PAICs.

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Due to lengthy author disclosures, author COI information will be provided directly to the congress.

### Abstract 367 Table 1

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Median PFS, yr</th>
<th>Median OS, yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simulated-PRIMA (n=472)</td>
<td>1.20</td>
<td>2.71</td>
</tr>
<tr>
<td>Simulated-stage III NVRD after PDS (n=69)</td>
<td>2.45</td>
<td>6.84</td>
</tr>
<tr>
<td>Simulated-broader (n=569)</td>
<td>1.26</td>
<td>3.07</td>
</tr>
</tbody>
</table>

| NVRD, no visible residual disease; OS, overall survival; PDS, primary debulking surgery; PFS, progression-free survival. |

Abstract 367 Figure 1

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**Introduction/Background** Niraparib is an oral, highly selective poly(ADP-ribose) polymerase inhibitor (PARPi). The PRIMA/ENGOT-OV26/GOG-3012 trial intention-to-treat population included stage III and IV ovarian cancer (OC) patients post-primary or interval debulking surgery (PDS/IDS) irrespective of residual disease (visible residual disease [VRD] or no VRD [NVRD]), except for stage III patients post-PDS with NVRD. A data gap therefore exists in the stage III post-PDS NVRD population. This study aims to use real-world evidence from the Edinburgh Ovarian Cancer Database to explore the difference in overall survival (OS) and progression-free survival (PFS) in: a) a ‘simulated-PRIMA cohort’ (stage III VRD after PDS, stage III and IDS, and stage IV OC), b) a ‘simulated-NVRD after PDS cohort’ (stage III NVRD after PDS) and c) a larger ‘simulated-broader cohort’ (both cohorts a and b plus the additional stage III non-evaluable debulking status cases).

**Methodology** A retrospective observational study was conducted to examine characteristics and long-term outcomes for patients diagnosed with advanced OC within the Edinburgh Cancer Centre between 1 January 2000 and 31 December 2015. Patients were followed until their last patient record or last data cut (January 2019) and were chosen to match the three defined populations. Main outcomes were OS and PFS, the latter defined as time from diagnosis to first progression as defined by radiology, tumour marker (CA125) or the treating physician where other investigations were not evaluable.

**Results** Baseline patient characteristics in the simulated-PRIMA (n=472), simulated-stage III NVRD after PDS (n=69) and simulated-broader (n=569) cohorts matched the PRIMA trial in most categories. PFS and OS for simulated cohorts are shown in the table 1. When compared with the simulated-PRIMA cohort, the simulated-stage III NVRD after PDS...
The simulated-broader cohort showed longer duration of OS and PFS outcomes as the survival curves lie above the simulated-PRIMA cohort. This difference is driven by the better prognosis for patients with stage III NVRD after PDS population; this population accounted for approximately 17% of the contemporary patient cohort at this UK centre.

Conclusion

The simulated-broader cohort showed longer duration of OS and PFS outcomes as the survival curves lie above the simulated-PRIMA cohort. Furthermore, the simulated-broader cohort demonstrated a survival curve above the simulated-PRIMA curve. Within the 2010–2015 diagnosis (contemporary) stage III cohort (n=169), 57.4% had IDS and 42.6% had PDS, of whom 23.1% had PDS VRD, 17.2% had PDS NVRD, and 2.4% were PDS not evaluable for residual disease.

Disclosures

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Dr. Hollis reports institutional grants and personal fees from GlaxoSmithKline.

Dr. Gourley reports personal fees from Roche, Clovis, Tesaro, Foundation One, Nucana, Aprea, Novartis, Chugai, and MSD; institutional grants from Clovis, Tesaro, Nucana, and Novartis.

Drs. Kiss, Roebuck, Heffernan and Starkie-Camejo are employees of GlaxoSmithKline.

Introduction/Background

Maintenance therapies have changed the treatment landscape in ovarian cancer (OC) in recent years. Here we sought to review safety and efficacy outcomes in clinical trials of first-line maintenance therapies.

Methodology

A systematic literature review (SLR) was performed on 27 February 2020 to identify clinical outcomes associated with first-line maintenance therapies and maintenance therapies initiated alongside first-line chemotherapy followed by a maintenance phase for advanced OC. Randomised controlled trials (RCTs), non-RCTs and observational studies were eligible. Selection criteria following the PICOS (population, interventions, comparators, outcomes and study type) principle were specified. Outcomes of interest were progression-free survival (PFS), overall survival (OS), and treatment emergent adverse events (TEAEs). Selected studies were then extracted by one reviewer and assessed for quality by a second reviewer. Disagreements were resolved by a third reviewer when required.
Results This SLR retrieved 8,631 unique references of which a total of 50 references were accepted and extracted in this SLR (figure 1).

The 50 references identified covered 18 clinical trials that evaluated maintenance therapies in OC patients following one prior line of chemotherapy. Of these 18 trials, 12 were RCTs and the remaining 6 were observational, dose escalation and retrospective review studies.

Of the 18 trials, only 2 did not assess PFS as an efficacy endpoint (NCT00058435 and MIMOSA). PARP inhibitors across the board reported a better PFS hazard ratio (HR) than other OC maintenance therapies (table 1). No pattern was identified in relation to PFS amongst patients who were treated with a maintenance therapy following first-line platinum-based chemotherapy versus those who received a maintenance drug concurrently with first-line platinum-based chemotherapy and then continued with the maintenance treatment.

OS was reported as a secondary endpoint in 12 trials (MIMOSA, AGO-OVAR16, SOLO-1, ICON-7, GOG-0218, AGO-OVAR12, VELIA/GOG-3005, TRINOVA-3, ESME, CHIVA/GINESCO, PRIMA and PAOLA-1). Only PARP inhibitor-containing therapies reported significant OS HRs below 1 across all trial populations.

TEAEs were reported for 11 of the 18 trials. Discontinuation due to AEs was reported in 10 of the 18 trials.

Conclusion Therapies that included PARP inhibitors reported better PFS HR than other OC maintenance therapies. In study populations including both BRCA mutation positive and wild type, clinical benefit is conferred by both olaparib plus bevacizumab and niraparib as indicated by PFS. OS data remain immature.

Disclosures This study was funded by GlaxoSmithKline.

Clinical Trial Registration: N/A

Dr Guy and Walder report institutional reimbursements from GlaxoSmithKline.

Drs. Travers, Hawkes, Malinowska, and Gupta are employees of GlaxoSmithKline.

Introduction/Background Although most patients with ovarian cancer (OC) respond to first line (1L) treatment, 70% of women experience disease progression (PD) within 3 years. Identifying prognostic factors that impact survival is crucial to identify patients who may benefit from new treatment regimens such as maintenance therapies. The objective of this study was to assess the association between visible residual disease (VRD) following interval (IDS) or primary debulking surgery (PDS) and other clinical factors, and the risk of PD or death in patients with advanced OC in a real-world setting.

Methodology This retrospective cohort study included patients diagnosed with invasive ovarian cancer between January 1, 2011 and February 29, 2020, from the Flatiron Health electronic health record-derived de-identified US database (most OC patients (87%) originate from community oncology practices). Inclusion/exclusion criteria are shown in table 1. The index date (ID) was defined as the last date of 1L treatment. Multivariate Cox regression models were used to identify demographic and clinical factors associated with time to next event (PD or death).
treatment (TTNT, a proxy for PD), defined as time from ID to start date of second line treatment, death, or last confirmed structured activity. Overall survival (OS) was defined as time from ID to death or last confirmed structured activity. Kaplan Meier analysis was used to assess median TTNT and OS.

Results A total of 1,920 advanced OC patients with a median (25th, 75th percentile) age of 67.0 (58.0, 75.0) years were included. Most patients were white (74%) and originated from a community oncology practice (88%). While 67% of patients had evidence of a BRCA biomarker test, only 5% had evidence of a homologous recombination deficient (HRD) test.

Results are shown in table 2. Statistically significant predictors of OS were VRD, age, BRCA status, Eastern Cooperative Oncology Group (ECOG) score, extent of debulking, histology, stage of disease, and therapy modality. Statistically significant predictors of TTNT included: VRD, BRCA status, extent of debulking, histology, practice type, race, stage of disease, and therapy modality.

Conclusion VRD was a key predictor of TTNT and mortality in patients with advanced OC. Among biomarkers, BRCA status was a key predictor of OC outcomes; HRD could not be assessed due to lack of data. A key strength of this study is that it presents outcomes from community practices primarily, whereas most retrospective studies contain a higher proportion of academic practices.

Disclosures Dr. Chase reports speakers’ bureau fees from GSK.

Dr. González-Martín reports personal fees and non-financial support from AstraZeneca; Grant and personal fees from GSK, Clovis Oncology, Roche Holding AG, Merck & Co., Inc., Gemab, INMUNOGEN, Pharma Mar, S.A., and Oncovent AS.

Drs. Kalilani, Perhanidis, Sansbury, Woodward and Gupta are employees of GlaxoSmithKline.

### Abstract 379 Table 1

<table>
<thead>
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<th>Characteristics</th>
<th>Group/Result</th>
<th>Treatment centre</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n %</td>
<td>Institute of Oncology (Ion Chiricuta, Cluj, Romania)</td>
</tr>
<tr>
<td>Total site cohort size</td>
<td>427</td>
<td>180</td>
</tr>
<tr>
<td>Age Median</td>
<td>55</td>
<td>61</td>
</tr>
<tr>
<td>IQR 45–53</td>
<td>51–58</td>
<td>56–72</td>
</tr>
<tr>
<td>Low-grade serous</td>
<td>40</td>
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<tr>
<td>High-grade serous</td>
<td>276</td>
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<tr>
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</tr>
<tr>
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<td>23</td>
<td>5.4%</td>
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<tr>
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<td>FIGO Stage</td>
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<td>I</td>
<td>65</td>
<td>22%</td>
</tr>
<tr>
<td>II</td>
<td>58</td>
<td>6.4%</td>
</tr>
<tr>
<td>III</td>
<td>249</td>
<td>56%</td>
</tr>
<tr>
<td>IV</td>
<td>247</td>
<td>11%</td>
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<tr>
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</tr>
</tbody>
</table>
**Introduction/Background** In the Phase III SOLO1 study (NCT01844986) of patients with newly diagnosed advanced ovarian cancer and a BRCA mutation (BRCAm), maintenance olaparib significantly improved investigator-assessed progression-free survival (PFS) versus placebo (hazard ratio [HR] 0.30, 95% CI 0.23–0.41; P<0.001; Moore et al. N Engl J Med 2018). We present an exploratory analysis from higher-risk and lower-risk subgroups.

**Methodology** Patients received olaparib 300 mg twice daily or placebo for up to 2 years or until disease progression. In this exploratory analysis (primary data cut-off: 17 May 2018), patients in the higher-risk group had stage IV disease, stage III disease with residual disease following primary debulking surgery, inoperable stage III disease, or had stage III disease and underwent interval surgery. Patients in the lower-risk group had stage III disease without residual disease following primary debulking surgery. PFS was assessed by investigators and blinded independent central review (BICR). Response was assessed using modified RECIST v1.1.

**Results** Of 391 patients, 56% were higher risk and 44% were lower risk. After a median follow-up overall of ~41 months, the risk of disease progression/death per investigator was significantly reduced with olaparib versus placebo in the higher-risk group (HR 0.34, 95% CI 0.24–0.48; 66% reduction) and the lower-risk group (HR 0.33, 95% CI 0.20–0.52; 67% reduction) (figure 1). Investigator-assessed median PFS was 39.0 versus 11.1 months for olaparib versus placebo, respectively in the higher-risk group, and not reached (NR) versus 21.9 months in the lower-risk group (figure 1). Results were similar per BICR (table 1).

**Conclusion** In this exploratory analysis of data from the SOLO1 study, maintenance olaparib provided a substantial PFS benefit over placebo in patients with both higher-risk and lower-risk newly diagnosed advanced ovarian cancer and a BRCAm, with an investigator-assessed median PFS of 39 months and NR with olaparib treatment in higher-risk and lower-risk groups respectively after a median follow-up of ~41 months. SOLO1 is the only trial of maintenance monotherapy with a PARP inhibitor to have demonstrated a consistently high reduction in the risk of progression/death in both higher-risk and lower-risk patients with newly diagnosed advanced ovarian cancer.

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**MAINTENANCE OLAPARIB IN PATIENTS WITH NEWLY DIAGNOSED ADVANCED OVARIAN CANCER AND A BRCA MUTATION: SUBGROUP ANALYSIS BY RISK IN THE PHASE III SOLO1 STUDY**

1 Nicoletta Colombo, 2 William Bradley, 3 Kathleen Moore, 4 Antonio González-Martin, 5 Giovanni Scambia, 6 Ana Oaknin, 7 Michael Lowe, 8 Phil Rowe, 9 Paul Disilvestro. 1 University of Milan-Bicocca and Istituto Europeo di OncoLogo; 2 Froedtert and the Medical College of Wisconsin; 3 Stephenson Oklahoma Cancer Center; 4 Clínica Universidad de Navarra; 5 Università Cattolica del Sacro Cuore-Fondazione Policlinico A. Gemelli, Ircss; 6 Vall D’hebron University Hospital, Vall D’hebron Institute of Oncology (Viho); 7 University of New South Wales Clinical School, Prince of Wales Hospital; 8 Astrazeneca; 9 Women and Infants Hospital

Abstract 392 Figure 1 Investigator-assessed PFS in higher-risk and lower-risk SOLO1 subgroups
Introduction/Background Recent randomized clinical trials have demonstrated convincing effects of integrating PARP inhibitors (PARPi) and combination of PARPi + bevacizumab (anti-VEGF) into first line (1L) treatment of selected groups of advanced stage ovarian cancer (OC) patients. However, it remains unclear to which extent eligibility of PARPi treatment translates into a real-world setting, where the impact of patient heterogeneity and differences in national clinical practices may influence the potential for PARPi treatment. The aim of this study is to describe treatment strategies and outcomes of advanced OC; and to estimate the proportion of patients potentially eligible for 1L PARPi maintenance therapy and for concomitant anti-VEGF treatment practice using observational data in a multi-national setting (RESPONSE).

Methodology This international, multi-centre, observational study, includes real-world data on diagnostic work-up, standard of care, clinical outcomes and treatment for around 1000 patients with advanced OC (C21120 patients/country). Last index date is 1st April 2018, ensuring at least 20 months of follow-up. Potential PARPi eligibility is defined as having no macroscopic residual disease (<1 cm) following upfront surgery and/or having a clinical complete response/partial response.

Abstract 405 Figure 1

Abstract 405 Table 1 PFS in higher-risk and lower-risk SOLO1 subgroups by investigator and BICR assessment

<table>
<thead>
<tr>
<th>Median PFS, months</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olaparib Placebo</td>
<td>Olaparib vs Placebo</td>
</tr>
<tr>
<td>Investigator</td>
<td></td>
</tr>
<tr>
<td>Higher risk</td>
<td>39.0</td>
</tr>
<tr>
<td>Lower risk</td>
<td>NR</td>
</tr>
<tr>
<td>BICR</td>
<td>NR</td>
</tr>
<tr>
<td>Higher risk</td>
<td>NR</td>
</tr>
</tbody>
</table>

Abstracts
response (CR/PR) following completion of 1L chemotherapy according to the label. Eligibility for PARPi treatment will be analysed prospectively by time-to-event by individual country, all countries combined, and in relation to treatment patterns. Finally, between-country variations will be described in relation to 1L treatment patterns and national guidelines.

Results In total, eight countries, Austria, Belgium, Denmark, Finland, Israel, Netherlands, Norway, and Portugal, are included in the study (study flow chart; figure 1). Data collection is ongoing and will be finalized by Q1 2021. Inclusion of 120 patients per site will provide precise estimates of local PARPi eligibility (error margin of 4%) and sufficient power to detect clinical meaningful differences in PARPi eligibility between any two countries.

Conclusion International real-world OC data is currently scarce. RESPONSE will add to the current knowledge regarding factors influencing eligibility to 1L PARPi or PARPi + anti-VEGF maintenance treatment in individual countries, and enable mapping of patient characteristics and key variables in the 1L treatment pathway, such as timing and outcome of surgery, including concomitant anti-VEGF treatment.

Disclosures Professor Christian Marth has received funded research from EU, FWF, AstraZeneca and Roche, Honoraria/Expenses from Roche, Novartis, Amgen, MSD, Pharmamar, AstraZeneca, and Tesaro, and has performed Consulting/Advisory Boards for Roche, Novartis, Amgen, MSD, AstraZeneca, Pfizer, Pharmamar, Cerulean, Vertex, and Tesaro.

Dr Jacob Korach has nothing to disclose.

Dr Kristina Lindemann has acted as Consultant for AstraZeneca, Speaker for AstraZeneca and GSK, and participated in Advisory Boards for AstraZeneca and GSK.

Dr Anne Weng Ekmann-Gade has received research grants for the current trial.

Dr E Van Nieuwenhuysen has nothing to disclose.

Dr Heini Lassus has nothing to disclose.

Dr Klaus Kaae Andersen is employed by AstraZeneca.

Jesper Hansen is employed by AstraZeneca.

413 PROGNOSTIC VALUE OF THE TUMOR INFILTRATING LYMPHOCYTES AND THE NEUTROPHIL-TO-LYMPHOCYTE RATIO IN PATIENTS WITH ADVANCED OVARIAN CANCER

Introduction/Background Tumor infiltrating lymphocytes (TIL) and Neutrophil-to-lymphocyte ratio (NLR) have been objectified as independent prognostic factors in different tumours. There is not enough knowledge about the prognostic value of these two factors as a combination. This analysis aims to study the prognostic significance of TIL and NLR in patients with advanced ovarian cancer (OC).

Methodology Observational, single-center and retrospective analysis of a cohort of 135 patients with advanced stage OC treated between 2002 and 2019. Histological samples of ovarian tissue from the surgery of 92 patients were requested, with informed consent, and tissue microarrays (TMA) were constructed. For the TIL study, immunohistochemical staining of the TMA was made and a quantitative analysis was performed through the morphometric analysis of the lymphocytes. Samples were categorized in relation to total area as TIL 0 = absence; 1 = <25%; 2 = 25–50%; 3 = 50–75%; 4 ≥ 75%. Neutrophils and lymphocytes levels in peripheral blood at the diagnosis were collected to estimate NLR. Survival analysis was performed using Cox regression.

Results Average age 66 years (36–84 years). Median overall survival (OS): 56 months (0.92–154 m). FIGO stage: 80% III, 20% IV. Histology: 87.2% papillary serous. ECOG: 18.5% ECOG 2 at diagnosis. Surgery: primary cytoreduction/after neoadjuvant treatment: 59/59 patients. TIL and NLR study; Both variables were not correlated (Spearman’s rho: -0.259, p = 0.106). 75% of patients had TILCD3 infiltration <25%. Median NLR = 3.72. The univariate analysis showed a higher OS in patients with TILCD3> 25% (HR 0.448, 95% CI 0.19 – 1.02;
ELUCIDATING RESISTANCE MECHANISM TO PARPi FOR THE DEVELOPMENT OF NOVEL THERAPEUTIC APPROACHES IN HIGH-GRADE SEROUS OVARIAN CANCER

Hagen Kulbe, Wanja Kasuhn, Frauke Ringel, Gabriele Welsch, Peggy Treffkorn, Eliane Taube, David Horst, Jailed Seshouli, Elena Braicu, Charité Universitätsmedizin Berlin, Department of Gynecology, Campus Virchow Clinic, Charité – Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health

Abstracts

First Real-World Hematologic Adverse Events Experience with Niraparib in Advanced Ovarian Cancer

Junjian Wang, Jianqing Zhu. Cancer Hospital of the University of Chinese Academy of Sciences (Zhejiang Cancer Hospital)

Introduction/Background Niraparib, a poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor, has been approved by Food and Drug Administration (FDA) for ≥3 line recurrence ovarian cancer (OC), the platinum-sensitive recurrence maintenance treatment and new diagnosed maintenance treatment using individual starting dose (ISD, 200 mg daily for body weight <77 kg or platelet count <150,000/L). This study aimed to retrospectively assess the incidence of hematologic adverse events (AEs) in real-world Chinese OC patients using ISD niraparib in Zhejiang Cancer Hospital.

Methodology All medical records of OC patients with ISD niraparib in the Zhejiang Cancer Hospital from February 2019 to January 2020 were reviewed. Treatment-emergent hematologic AEs including leucopenia, anemia and thrombocytopenia were collected and analyzed.

Results A total of 43 patients with OC were included in this study. The median body weight was 50.5 (33, 75) kg. 200 mg QD was taken as ISD for all patients. Twenty seven (62.8%) patients were of BRCA wild-type, 14 (32.6%) were of BRCA mutants and 2 (4.6%) were unknown. Niraparib treatment resistance are poorly understood and novel approaches are urgently required.

Methodology Here we created gene expression data of HGSOC patients (n=52) before PARPi treatment to elucidate key signaling pathways of resistance to increase their efficacy in combinatorial therapeutic strategies. We performed a comprehensive bioinformatics analysis of the differentially expressed genes between the 25% extreme responders (n=26; 13 each group), including gene set enrichment analysis (GSEA) and causal inference analysis with the CARNIVAL pipeline to elucidate the underlying molecular and regulatory mechanisms governing treatment efficacy and resistance.

Results In accordance with recent publications, we found higher levels of MYC activity in non-responders and deregulation of the Wnt/β-catenin signaling pathway resulting in PARPi treatment resistance. The pathway enrichment analysis also revealed specific pathways especially PDGFR, FGFR, PI3K/mTOR and MAPK signaling pathway associated with resistant phenotype. Furthermore, we have identified key kinases, particularly JAK1/2 and SRC that might mediate resistance to PARP inhibition. In addition, differential gene expression analysis revealed folate receptor 1 (FOLR1) to be significantly higher expressed in non-responders (logFC = 2.66; p < 0.0026) with the potential as a serum-based biomarker not only for ovarian cancer, as it correlates closely with CA125, but also PARPi treatment efficacy.

Conclusion In conclusion, these findings define a network of pathways, that are crucial to mediate mechanism of PARPi resistance and identified key signaling kinases as therapeutic targets in ovarian cancer.

Disclosures The authors declare no conflict of interest.
was used as newly diagnosed maintenance treatment in 25 (58.1%) patients, as treatment for ≥3 line recurrence treatment in 14 (32.6%) patients, and as platinum-sensitive recurrent maintenance treatment in 4 (9.3%) patients. Overall, 28 (65.1%) patients experienced ≥1 grade hematologic AEs, which included leukopenia (37.2%), anemia (34.9%) and thrombocytopenia (39.5%). Only 10 (23.3%) patients had grade 3/4 AEs including leukopenia (9.3%), anemia (7.0%) and thrombocytopenia (11.6%). Until last follow up, the median time for the occurrence of leucopenia, anemia and thrombocytopenia were 30 (range: 7, 162), 34 (range: 7, 108) and 20 (range: 13, 180) days, respectively. No deaths were reported. Of those patients who experienced AEs during treatment, the dose was reduced in 4 (14.3%) patients, and treatment was interrupted in 9 (32.1%) patients. Additional recombinant human granulocyte colony stimulating factor (n=5, 17.9%), erythrocyte (n=2, 7.1%) and recombinant human thrombopoietin (n=5, 17.9%) were provided for treating the AEs. After intervention, 8 (18.6%) patients restart the treatment and only 1 (2.3%) patient discontinued the treatment.

Conclusion The incidence of hematologic AEs in real-world experience was lower than reported by niraparib 300 mg/day in ENGOT-OV16/NOVA trial. In addition to maintenance treatment in the first line, the patients in platinum-sensitive recurrence treatment and later line treatment might benefit from ISD niraparib.

Disclosures The authors declare that they have no competing interests.

419 SIGNALING PATHWAYS RELATED WITH ITGBL1 IN OVARIAN CANCER CELLS

1Alexander J Cortez, 2Katarzyna A Kujawa, 3Agata M Wilk, 3Marcela K Krzempek, 2Joanna P Sykis, 2Magdalena Olbynt, 2Katarzyna M Lisowska, 1Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch; Department of Biostatistics and Bioinformatics, Center for Translational Research and Molecular Biology of Cancer; 3Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch; Center for Translational Research and Molecular Biology of Cancer; 419

Introduction/Background Integrin beta-like 1 (ITGBL1) is a poorly characterized protein comprised of ten EGF-like repeats. Our previous studies suggested that higher ITGBL1 mRNA expression level in the tumor is related with shorter survival of ovarian cancer patients. 1, 2 Subsequent functional in vitro studies revealed that ITGBL1 overexpression in ovarian cancer cells resulted in the altered adhesion, migration and invasiveness, while it had no effect on proliferation rate and the cell cycle. ITGBL1-overexpressing cells were significantly more resistant to cisplatin and paclitaxel, 3 major drugs used in OC treatment. 4 In the current study we analyzed gene expression profiles of ITGBL1-overexpressing and control ovarian cancer cells and investigated ITGBL1 influence on ovarian cancer cell signaling pathways.

Methodology ITGBL1 coding sequence was PCR-amplified from cDNA and cloned into pLNCX2 vector. Retroviral system was used to obtain two ovarian cancer cell lines: OAW42/ITGBL1(+) and SKOV3/ITGBL1(+) with overexpression of ITGBL1. Control cell lines were obtained by transduction with an empty vector. RNA was isolated from wild type, ITGBL1-overexpressing and control cells. DNA microarray experiment was performed using GeneChip™ Human Transcriptome Array 2.0 (Affymetrix, Santa Clara, CA, USA) according to the manufacturer’s instructions. Bioinformatical analysis was carried out in R environment (version 3.5.3) with Bioconductor packages.

Results Using Principal Component Analysis, an unsupervised method of data analysis, we selected gene sets related to major sources of variability in our dataset. Then, by performing Gene Set Enrichment Analysis we found 76 and 146 significantly affected cellular signaling pathways (in OAW42 and SKOV3 cell line, respectively). Majority of them (22 and 44, respectively) were related to extracellular matrix structure and function, integrin signaling, focal adhesion, cell junction, cellular motility, ERBB2 and ERBB4 signaling, etc.

Conclusion Global gene expression analysis revealed that signaling pathways affected by ITGBL1 overexpression were mostly those related to extracellular matrix organization and function, integrin signaling, focal adhesion, cellular communication and motility. These results are concordant with functional changes observed in ITGBL1-overexpressing cells, like altered adhesiveness, enhanced motility and invasiveness. Overall, our results indicate that higher expression of ITGBL1 in ovarian cancer cells is associated with features that may worsen clinical course of the disease.

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Disclosures Authors have nothing to disclose.

423 FIBRONECTIN AND PERIOSTIN AS PROGNOSTIC MARKERS IN OVARIAN CANCER

1Katarzyna A Kujawa, 2Ewa Zembala-Nożyńska, 3Alexander J Cortez, 3Jolanta Kupniarczyk, 1Katarzyna M Lisowska, 1Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch; Center for Translational Research and Molecular Biology of Cancer; 2Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch; Tumor Pathology Department; 3Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch; Department of Biostatistics and Bioinformatics, Center for Translational Research and Molecular Biology of Cancer; 4Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology, Tumor Pathology Department; 5Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch; Center for Translational Research and Molecular Biology of Cancer

Introduction/Background In our previous microarray study we identified a 96-gene prognostic signature associated with the shorter overall survival (OS) of ovarian cancer patients. 1 Two genes from this signature, both coding for extracellular matrix proteins, were objects of the present study: FN1 and POSTN. We analyzed, by immunostaining, expression of encoded proteins in the independent set of ovarian cancer samples and evaluated its correlation with clinical, pathological, and molecular features.

Methodology Ovarian cancer samples from 108 patients were analyzed by immunohistochemistry using rabbit anti-human fibronectin polyclonal antibody (1:3000 dilution, A0245, Dako, Glostrup, USA) and rabbit anti-human peristin
polyclonal antibody (1:200 dilution, ab14041, Abcam, Cambridge, UK). Correlation with survival was evaluated with Cox proportional-hazards model and Kaplan–Meier estimator with log-rank test. Two-sided p-values < 0.05 were considered statistically significant. Analyses were carried out using Statistica 13.1 (TIBCO Software Inc., Palo Alto, CA, USA).

**Results** We observed that the higher expression of FN1 and POSTN was associated with shorter OS (log-rank: p-value 0.003 and 0.04 respectively). Next, we analyzed performance of the combined FN1&POSTN score calculated as a sum of individual FN1 and POSTN scores. We hypothesized that two-protein score would be more robust than evaluation of single proteins. Indeed, Cox regression demonstrated that FN1&POSTN score was an independent prognostic factor for OS (HR = 2.16; 95% CI: 1.02–4.60; p-value 0.044). However, we observed two outliers: out of the entire cohort one patient with a score 2 (indicating favorable prognosis) had the shortest OS and one patient with score 6 (indicating worst prognosis) had the second longest OS (131.17 month). These observations indicate that the FN1&POSTN score behaves similarly to classical prognostic factors: some patients having good prognosis, progress quickly and die early, while some patients with bad prognosis live unexpectedly long. In addition, our study showed that expression of fibronectin and periostin was associated with the source of OC sample: metastases showed higher expression of these proteins than primary tumors (chi2 test, p-value 0.024 and p-value 0.032). Elevated expression of fibronectin and periostin was also more common in fallopian cancers than in ovarian cancers.

**Conclusion** In summary, we found that the joint FN1&POSTN score is an independent prognostic factor for OS in ovarian cancer patients. Moreover, our results support the role of the cancer microenvironment in tumor progression and prognosis and add to the concept that some ovarian cancers originate from fallopian tube epithelium.

**Disclosures** Authors have nothing to disclose.

**REFERENCES**

**425 HIPEC IN OVARIAN CANCER: THE FIRST CASE-CONTROL STUDY IN MEXICAN PATIENTS**
1. Juan Manuel Medina-Castro, 2Avela González, 3Flavia Morales, 4Maria Antonia Morales.
2. Grupo Oncológico de Toluca; Martin Alonso Pizarín 135; 3Instituto Nacional de Cancerología; National Cancer Institute Mexico; Gynecology Oncology; 4National Cancer Institute Mexico; Medical Oncology; 5State National Cancer Center; Radiology

**Introduction/Background** Describe the global survival of ovarian cancer patients treated with HIPEC procedure.

Compare overall survival (OS) and progression-free survival (PFS) among ovarian cancer patients who underwent cytoreduction and HIPEC procedure vs patients treated with systemic chemotherapy.

**Methodology** Cases: patients treated with cytoreduction and HIPEC (N=46)

Controls: patients treated with systemic chemotherapy (N=92)

Follow-up: 2007–2017

PFS was calculated from the beginning of the treatment to the date when progression, death or the last visit was documented. OS was calculated from the beginning of the treatment to the death or to the last known follow-up.

**Results** The estimated median OS in the HIPEC group was 99.1 months vs 38.9 months in the control group (p=0.0002) PFS was 32.8 months in the HIPEC group and 17.8 months in the control group (p=0.05).

**Conclusion** Platinum resistance plays an important role in patient survival, with a difference of 40 months between those who are resistant and those who are not at the moment of HIPEC.

This study suggests that CRS and HIPEC in patients with recurrent complete cytoreduction (CCR0) was performed in 33 patients (71.7%) and optimal (with residual of less than 0.5 cm) in 13 patients (28.3%).

Severe complications occurred in 11 patients (37.93%).

Ovarian cancer may be beneficial compared to conventional secondary debulking or systemic therapy as treatment alone.

The measurement of OS from initial diagnosis is substantially modified to more than 104 months, a figure not seen before in advanced or recurrent disease of this neoplasm.

**Disclosures** The effort of the surgical oncology community to find the ideal patient and the ideal moment for this procedure should be directed not only to treatment, but to a sequence that offers patients a possibility of cure.

**431 HISTOPATHOLOGICAL RESULTS AFTER RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY IN BRCA1/2 MUTATION CARRIERS: SINGLE CENTER EXPERIENCE**
1Sarah Ehrmann, 1Jan Philipp Ramsott, 2Andreas de Bois, 3Philipp Harter, 4Stephanie Schneider, 2Thais Baert, 1Alexander Traut, 1Sebastian Heikaus, 4Nina Pauly, 4Beyhan Ataseven. 1Ev. Kliniken Essen-Mitte; Department of Gynecology and Gynecologic Oncology; 2Ev. Kliniken Essen-Mitte, Department of Gynecology and Gynecologic Oncology, Essen, Germany; 3Ku Leuven, Department of Oncology, Laboratory of Tumor Immunology and Immunotherapy, Immunovar Research Group, Leuven; 4Ev. Kliniken Essen-Mitte, Department of Pathology; 5Ev. Kliniken Essen-Mitte, Department of Gynecology and Gynecologic Oncology, Essen, Germany; University Hospital, LMU Munich, Department of Obstetrics and Gynecology, Munich

**Introduction/Background** Women with BRCA1 and 2 mutation are at increased risk for developing ovarian and breast cancer. Risk-reducing salpingo-oophorectomy (RRSO) can be offered to these women to minimize their risk. The pathologic sectioning and extensively examining the fimbriated end (SEE-FIM)-protocol is applied by the pathologist to detect premalignant lesions and early stage cancer. The rate of occult serous tubal intraepithelial carcinoma (STIC) lesions and ovarian cancer in this RRSO-population ranges between 0.6–10.0%. The prevalence of pathogenic lesion in RRSO is clinically relevant.

**Methodology** All consecutive patients with a pathogenic mutation (BRCA1/2, RAD51C, Lynch gene mutation, PALB2, BRIP1) who underwent RRSO between 11/2011 and 05/2020 in our Department of Gynecologic Oncology at Kliniken-Esben-Mitte were assessed from our prospectively managed database. All specimens were analysed according to the SEE-FIM-protocol.

**Results** In total, 241 women underwent RRSO of whom 216 were included in the final analysis. Median age was 48 years (range 22–79). 134 (62.0%) women had breast cancer in their
Introduction/Background Worldwide, ovarian cancer (OC) is the seventh most common cancer in women, with a five-year survival rate below 45%. Every year around the world, OC is diagnosed in 240,000 women. Studies on the epidemiology of OC were carried out in different regions of the world, taking into account various factors. At the same time, the issues of the relationship between morbidity and mortality from OC with genetic, hormonal factors, as well as nutritional factors, morphometric factors, somatic pathology, socio-demographic and other factors were taken into account.

The problem of OC epidemiology is extremely relevant for the Republic of Kazakhstan due to the significant prevalence of this disease among the female population, the still high level of neglected cases, as well as high mortality.

Methodology To analyze the epidemiological data of OC in the world, materials from the Globocan 2018 database of the International Agency for Research on Cancer (IARC) were used. To analyze the main statistical data for the regions of Kazakhstan, statistical data from the Cancer Register of the Republic of Kazakhstan for 2013–2018 were used.

Results In the Republic of Kazakhstan alone, there are more than 1000 new cases of OC and more than 400 deaths from this disease per year [5], while in the United States there are more than 22,000 new cases of OC and 14,000 deaths per year [6, 7].

In Kazakhstan, malignant neoplasms of the ovaries occupies the 3rd rank position among gynecological cancers. When analyzing rough intensive indicators of the incidence of ovarian cancer, there is an increase in the detection rate of this disease for the period from 2013 to 2018 [8–10].

The analysis of age-related incidence rates showed that malignant neoplasms of the ovaries are found in all age groups, with a noticeable increase by 65–69 years. The main contingent of the sick are women of working age. Also, when analyzing this five-year period (2013–2018), there is a decrease in the incidence in childhood and adolescence, so in 2014, 5 cases of ovarian cancer were recorded in the age group 5–19 years, and in 2019 - 1 case of this disease. Over the past decade, there has been an increase in morbidity at the age of 55–65 years [5].

Conclusion Morbidity and mortality from OC remain an urgent epidemiological problem in Kazakhstan and require further scientific research to identify risk factors. There are regions in the Republic of Kazakhstan that exceed the national average. In these regions, it is necessary to more widely apply modern methods of early diagnosis and treatment of ovarian cancer.

If detected at earlier stages, it is possible to obtain significant results of OC treatment. The main tasks of OC epidemiology are: continuation of in-depth studies of the prevalence in the regions of the Republic of Kazakhstan with the identification of population groups and regions with the lowest and highest rates of morbidity and mortality from OC.

Disclosures Epidemiological data on the incidence rates of malignant neoplasms of the ovaries according to Globocan 2018 show significant differences across countries (per 100,000 women); from 3.8 in Central Africa to 11.9 in Central and Eastern Europe [1].
Introduction/Background The 3-Tier Chemotherapy Response Score (CRS) was developed to quantify the response after neoadjuvant chemotherapy (NACT) in high-grade serous ovarian cancer patients undergoing interval debulking surgery. CRS3 (optimal response) identifies patients with a longer progression-free (PFS) and overall survival (OS) compared to patients with a CRS1/2 (no or minimal response/partial response). We critically evaluated the clinical value of CRS and compared its predictive power to standard serological (CA125) and radiological response in patients with advanced epithelial ovarian cancer.

Methodology A retrospective analysis of 277 patients, who received primary chemotherapy for advanced epithelial ovarian cancer was performed. CRS, serological, and radiological findings, and pathological complete remission (pCR) were correlated to PFS and OS.

Results Only 62.1% (172/277) patients treated with NACT could be assessed by CRS, as the CRS score can only be determined in patients that undergo interval debulking surgery, have a representative biopsy of the omentum, and have tumours with a high-grade serous histology. In patients with CRS3 (n=50) a longer median PFS and OS was observed compared to patients with CRS1/2 (n=122) (31.2 vs. 18.9, P<0.001; 55.0 vs. 36.1 months, P=0.050). Patients with serological and radiological complete response showed longer PFS (23.0 vs. 14.4, P=0.011; 21.4 vs. 9.6 months, P<0.001) and OS (49.5 vs 29.0, P=0.003; 45.0 vs. 12.9 months, P<0.001). Patients with a pCR had the best median PFS (52.8 months), even compared to non-pCR CRS3 (27.8 months).

In the total study cohort, serological and radiological complete response was better at predicting PFS (hazard ratio 2.23 and 2.77). Radiological complete response was better at predicting OS (hazard ratio 2.34).

Conclusion In this study, evaluation of response to chemotherapy by CRS was not superior to conventional methods (CA125 or radiology). Independent of the used evaluation method, response to NACT was predictive of PFS and OS. Conventional methods should even be considered more clinically relevant, as these can be applied to all ovarian cancer patients receiving upfront chemotherapy, while only 62% of patients in our cohort could be assessed by CRS. Conventional response assessment, based on radiology and/or CA125, is used to evaluate whether a patient should be offered IDS and can, similar to CRS, be used to predict PFS and OS. As CRS has no influence on the treatment of patients undergoing NACT for ovarian cancer, the added value of response assessment using CRS is negligible.

Disclosures JPR has no conflict of interest to declare.

Abstracts

441 CHEMOTHERAPY RESPONSE SCORE: CORRELATION WITH PREOPERATIVE SEROLOGICAL AND RADIOLOGICAL ASSESSMENT OF RESPONSE AND CLINICAL IMPLICATIONS IN OVARIAN CANCER PATIENTS

1 Jan Philipp Ramsgott, 2Thais Baert, 3Michelle Louise Macintosh, 4Alexander Traut, 5Kai-Uwe Waltering, 6Sebastian Heikalas, 7Philipp Harter, 8Andreas du Bois, 9Ev. Klinikum-Essen-Mitte; Department of Gynecology and Gynecologic Oncology, 10Ev. Klinikum-Essen-Mitte, Department of Gynecology and Gynecologic Oncology, Essen, Germany; Ku Leuven, Department of Oncology, Laboratory of Tumor Immunology and Immunotherapy, Immunovar Research Group, Leuven; 2St Mary’s Hospital, Manchester University Hospitals NHS Trust; Department of Gynaecological Oncology, 3Ev. Klinikum Essen-Mitte; Department of Radiology

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Introduction Bevacizumab is a recombinant humanized monoclonal antibody to vascular endothelial growth factor. It is an effective treatment for epithelial ovarian cancer, both in primary and recurrent disease. The incidence of ovarian cancer increases with advancing age. Despite the high prevalence of the ovarian cancer in elderly, the management of these patients is often less aggressive than that in younger patients. Our aim was to investigate the safety of bevacizumab administration in patients older than 65 years.

Methodology Retrospectively, we have analysed the medical data of 65 patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who started treatment with bevacizumab in primary advanced and in first relapse of the disease at the Department of Gynaecologic Oncology in the University Hospital Centre Zagreb in the period from April 2017 to December 2018. Patients are divided in two categories according to age: group 1 (>65 years) and group 2 (≤65 years).

Results Our analysis included 65 patients: 18 (27.7%) patients in group 1 compared with 47 (72.3%) in group 2. Bevacizumab have been administered to 38 (58.5%) patients as first-line treatment and to 27 (41.5%) patients as second-line treatment. The median age was 70 (range 66–76) years in group 1 and 55 (range 35–65) in group 2. ECOG performance status 0 had 44.7% of patients in group 2 compared with only 33.3% in group 1. At the time of diagnosis, elderly patients had presented with at least one comorbidity in 66.6% of the cases, compared with 40.4% in group 2. The median number of cycles of bevacizumab was 9 in elderly patients and 17 cycles in group 2. Among those patients receiving bevacizumab in the first-line setting, median progression free interval (PFI) was 12 months in younger patients versus 7 months in elderly patients. Similarly, among those receiving bevacizumab in the second-line setting PFI was 9 months in younger patients versus 1 months in elderly patients. The occurrence of adverse events did not increase in elderly patients; 51.1% of patients TB has been an advisor for Tesaro and received research grant from Amgen, non-financial support from Amgen, MSD, Roche, and Tesaro, outside the submitted work.

MLM, AT, KUW, SH have no conflict of interest to declare.

PH reports grants and personal fees from Astra Zeneca and Roche, personal fees from Sotio, and personal fees from Tesaro and GSK, personal fees from Stryker, Zai Lab, and MSD, grants from Public funding (DKH, DFG, EU), personal fees from Clovis, and Immunogen, grants from Boehringer Ingelheim, Medac, and Genmab, outside the submitted work.

AdB reports personal fees from Roche, Astra Zeneca, Tesaro, Clovis, Pfizer, Genmab, Pharmar, and Biocad, outside the submitted work.
in group 2 reported some adverse events versus only 27.8% in elderly patients.

Conclusion In Croatia, from February 2017 we have opportunity to treat patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer with bevacizumab in the first-line and second-line settings. Our experience in treating patients with bevacizumab shows good results with acceptable toxicity and our findings suggest that its use in the elderly population should be considered as safe and manageable.

Disclosures The authors have declared no conflicts of interest.

470 MALIGNANT OVARIAN TUMORS IN PREGNANCY: A CASE SERIES
Helena Azimi. Mashhad University of Medical Sciences
10.1136/ijgc-2020-ESGO.142

Introduction/Background Adnexal masses are commonly detected during routine fetal ultrasound screening. Nonetheless, since malignant adnexal tumors rarely occur in pregnancy, limited data is available regarding the management of this condition. Herein, we describe a series of ovarian cancer cases diagnosed and managed during pregnancy.

Methodology This case series describes 22 pregnant patients with ovarian cancer who were referred to the gynecology oncology department of an academic hospital within 6 years. Demographic and clinical characteristics of cases were gathered in checklists. Surgical staging of the tumors as well as disease-free survival (DFS) and overall survival (OS) were determined in all patients.

Results The pathologic subtype in 45.4% of the patients was epithelial. In another 45.4%, the subtype was germ cell, and the remaining 9.1% had sex-cord tumors. In epithelial tumors, the most common subtype was serous adenocarcinoma (60%). Most of the patients had a palpable mass during physical examination (72.7%) or an adnexal mass in ultrasonography (95.4%). We performed fertility-preserving surgery on 14 patients (63.6%) and 13 (59%) patients received chemotherapy. The recurrence rate was 22.7% and DFS and OS were 56% and 82%, respectively in a 6-year follow-up.

Conclusion Ovarian malignancy is a rare event during pregnancy and its management requires an experienced multidisciplinary approach. Further studies with larger sample sizes are required to provide more insight into the management of ovarian cancer throughout pregnancy.

Disclosures None.

487 LIQUID BIOPSY FOR DIAGNOSING OVARIAN CANCER: QUANTIFICATION OF CELL-FREE DNA AND P53 MUTATION ANALYSIS
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10.1136/ijgc-2020-ESGO.143

Introduction/Background Circulating tumor DNA found in women with malignancy, enters plasma due to lysis of cells at the interface between the primary tumor and the circulation. The primary objective of this study was to isolate and quantify cell-free DNA (cfDNA) from peripheral blood, analyze p53 mutations and correlate with tumor burden in epithelial ovarian malignancy. Secondary objective was to study the degree of agreement between cfDNA p53 mutations and tissue p53 immunohistochemistry.

Methodology This prospective case-control study was carried out over 18 months from November 2018 to April 2020 at a tertiary teaching institution. Considering the exploratory nature of the study, study group (n=20) comprised women with epithelial ovarian malignancy. Control groups were women with borderline tumors (n=10) and benign epithelial ovarian tumors (n=10). 58 women who were treatment naive and admitted for surgery entered the study but only those with a final histopathology of epithelial ovarian tumor (malignant, borderline and benign) were included. Peritoneal carcinomatosis index (PCI), surgical complexity score and cytoreductive score was calculated in women undergoing primary cytoreduction.

Plasma samples for cfDNA was collected just before surgery and stored at -20oC. cfDNA was extracted from plasma serum using a DNA isolation kit and quantified with Nanodrop Spectrophotometer. ARMS PCR was used to detect a point mutation in Exon 8, codon 239 of p53 using Nanodrop Spectrophotometer. ARMS PCR was used to detect a point mutation in Exon 8, codon 239 of p53 using primer pairs. p53 immunostaining was performed on tissue samples using monoclonal antibody directed against p53. Statistical analysis was done using SPSS version 21.

Results In women with malignant ovarian cancer isolated cfDNA was highest (1330 ng/mL) in comparison to those with benign or borderline ovarian tumors (748.5 ng/mL and 448.5 ng/mL, respectively) reaching statistical significance, p=0.023. Quantity of cfDNA also correlated well with the histopathological grade of the tumor and stage of the disease, p<0.05.

Analysis of cfDNA p53 mutation in exon 8 showed that 55% of the women diagnosed with malignant ovarian tumors harboured this mutation (p=0.043). Correlation of tissue p53 with cfDNA p53 mutation was statistically significant, p=0.007. All women with malignant ovarian tumor in whom cfDNA p53 mutation was present at codon 239 of exon 8 stained positive for tissue p53 mutation.

Conclusion cfDNA p53 mutation in exon 8 was detected at higher frequency in women with malignant epithelial ovarian cancer. Significant correlation was seen between tissue p53 and cfDNA p53 mutation suggesting that mutational analysis of cfDNA could act as biomarker for the diagnosis of ovarian tumors.

Disclosures Shalini Rajaram – No conflict of interest Aanchal Verma - No conflict of interest Rajarshi Kar - No conflict of interest Vinod Arora - No conflict of interest Bindiya Gupta - No conflict of interest Sandhya Jain - No conflict of interest
Introduction/Background Inoperable bowel obstruction (IBO) occurs in up to 50% of patients diagnosed with ovarian cancer. Nutrition support for patients with IBO is challenging. Parenteral feeding (PN) is the recommended route for patients with a prognosis of > 2 months, however there is little evidence that it improves quality of life and the cost of it is very high. If PN is not available patients are frequently discharged home from hospital with sips of clear fluids only. Management of inoperable bowel obstruction remains a major challenge and clear guidelines are needed.

Elemental diet (ED) is a liquid diet that contains proteins in the form of amino acids, fats in the form of medium chain triglycerides, vitamins and trace minerals. ED is almost completely absorbed in the upper small intestine.

Methodology The primary objective of the study was to establish if ED can be used as an alternative to home PN in patients with IBO. The secondary aim was to examine the impact of ED on quality of life. The primary endpoints of the study were acceptability and tolerability of ED with respect to taste, and incidence of vomiting and pain. The secondary endpoints included the number of patients alive at the end of the study, quality of life, nutritional intake, and the number of women who can tolerate ED and subsequently be treated with palliative chemotherapy (as per standard of care).

Results 29 women with IBO caused by metastatic ovarian cancer were recruited into the EDMOND study. Of those 8 could not complete the trial due to disease progression, and 2 had missing data that was deemed irrevocable, leaving 19 patients who contributed data to the primary endpoint analysis. The mean age of the patients who continued the trial was 68 (SD 12.5). Preliminary analysis shows that 68.4% of patients met the primary endpoint and tolerated ED; the ED did not worsen the vomiting or pain as measured by Memorial Symptoms Assessment Scale. At baseline 72% of patients experienced vomiting and this number reduced to 28% by the end of week1 of the study and to 23.5% by the end of week 2. Ninety-six percent of patients reported pain at baseline and this proportion reduced to 72% and 76% by the end of week 1 and 2 respectively.

Conclusion ED is well tolerated by patients with IBO and can provide an acceptable feeding option for this group of patients.

Disclosures The study was funded by Target Ovarian Cancer charity.

The author received educational grants from BMS, GSK, IPSEN, NOVARTIS, PFIZER CLOVIS, TESARO, ESAI; Advisory boards: CLOVIS, ESAI, IPSEN, ROCHE, TESARO
sensitive relapsed ovarian cancer between June 2017 and September 2019. Response to prior platinum, median progression-free survival (mPFS) after 1st and subsequent platinum, number of cycles of PARPi, dose, haematological toxicities, and PFS21 (start of subsequent therapy to physician assessed progression or death) were obtained through electronic records.

**Results**
37 patients received Niraparib in this timeframe. Median follow up was 16 months (range 5.7–37 months). Demographics were similar to previously published cohorts, however, only 11% (n=4) had a complete response (CR) to prior platinum therapy and 59% (n=22) had a partial response in comparison to 50% CR and 50% PR in the NOVA trial. 35 (95%) of patients had progressed on niraparib at the time of data collection. The mPFS on niraparib was 4.4 months (95% CI 3.7 – 6.7 months) in comparison to 9.3 months in the NOVA study. Patients who met the NOVA trial radiological and serological response criteria, had a mPFS at 5.1 months (n = 19) compared to 3.9 months (n = 18). Dosing and toxicity data will be reported in full at the meeting. 31 patients received subsequent therapy, 19 (61%) were treated with paclitaxel, 9 (29%) were treated with platinum-based chemotherapy. Median PFS21 was 5.8 months for platinum sensitive disease and 3.5 months for platinum resistant disease.

**Conclusion**
The real-world outcomes for niraparib treatment are worse than observed in the NOVA trial. Patients who meet NOVA trial eligibility criteria have better outcomes, however, these results are still inferior to those reported in the trial. Post PARP outcomes are poorer than expected in both platinum sensitive and platinum resistant settings. Strategies to effectively treat PARPi resistant disease are urgently needed.

**Disclosures**
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**REFERENCE**

**Abstract 518 Table 1 Safety in patients with ovarian, cervical or MSS endometrial cancer**

<table>
<thead>
<tr>
<th>Safety</th>
<th>Ovarian cancer (mPFS)</th>
<th>Cervical cancer (mPFS)</th>
<th>MSS endometrial cancer (mPFS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one monalizumab-related AE, n (%)</td>
<td>33 (87.8)</td>
<td>9 (56.3)</td>
<td>24 (68.6)</td>
</tr>
<tr>
<td>At least one durvalumab-related AE, n (%)</td>
<td>24 (60.0)</td>
<td>9 (56.3)</td>
<td>25 (69.4)</td>
</tr>
<tr>
<td>At least one monalizumab-related SAE, n (%)</td>
<td>3 (7.3)</td>
<td>2 (12.5)</td>
<td>3 (7.5)</td>
</tr>
<tr>
<td>At least one durvalumab-related SAE, n (%)</td>
<td>4 (10.5)</td>
<td>2 (12.5)</td>
<td>2 (5.4)</td>
</tr>
<tr>
<td>Death, grade 5 severity, n (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>At least one event leading to monalizumab discontinuation, n (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>At least one event leading to durvalumab discontinuation, n (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Abstract 518 Table 2 Efficacy in patients with ovarian, cervical or MSS endometrial cancer**

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>Ovarian cancer (n=27)</th>
<th>Cervical cancer (n=16)</th>
<th>MSS endometrial cancer (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete response, n (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Partial response, n (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stable disease, n (%)</td>
<td>15 (70.0)</td>
<td>6 (37.5)</td>
<td>15 (83.3)</td>
</tr>
<tr>
<td>Objective response rate, n (%)</td>
<td>2.9 (6.9)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Disease control rate at 24-weeks, n (%)</td>
<td>8 (16.2)</td>
<td>0</td>
<td>5 (13.8)</td>
</tr>
<tr>
<td>Median progression-free survival (months)</td>
<td>13.8</td>
<td>2.0</td>
<td>3.8</td>
</tr>
<tr>
<td>Median overall survival (months)</td>
<td>44.7</td>
<td>56.6</td>
<td>50.7</td>
</tr>
</tbody>
</table>
Disclosures Susana Banerjee has received institution research grants from AstraZeneca, Tesaro, and GlaxoSmithKline, and honoraria for advisory boards/lectures from AstraZeneca, Amgen, Clovis, Genmab, GlaxoSmithKline, Immunogen, Merck, Merck Serono, Merck Sharp & Dohme, Pfizer, Roche, Seattle Genetics, and Tesaro.

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523 SOX2 EXPRESSION IN OVARIAN SEROUS EPITHELIAL CANCER

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10.1136/ijgc-2020-ESGO.149

Introduction/Background The transcription factor Sox2 is highly expressed in embryonic stem cells and is considered to act as a key driver of stem-like properties of cancer cells.

Methodology This study aimed to investigate the immunohistochemical expression profile of Sox2 in ovarian serous epithelial cancer, to determine its potential significance in disease prognosis, association with clinical and pathological parameters, as well as with patient survival.

Results A total of 270 patients were enrolled in the study. In FIGO stage I tumors Sox2 expression was absent in 28.9% of the tumors, while high Sox2 expression was significantly less frequent (7.0%, p < 0.01). Significantly higher Sox2 expression compared with low expression was found in the third FIGO stage (65% vs 43.2%; p < 0.01). Disease progression was recorded in 23.1% of patients with high Sox2 expression, which is significantly higher in comparison to patients without Sox2 expression (11.4%; p < 0.05). Partial remission was observed in 14.1% with high Sox2 expression and this was significantly lower than in subjects with low Sox2 expression (28.8%; p < 0.05) or without Sox2 expression (34.3%; p < 0.01). Overall survival was the longest in the group without Sox2 expression, while the mortality was more prevalent in the group with high expression, but without statistical significance.

Conclusion The study showed that Sox2 overexpression in ovarian serous epithelial cancer was associated with the unfavorable clinical course of the disease.

Disclosures No
Robotic Interval Debulking Surgery for Advanced Epithelial Ovarian Cancer. Current Challenge or Future Direction? A Systematic Review

Victoria Pomiadou, Anastasia Prodromidou, Alexandros Fiotis, Sofia Lekka, Christos R Iavazzo, Metaxa Cancer Hospital, Piraeus, Greece; Metaxa Memorial Cancer Hospital; Department of Gynecologic Oncology

10.1136/ijgc-2020-ESGO.150

Introduction/Background Safety and efficacy of robotic interval debulking surgery (IDS) after treatment with neoadjuvant chemotherapy (NACT) in advanced epithelial ovarian cancer (EOC) was evaluated.

Methodology A systematic review of the literature was conducted.

Results We evaluated 102 patients in total. Perioperative outcomes were estimated as following: mean estimated blood loss ranged from 106.9 to 262.5 ml (mean± SD: 168±68 ml), mean operative time ranged from 164 to 312 min (mean± SD: 246±61 min), mean hospital stay was 2.4 days and post-operative blood transfusion rate was 19% (n=19/98). Regarding the oncological outcomes, 75 patients received a R0 resection (complete cytoreduction), while by 21 women there was a residual disease ≤1 cm. Regarding complications, no intraoperative and 6 postoperative (14.6%) complications were recorded, with a 30-d mortality rate of 9.2% (n=9/98), whereas the laparotomy conversion rate was 9.2% (9/98) as well, mostly in the terms of achieving complete cytoreduction.

During a median follow up period of 2 to 86 months (median 25.3 months), the median overall survival from 39.7 to 47.2 months and the progression free survival varied from 20.6 to 21.2 months. Recurrent disease was reported in 60 women (61%). Our results are in harmony (p=0.02) with those of the one study that presented significantly improved OS and PFS in the robotic arm compared to laparotomy (47.2 vs 37.8 vs 37.9, p=0.004 for OS and 20.6 vs 13.9 vs 20.6 to 21.2 months. Recurrent disease was reported in 60 patients (61%). Our results are in harmony (p=0.02) with those of the one study that presented significantly improved OS and PFS in the robotic arm compared to laparotomy (47.2 vs 37.8 vs 37.9, p=0.004 for OS and 20.6 vs 13.9 vs 11.9, p=0.005 for PFS, respectively).

Conclusion Robotic interval debulking surgery is a safe and efficient regarding the management of advanced ovarian cancer patients who receive neoadjuvant chemotherapy. The patients that are more eligible and could benefit from this treatment strategy should be specified through larger, double-blind randomized control trials.

Disclosures All authors declare no conflict of interest.

Abstracts

Peritoneal Cancer Index (PCI) as a Predictor of Completeness of Cytoreduction at Primary and Interval Debulking Surgery in Advanced Ovarian Cancer

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Background The completeness of surgical cytoreduction is the most important prognostic factor in advanced epithelial ovarian cancer (AOC). The FIGO staging system for ovarian cancer does not accurately account for disease distribution and tumour burden within the peritoneal cavity.

The peritoneal cancer index (PCI) quantitatively assesses cancer distribution and tumour burden in the peritoneal cavity in 13 abdominopelvic regions. It does not, however, include retroperitoneal nodal disease. First described by Sugarbaker, it was widely used in colorectal cancer and peritoneal mesothelioma. More recently, the PCI has been used to quantify tumour burden in patients with AOC. It may be a suitable tool to predict the completeness of cytoreduction at primary and interval debulking surgery. The aim of this study was to analyse the prognostic value and clinical correlations of PCI in patients with AOC.

Methodology We evaluated the correlation between PCI and cytoreductive score (GOG-score) in patients with AOC who were treated with primary and interval debulking surgery at a UK tertiary cancer centre. Data for 36 consecutive patients with AOC were collected prospectively from January to September 2020. An Ovarian Cancer Reporting Tool was developed according to the ESGO Ovarian Cancer Surgery Guideline and the Dutch Hyperthermic Intra-peritoneal Chemotherapy Protocol. Intra-operative PCI scores prior to and after resection were calculated using the report sheet, intra-operative findings and surgical notes. The scores were correlated to completeness of cytoreduction according to the GOG-score (1 = no macroscopic residual disease, 2 = 0.1–1 cm residual disease, 3 = 1–2 cm residual disease, 4 ≥ 2 cm residual disease).

Results Of the 36 patients, 25% (9/36) were staged FIGO IIIb, 33.3% (12/36) were FIGO IIC and 41.6% (15/36) were FIGO IV. Twenty-five percent (9/36) underwent primary debulking surgery and 75% (27/36) underwent interval debulking surgery after neoadjuvant chemotherapy. Thirty-one (86%) patients had high grade serous histology and five (14%) low grade serous carcinoma. Table 1 illustrates the distribution of intra-operative PCI scores and completeness of cytoreduction.

Twenty-three (64%) patients had a PCI of 0 to 15. In 22 (96%) complete cytoreduction (GOG-1) was achieved and in 1 (4%) there was 0.1–1 cm residual disease (GOG-2). Four patients had a PCI of 16 to 20 with GOG-1 achieved in 3 (75%) and GOG-2 in 1 (25%).

Nine patients had a PCI greater than 20 and rates of cytoreduction were: GOG-1 = 4 (44%), GOG-2 = 2 (22%), GOG-3 = 2 (22%) and GOG-4 = 1 (11%).

Conclusion PCI is a reproducible and objective tool for assessing the likelihood of complete resectability at primary and interval debulking surgery for AOC. A PCI of 0–20 was...
associated with a high likelihood of complete cytoreduction (93%) compared to a PCI of greater than 20, where complete cytoreduction was achieved in the minority (44%). Assessment and validation of PCI by radiology, laparoscopy and laparotomy may help in the selection of patients for cytoreductive surgery, neoadjuvant chemotherapy or chemotherapy alone.

Disclosures None.

565 POSTOPERATIVE OUTCOMES OF PRIMARY AND INTERVAL CYTOREDUCTIVE SURGERY FOR ADVANCED OVARIAN CANCER REGISTERED IN THE DUTCH GYNECOLOGICAL ONCOLOGY AUDIT (DGOA)

Introduction/Background The challenge when performing cytoreductive surgery (CRS) for advanced ovarian cancer is to balance the benefits (obtaining complete CRS) and risks (perioperative complications). The aim of this study was to report short-term postoperative morbidity and mortality in relation to surgical outcome in patients undergoing primary cytoreductive surgery (PCS) and/or interval cytoreductive (ICS) surgery in 8 gynaeco-oncological regions in the Netherlands.

Methodology Data from the prospective Dutch Gynecological Oncology Audit (DGOA) data base were used for this retrospective analysis with population-based data. All patients with advanced ovarian cancer (FIGO IIB-V) undergoing PCS or ICS between January 1st, 2015 - December 31st, 2018 were included. Primary outcome was the frequency of postoperative complications. In addition, median time to adjuvant chemotherapy was shown in relation to CRS outcomes and complication severity. Hospitals were clustered in 8 regions consisting of a gynaeco-oncological center and its referring hospitals. Complications with Clavien Dindo ≥3 were analyzed per region and casemix corrected.

Results A total of 2382 patients met the inclusion criteria corresponding to 2458 surgical procedures. 1027 patients underwent PCS and 1355 patients underwent ICS, a third group contained patients with both PCS and ICS (n=76). Complications with re-invention were significantly higher in PCS compared to ICS (5.7% vs. 3.6% respectively, p =0.048), but complete CRS was achieved more often in PCS compared to ICS (69.7% vs 62.1% respectively<0.001). Clavien Dindo ≥3, ICU stay, and 30-day mortality were not statistically different between PCS and ICS. Time to adjuvant chemotherapy was the longest in patients with complete CRS and a complication with re-intervention:47 days (figure 2c). Regional variation for Clavien Dindo ≥3 was apparent with 1 region as outlier in PCS and ICS (figure 3a and 3b).

Conclusion Complete PCS is more often achieved, but there are more complications with re-intervention resulting in more time to start with adjuvant chemotherapy. This exceeds the advised maximum of 42 days. This finding underlines the importance of maintaining a balance in aggressiveness of surgery and result of CRS in relation to survival. In addition, complications in the Netherlands show regional hospital variation after casemix correction.

In the future these outcomes should be discussed to minimize complications and therefore improve quality of care within the nation.

Disclosures None.
Supportive function of pegteograstim and efficacy of individualised starting dose (ISD) of niraparib per investigator assessment (IA) in newly diagnosed advanced ovarian cancer (OC) patients

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Introduction/Background Critical complication during chemotherapy is febrile neutropenia. Granulocyte-colony-stimulating factor (G-CSF) is used to prevent febrile neutropenia associated with myelosuppression. Pegfilgrastim, a pegylated form of filgrastim, has an increased half-life. Pegteograstim is novel recombinant human G-CSF of another form of pegylated filgrastim. We undertook investigation to evaluate efficacy and safety of pegteograstim and pegfilgrastim women with ovarian carcinoma that are treated with paclitaxel/carboplatin.

Methodology After chemotherapy minimum 24 hours, pegteograstim or pegfilgrastim was given a single subcutaneous injection of 6 mg during each chemotherapy cycle. We evaluated to ANC (absolute neutrophil count) change and febrile neutropenia incidence.

Results There were 30 of pegteograstim cases and 12 pegfilgrastim. Median ANC between pegteostim were 2960 pegfilgrastim was 2396. After pegteograstim, ANC was elevated till 13847 from 2960 (difference was 10,887) in case of pegteograstim. In pegfilgrastim, ANC increased to 12933 (difference was 10537). There was no febrile neutropenia in both cases. Safety profiles of two groups did not differ significantly.

Conclusion We conclude Pegteograstim and pegfilgrastim have similar efficacy and safety profile in the reduction of chemotherapy-induced neutropenia in the ovary cancer patients who were undergoing chemotherapy.

Disclosures NO COI.

Efficacy of individualised starting dose (ISD) and fixed starting dose (FSD) of niraparib per investigator assessment (IA) in newly diagnosed advanced ovarian cancer (OC) patients

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Introduction Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for maintenance treatment of patients with newly diagnosed or recurrent OC that responded to platinum-based chemotherapy and treatment in heavily pretreated recurrent OC. Here we report efficacy in patients receiving the FSD and ISD in the PRIMA/ENGOT-OV26/GOG-3012 trial (NCT02655016).

Methods This double-blind, placebo-controlled, phase 3 study randomised 733 patients to receive niraparib or placebo for 36 months or until disease progression/toxicity. A protocol amendment introduced ISD: 200 mg in patients with body weight <77 kg or platelets <150,000/μL, or 300 mg in all others. The primary endpoint was PFS by blinded independent central review (BICR). IA PFS was a sensitivity analysis. At the primary analysis data cut, follow-up was 11.2 months and 17.1 months in the ISD and FSD subgroups, respectively. An ad hoc analysis of IA PFS was performed using an updated data cut with additional 6 months follow-up.

Results BICR and IA PFS were highly concordant in the overall population. Efficacy of niraparib based on IA PFS in FSD vs ISD subgroups for each data cut were similar (table 1). Dose interruptions, modifications, and hematologic toxicity were lower with the ISD. Exposure–response data supported the clinical data.

Conclusion The 200- or 300-mg ISD by baseline body weight and platelet counts demonstrated comparable efficacy while improving the safety profile of niraparib. Use of this regimen for first-line maintenance of advanced OC patients is approved by the US FDA.

Disclosures NO COI.
Prevention of gynaecologic cancer

**PERFORMANCE OF CONE BIOPSY EXCISION FOR TREATMENT OF CERVICAL INTRAEPITHELIAL NEOPLASIA**

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Introduction/Background Cervical cancer is to a great extent preventable disease through detection and treatment of cervical intraepithelial neoplasia (CIN). All local treatment modalities are efficient in preventing CIN. The influence of different techniques on the risk of recurrence remains therefore unclear. The minimum radicality of treatment to prevent treatment-induced morbidity and the increased risk of future invasion is required. The aim of the study was to assess the adequacy of cone biopsy excision of naked eye lesions as a method of treatment of cervical intraepithelial neoplasia (CIN). Women treated with LEEP were used as control.

Methodology The current study was randomized clinical trial. Cone biopsy excision of naked eye lesions was compared to LEEP of the transformation zone in women undergoing surgical treatment of CIN. The primary outcome was involvement status of the margin of the resected cone. Secondary outcomes were procedure time, blood loss, hemostasis time, intraoperative and postoperative complications, size of the resected area and postoperative pain, validated by visual analog scale (VAS).

Results Ninety women were evaluated for disease persistence after excision of the naked eye lesions using cone biopsy excision. Eighty-five cases treated with excision of the transformation zone using LEEP. There is no statistically significant difference as regarding the margin involvement of the resected cone, the primary outcome, was observed between cone biopsy excision and LEEP (11/90 [12%] vs 8/85 [9.4%], respectively; p = 0.55, OR=1.34 95% CI: 0.5115). Postoperative pain was lower after cone biopsy excision (VAS: 0 [0–2] vs1 [0–3]; p = 0.02). The secondary outcome parameters; procedure time, blood loss, hemostasis time, intraoperative and postoperative complications and size of the resected area were not different between the study groups. Age, parity, contraception method and body mass index did not influence the primary and secondary outcome parameters using multivariate analysis.

Conclusion Cone biopsy excision and LEEP are evenly effective and safe procedures.

Disclosures No conflict of interest related to this research.

**PROPHYLACTIC HUMAN PAPILLOMAVIRUS HPV VACCINATION TO PREVENT RECURRENT CERVICAL INTRAEPITHELIAL NEOPLASIA: A META-ANALYSIS**

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Introduction/Background The aim of this systematic review and meta-analysis was to review evidence supporting the use of prophylactic human papillomavirus vaccines to influence the risk of recurrence of cervical intraepithelial neoplasia after surgical treatment.

Methodology A systematic literature search was performed for publications reporting risk of recurrence of cervical intraepithelial neoplasia after surgical treatment in patients receiving human papillomavirus vaccination (either in the prophylactic or adjuvant setting). Comprehensive searches of 6 electronic databases (MEDLINE, Embase, Web of Science, PubMed, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and references of identified studies) from their inceptions were performed (English language only), and hand search reference lists were performed. Two independent reviewers applied inclusion and exclusion criteria to select included papers, with differences agreed by consensus. The literature search was performed using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Results were reported as mean differences or pooled odds ratios (OR) with 95% confidence intervals (95% CI).

Results A total of 5744 citations were reviewed; 5 studies comprising 3562 patients were selected for the analysis. There were 1453 patients in the vaccinated group and 2109 in the placebo or unvaccinated group. The incidence of histologically confirmed cervical intraepithelial neoplasia 2+ was reduced in the vaccinated compared to the unvaccinated group (OR 0.51, 95% CI 0.35 – 0.74, p = 0.0003). The number needed to treat (NNT) to prevent one recurrence was 43. Both pre-treatment vaccination (OR 0.48, 95%CI 0.25–0.94, p=0.03, NNT-40) and adjuvant vaccination (OR 0.53, 95%CI 0.34–0.81, p=0.004, NNT–38) reduced recurrence rates.

Conclusion Prophylactic or adjuvant human papillomavirus vaccination reduces the risk of recurrent cervical intraepithelial neoplasia 2+. These data support further investigation of its role as an adjuvant to surgical treatment.

Disclosures No conflict of interest to declare.

**ATAXIA-TELEANGIECTASIA FOLLOWED UP IN A HEREDITARY GYNAECOLOGICAL CANCER UNIT OF A TERTIARY HOSPITAL**

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Conclusion Cone biopsy excision and LEEP are evenly effective and safe procedures.

Disclosures No conflict of interest related to this research.
Ataxia-telangiectasia is an autosomal recessive neurodegenerative disorder with immunodeficiency and an increased risk of developing cancer, caused by mutations in the ataxia-telangiectasia mutated (ATM) gene. Female carriers have an increased risk (20–30%) of developing breast cancer.

It is known that heterozygosity for a pathogenic ATM variant is present in 1%–2% of the adult population.

**Methodology** Retrospective observational study. Review of patients followed in the inherited cancer unit at Gregorio Marañón University General Hospital between 1st January 2012 until 28th February 2020.

The statistical analysis was carried out using SPSS 26.0.

**Results** During the indicated period, we followed 333 patients with confirmed genetic mutations that predispose to developing gynaecological cancer. Of the total, 1.5% (5/333) were carriers of a pathogenic ATM mutation and 0.6% (2/333) of a variant of uncertain meaning ATM mutation.

Within the cohort of patients carrying a pathogenic ATM mutation, all of them had family history of breast cancer and one also of ovarian cancer. 3/5 of the patients were diagnosed with breast cancer at 38, 40 and 48 years old, respectively. One of them, had a second contralateral breast cancer at 58 years old.

The histology of the primary breast cancer was: ductal carcinoma in situ, invasive ductal carcinoma and invasive lobular carcinoma. Tumor stage was 0 in one case and stage I in two cases. Primary treatment was surgery in all patients: unilateral mastectomy with homolateral axillary lymphadenectomy in one patient and conservative surgery with selective sentinel lymph node biopsy in the other 2. Adjuvant treatment was only needed in 2 patients: radiation therapy and hormone therapy in one case and radiation therapy, chemotherapy and hormone therapy in the other.

Characteristics of these patients are summarized in table 1.

**Conclusion** Patients carrying ATM mutations have a moderate-high risk of developing breast cancer and should be followed in specialized hereditary cancer units, in tertiary hospitals.

**Disclosures** No conflicts of interest to disclose.
Faiza Gaba, Oleg Blyuss, Jatinderpal Kalsi, Saskia Sanderson, Andrew Wallace, Antonis C. Antoniou, Rosa Legood, Usha Menon, Ian Jacobs, & Ranjit Manchanda, on behalf of the PROMISE-FS team.

Introduction/Background The current approach to genetic-testing and risk assessment is based on family-history and misses the majority of people at risk. Unselected population-based testing can enable personalised ovarian cancer (OC) risk prediction combining genetic/epidemiology/hormonal data. This permits population risk stratification for risk adapted targeted screening and prevention. Such an intervention study has not previously been undertaken. We aimed to assess the feasibility of OC risk stratification of general population women using a personalised OC risk tool followed by risk management.

Methodology Volunteers were recruited through London primary care networks. Inclusion criteria: women ≥18 years. Exclusion criteria: prior ovarian/tubal/peritoneal cancer, previous genetic testing for OC genes. Participants accessed an online/web-based decision aid along with optional telephone helpline use. Consenting individuals completed risk assessment and underwent genetic testing (BRCA1/BRCA2/RAD51C/RAD51D/BRIP1, OC susceptibility single-nucleotide polymorphisms). A validated OC risk prediction algorithm provided a personalised OC risk estimate using genetic/lifestyle/hormonal OC risk factors. Population genetic testing (PGT) for OC-risk stratification uptake/acceptability, satisfaction, decision aid/telephone helpline use, psychological health and quality of life were assessed using validated/customised questionnaires over six months. Linear-mixed models/contrast tests analysed impact on study outcomes. Main outcomes: feasibility/acceptability, uptake, decision aid/telephone helpline use, satisfaction/regret, and impact on psychological health/quality of life.

Results In total, 123 volunteers (mean age = 48.5 (SD=15.4) years) used the decision aid, 105 (85%) consented. None fulfilled NHS genetic-testing clinical criteria. OC-risk stratification revealed 1/103 at ≥10% (high), 0/103 at ≥5%<10% (intermediate), and 100/103 at <5% (low) lifetime OC risk. Decision aid satisfaction was 92.2%. The telephone helpline use rate was 13% and the questionnaire response rate at six months was 75%. The high-risk woman underwent surgical prevention. Contrast tests indicated that overall depression (p=0.30), anxiety (p=0.10), quality-of-life (p=0.99), and distress (p=0.25) levels did not jointly change, while OC worry (p=0.021) and general cancer risk perception (p=0.015) decreased over six months. In total, 85.5%–98.7% were satisfied with their decision.

Conclusion Findings suggest population-based personalised OC risk stratification is feasible and acceptable, has high satisfaction, reduces cancer worry/risk perception, and does not negatively impact psychological health or quality-of-life. Larger implementation studies evaluating long-term impact and cost-effectiveness of this strategy are needed.

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IJ, UM- Financial interest in Abcodia, company for development of biomarkers for early detection of cancer. Other authors- No disclosures.
likely to find RRESDO acceptable in retrospect (OR=5.3, 95%CI=1.2–27.5, p<0.031). 88.8%(143/161) premenopausal women versus 95.2%(80/84) postmenopausal women who underwent RRSO respectively were satisfied with their decision. 9.4%(15/160) premenopausal and 1.2%(1/81) postmenopausal women who underwent RRSO regretted their decision. HRT-uptake in breast-cancer (BC) unaffected premenopausal individuals was 74.1% (80/108). HRT-use did not significantly affect satisfaction/regret levels but reduced symptoms of vaginal-dryness (OR=0.4, 95%CI=0.2–0.9, p=0.025).

Conclusion Data show high RRESDO acceptability particularly in women concerned about sexual-dysfunction. Although RRSO satisfaction remains high, regret rates are much higher for premenopausal women than postmenopausal women. HRT use following premenopausal RRSO does not increase satisfaction and reduces vaginal dryness.

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507 SURGICAL DECISION MAKING IN PREMENOPAUSAL BRCA CARRIERS CONSIDERING RISK REDUCING EARLY-SALPINGECTOMY OR SALPINGO-OOPHORECTOMY: A QUALITATIVE STUDY

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521 PAP SMEAR SCREENING AMONG FEMALE PATIENTS OF THE IBN ROCHD UNIVERSITY HOSPITAL CENTER: A CROSS SECTIONAL SURVEY

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Introduction/Background Cervical cancer is preceded by a period of pre-invasive state, and is characterized histologically by a broad spectrum of events ranging from cellular atypia to different degrees of cervical intraepithelial neoplasia before progressing to invasive cancer. The association between certain oncogenic (high-risk) strains of HPV and cervical cancer is well established. The purpose of this study is to highlight – through the findings - the importance of emphasizing accurate information about cervical cancer and the purpose of Pap smear for Moroccan women.

Methodology This cross-sectional study was carried out among 500 female patients who had a pap screening at the gynecology and obstetrics department at the UHC Ibn Rochd over a period of 2 years (2016 – 2017).

Results The average age of the patients having a pap smear screening is 39.5 years. The most affected age group is between 30 and 40 years old. 67% of the patients had started sexual activity before the age of 20. A history of recurrent surgical decision making were identified: fertility, menopause, cancer risk reduction, surgical choices, surgical complications, sequence of ovarian and breast prophylactic surgeries, support, satisfaction. Women for whom maximising ovarian cancer (OC) risk reduction was relatively more important than early menopause/quality of life preferred RRSO, whereas those more concerned about detrimental impact of menopause chose RRESDO. Women preferred educational support groups to online support groups to help with decision-making. Women engage concurrently in both OC and breast cancer (BC) prevention decision-making and we identified a demand for combined OC and BC prevention-surgery. While preventative surgery reduced anxiety, interviewees wished to be routinely offered an ‘optional’ (not compulsory) consultation with a psychologist. Women managed in specialist familial cancer clinic (FCC) settings compared to non-specialist settings received better quality care, improved HRT access and were more satisfied.

Conclusion Medical, physical, psychological, social contextual factors influence timing of risk reducing surgeries. RRESDO offers women delaying/declining premenopausal oophorectomy, particularly those concerned about menopausal effects, a degree of ovarian cancer risk reduction whilst avoiding premature menopause. Care of high risk women should be centralised to centres with specialist familial gynaecological cancer risk management services to provide a better quality, streamlined, holistic multidisciplinary approach.

Disclosures Funding: Barts Charity and Rosetrees Trust.

RM declares research funding from Cancer Research UK and The Eve Appeal outside this work, an honorarium for advisory board membership from Astrazeneca/MSD and Israel National Institute for Health Policy Research. RM is supported by an NHS Innovation Accelerator (NIA) Fellowship. The other authors declare no conflict of interest.
genital infections was found in 11% of patients. 80% of the patients were in their genitally active period. 2% of the patients had multiple sexual partners. Pap smear results were distributed as follows: 8.4% normal, 53.6% non-specific inflammation, 14.8% specific HPV infection, 6% atrophy, 4.2% ASC-US (Atypical squamous cells of undetermined significance), 2.8% ASC-H (Atypical squamous cells of undetermined significance—cannot exclude HSIL), 5.2% LSIL (Low-grade squamous intraepithelial lesion), 2% AGUS (Atypical glandular cells of undetermined significance), 1.8% HSIL (High-grade squamous intraepithelial lesion), 0.6% detecting the presence of cancer cells.

Conclusion In Morocco, the establishment of a national mass cervical cancer screening program adapted to our epidemiological and socioeconomic context as well as the improvement of hygienic living conditions remains the best means to reduce the incidence and mortality related to cervical cancer.

Disclosure The authors declare that they have no conflict of interest.

Quality of life after treatment

Impact of Cervical Cancer on Quality of Life and Sexual Functioning of Filipino Patients who Underwent Definitive Chemoradiation in the University of Santo Tomas Hospital, Manila, Philippines

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Introduction/Background Cervical cancer is a serious health problem, with nearly 500,000 women developing the disease each year worldwide. The burden of disease of cervical cancer in the Philippines as a developing nation is high. Its incidence rate has persisted from the 1980s up to the present with an annual age-standardized rate of 22.5 cases per 100,000 women. Of the thousands of Filipino women who are diagnosed with cervical cancer, 56% will die within 5 years from the diagnosis.

The aim of this study was to determine the quality of life (QoL) and sexual functioning of Filipino patients with cervical cancer on first consult, 3 months, and 6 months of completion of definitive chemoradiation.

Methodology The study is a 2-year prospective longitudinal observational study. Patients were assessed for QoL and sexual functioning on first consult, 3 months, and 6 months of completion of chemoradiation using the European Organization for Research and Treatment of Cancer (EORTC) QoL Questionnaire (QLQ-C30) and EORTC (QLQ-CX24), respectively.

Results Fifty five patients were included for the analysis, and the mean age at the time of the interview was 52 years. Six months after the definitive chemoradiation, patients showed improved global health status/QoL and better physical role, cognitive, and emotional functioning than first day of treatment. Patients updated lower recurrence of symptoms. As to the sexual functioning impact of definitive chemoradiation on patients with cervical cancer, the patients experienced more problems with sexual activity and sexual enjoyment. Moreover, it is reported that all sexual function scales are correlated with health status of patients 6 months after treatment.

Conclusion This paper aided the health care providers to have a better understanding of the QoL and sexual functioning of cervical cancer patients who deal with its treatment sequelae. In addition, this will help counsel cervical cancer patients on what they could expect in a long term since definitive chemoradiation will have a great impact on their QoL. Furthermore, this study will also contribute on how to improve further research for Filipino women with cervical cancer.

Disclosure This paper has no relevant financial or nonfinancial relationships to disclose.

144 SEXUAL FUNCTION AFTER PELVIC RADIOThERAPY: A BRIEF DESCRIPTIVE STUDY IN LOCALLY ADVANCED CERVICAL CANCER PATIENTS

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Introduction/Background Cervical cancer is the most common gynecological cancers in Indonesia, 74% of all cases of gynecologic cancers. In 2018, the incidence of cervical cancer is 9.3% in Indonesia, 84.6% were diagnosed as advanced stage. The primary treatment in advanced cervical cancer is radiotherapy, especially pelvic radiotherapy. Although pelvic radiotherapy is the modality of choice for treatment in advanced cervical cancer, but it has side effects that can affect woman’s sexual function.

Methodology The subjects of this study were 34 patients who were diagnosed with cervical cancer stage IB-IIA and underwent pelvic radiotherapy based on local hospital database in Gynecologic Outpatient Clinic in Kandou Hospital from September 1st 2019 to February 29th 2020. All patients were interviewed with Female Sexual Function Index (FSFI) questionnaire. This questionnaire measures five groups of questions, which are sexual desire, arousal, lubrication, orgasm, satisfaction, and pain to assess sexual function in women.

Results From 34 patients who have undergone pelvic radiotherapy, the FSFI scores of 32 patients are below 26.5 and categorized as female sexual dysfunction (FSD), while two patients have score more than 26.6. The mean of FSFI Score is 10.0.

Conclusion Pelvic radiotherapy has negative effect on the vaginal mucosa. This effect has significantly reduced the sexual function in women after pelvic radiotherapy. Assessment of the Sexual Function of every patients who have undergone pelvic radiotherapy is important to improve comprehensive care for female cancer patients.

Disclosure The authors declare no conflict of interest, financial, or otherwise.
Introduction Many gynaecological cancer patients suffer from psychosocial distress. The goal of this evaluation was to assess the level of distress and desire for psychosocial support in this group of patients based on the psychosocial distress screening at the Department of Gynaecology and Obstetrics, University Hospital of the Technical University of Munich, Germany.

Methodology As part of the self-reporting 10-item Questionnaire on Stress in Cancer Patients-Revised (QSC-R10), which has been validated for the evaluation of psychosocial distress in oncological patients (Book et al., 2011), patients state whether or not and, if applicable, how severely each item applies to them. Answers range from 0 (‘the problem does not apply to me’) to 3 (‘the problem applies to me and is a very serious problem’) and refer to potential disease-related situations. A validated cut-off score >14 indicates significant psychosocial distress. A question regarding the patient’s desire for psychological support was added to the screening. Psychosocial support was actively offered in case of significant distress. A validated cut-off score >14 indicates significant psychosocial distress. A question regarding the patient’s desire for psychological support was added to the screening. Psychosocial support was actively offered in case of significant distress or patient’s desire. Between November 2013 and April 2018, 860 questionnaires were filled in by 325 outpatients at the Department of Gynaecology and Obstetrics and evaluated for the present study.

Results On average, each patient filled in 2.65 questionnaires. The mean patient age on the date of the first filled questionnaire was 60 years. The most frequent cancer diagnosis was ovarian cancer (43%), followed by endometrial cancer (17%). In 10% of questionnaires, patients expressed a desire for psychosocial support, in 74% declined such support and 16% of the surveys showed no answer. 31% of all questionnaires indicated clinically relevant psychosocial distress, 62% remained under the cut-off and 6% were not evaluable due to missing information. Of those exceeding the cut-off, 14% desired psychosocial support, 73% declined support and in 13% of the questionnaires, patients did not comment on their desire.

Conclusion 31% of questionnaires showed clinically relevant psychosocial distress of patients. However, only in 14% of these cases patients showed desire for psychosocial support. This discrepancy is a common phenomenon described in the literature. Further research concerning potential causes and factors associated with high distress-levels will be necessary. For this analysis, the development of the score and the desire for support over time in patients who received several questionnaires has not been taken into account yet. Further investigations in this regard should be considered in order to facilitate needs-based support over time of treatment and disease.

Disclosures Authors did not state any conflicts of interest within the last three years.

INTRODUCTION/BACKGROUND

Women with breast cancer (BC) often suffer from severe vulvovaginal atrophy (VVA) linked to endocrine deprivation, which is worsened by BC treatments and ultimately leads to urinary symptoms, dyspareunia and poor sexual quality of life. Treatment side effects, including gynaecological side effects, could affect adherence to treatment, such as endocrine therapy. We conducted a prospective study on women with BC to evaluate the effect of fractional microablative CO2 laser therapy on VVA in the long term.

Methodology Women with a history of BC, without contra-indication to laser therapy and suffering from VVA were proposed to have fractional microablative CO2 laser therapy (MonaLisaTouch®, DEKA) once per month for 3 months. Vaginal health was objectively determined with pH level and trophicity on pap smear. Sexual and urinary quality of life status were assessed using the Female Sexual Function Index (FSFI) score and the Ditrovie score. Measurements were performed at baseline and 6 months. Quality life scores were also assessed about 18 months after the last laser session. Paired statistical tests between baseline and 6 months and between baseline and end of study were computed using R software (version 4.0.2).

RESULTS

46 women with BC (median age [interquartile range] = 56.5 [47.0 – 59.4]) were treated between May and December 2018, of whom 36 were taking endocrine therapy (tamoxifen n=6, aromatase inhibitors ± LHRH agonist n=30). pH level slightly decreased over time (mean = 6.5 (SD 0.9) at baseline versus 6.4 (SD 0.9) at 6 months, p=0.02) whereas trophicity on pap smear did not change. Sexual quality of life was significantly improved at 6 months and at the end of study (mean = 11.3 (SD 7.5) at baseline versus 19.4 (SD 6.7) (p<0.0001) and 15.2 (SD 9.0) (p=0.0099). Ditrovie total score improved at 6 months (mean = 1.05 (SD 0.5) versus 1.2 (SD 0.6) at baseline, p=0.01) but not at the end of study. About 56% of treated women asked for a maintenance laser session at the end of the study.

CONCLUSION

Our data show that fractional microablative CO2 laser is effective for women with BC on VVAs symptoms and gynaecological quality of life. Effects are long-lasting but decrease after a certain time suggesting that maintenance sessions might be necessary. More research has yet to be done on treatment schedule for women with BC, such as number of laser sessions at initiation (3 or 4) and duration before maintenance sessions.

Disclosures he microablative laser was provided by DEKA. There was no financial support from DEKA.
MENOPAUSAL SYMPTOMS AND SEXUAL DISORDERS IN EPITHELIAL OVARIAN CANCER SURVIVORS, A GINECO VIVROVAIRE2 STUDY

Introduction/Background We have previously shown that Epithelial Ovarian Cancer (EOC) and its treatments have significant negative effects on Quality of Life (QoL) and long term fatigue. The aim of the present multicentric VIVROVAIRE2 study was to report the main menopausal symptoms of Epithelial Ovarian Cancer survivors (EOCS).

Methodology One hundred sixty-six patients of the 322 EOCS without relapse ≥3 years after first line of treatment accepted to participate to a gynecological consultation carried out by a gynecologist, including a questionnaire related to menopausal symptoms (MS), sexuality, clinical examination, and osteodensitometry. MS (hot flashes and/or night sweats) were described according to natural menopause (NM) or surgically induced menopause (SIM). QoL, fatigue, insomnia and mood disorders were measured with the questionnaires (FACT-G, FACIT Fatigue, ISI, and HADS).

Results Median age was 62 years [20–83], FIGO stage III/IV (48%) and < 10% BRCA1&2 mutated. Histological subtypes were: high grade serous 28%, low grade serous 22%, endometrioid G2-3 (15%) endometrioid G1 (3%), clear-cell 21%, mucinous 5%. All EOCS had surgery, 97% of patients received platinum and taxane chemotherapy, median delay from treatment was 5 years [3–24] and 59 (36%) had SIM. 14% of EOCS had osteoporosis. Half of patients reported MS either hot flashes (47%) or night sweats (32%). 72% with SIM had MS compared to 41% with NM (p<.001). MS were not associated with poor global QoL, fatigue, insomnia or mood disorders. At the gynecological consultation, two-thirds of EOCS reported a decrease in sexual desire notably EOCS with SIM, which showed a greater decreased libido than NM (p<.02).

One hundred seven patients have never been treated with Hormone Replacement Therapy (HRT) including 59 who reported MS and 48 who (40%) had SIM.

Among 85 EOCS with MS, 80 (94%) (38 SIM and 42 NM) did not benefit from HRT after cancer treatment; 76% presented no CI of HRT.

Conclusion Menopausal symptoms and sexual disorders are frequently reported by EOCS, particularly among surgically induced menopause patients. A majority of EOCS with MS may benefit from HRT to improve these symptoms.

Disclosures The authors declare that they have no conflict of interest in relation to the subject of the article.

INT J GYNECOL CANCER

493 HOW TO RECONSTRUCT AN OPEN ABDOMINAL WALL AFTER NECROTIZING FASCIITIS: SURGICAL MANAGEMENT IN DIFFICULT CASES

Introduction/Background Necrotizing fasciitis (NF) is a rare but very fatal infection involving and causing necrosis of the subcutaneous tissue and fascia. The incidence of NF is 0.4/100000. NF has a high mortality rate so it is needed an early diagnosis and proper treatment. There are several risk factors of NF. NF presents as painful, patchy discoloration of the skin without margins and a black necrotic plaque at the wound area. Ischemia and tissue necrosis can develop and but very fatal infection involving and causing necrosis of the subcutaneous tissue and fascia. The incidence of NF is 0.4/100000. NF has a high mortality rate so it is needed an early diagnosis and proper treatment. There are several risk factors of NF. NF presents as painful, patchy discoloration of the skin without margins and a black necrotic plaque at the wound area. Ischemia and tissue necrosis can develop and local anaesthesia can occur because of the nerve damage.

Methodology A 59-year-old Turkish woman was admitted to hospital with a complaint of a postmenopausal bleeding.
Translational research

ACCUMULATION OF 53BP1 IN CIRCULATING TUMOR CELLS DURING TREATMENT WITH EIRUBIN IDENTIFIES CHEMOTHERAPY-RESPONSIVE METASTATIC BREAST CANCER PATIENTS

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Introduction/Background Evidence suggests that the DNA end-binding protein p53-binding protein 1 (53BP1) expression in breast cancer is associated with poor prognosis, especially in triple-negative breast cancer (TNBC). Circulating tumor cells (CTCs) provide accessible 'biopsy material' to track cell traits and functions and their alterations during treatment.

Methodology We prospectively monitored the 53BP1 status, as a parameter for intact DNA damage response, in CTCs from 63 metastatic breast cancer (MBC) patients with HER2- CTCs before, during, and at the end of chemotherapeutic treatment with Eirubin in the DETECT-IV trail. Nuclear 53BP1 staining and genomic integrity were evaluated by immunocytochemical and whole-genome-amplification-based polymerase chain reaction (PCR) analysis. We used mean 53BP1 scores in CTC samples as dividing criteria, i.e. compared patients with 53BP1 scores <50% and ≥50%. We analyzed PFS of the patients from these two groups using scores obtained with samples at different time points during the study.

Results We found a decline of mean CTC numbers from baseline to 12 weeks of treatment but a dramatic rise at the final visit due to disease progression in 10/13 of the cases (mean CTC-values at baseline: 18, 2nd visit: 2, final visit: 118). Comparative analysis of CTCs from patients with 15 triple-negative and 48 hormone receptor positive tumors revealed elevated 53BP1 levels in CTCs from patients with HR+ metastases, particularly following chemotherapeutic treatment. Kaplan-Meier analysis between nuclear 53BP1-positivity in CTCs and progression-free survival (PFS) revealed an increasing association during chemotherapy until last examination (p=0.065).

Conclusion Our data suggest that 53BP1 detection in CTCs could be a useful marker to capture dynamic changes of chemotherapeutic responsiveness in triple-negative and HR+ MBC.

Disclosures FSch received speaker honoraria and a travel grant from Roche, Novartis, Pfizer and Lilly.

VM speaker honoraria from Aman, Astra Zeneca, Celgene, Daiichi-Sankyo, Eisai, Pfizer, MSD, Novartis, Roche, Teva, and consultancy honoraria from Genomic Health, Hexal, Roche, Pierre Fabre, Aman, ClinSol, Novartis, MSD, Daiichi-Sankyo, Eisai, Lilly, Tesaro, and Nektar, as well as institutional research support from Novartis, Roche, Seattle Genetics, and Genentech. Otherwise, no potential conflicts of interest were disclosed by the authors.
dissemination patterns. Tumour biopsies were collected (range 4–15, median 9), placed in short-term cultures, treated with cisplatin (25 μM overnight) and apoptosis/viability assayed. When relapsed, patients also had paired biopsies collected for genomic and phenotypic analysis. DNA was extracted from tumours (5 per patient, n=49 patients plus relapse samples) and Illumina Human OmniExpress genotyping performed. Allele-specific copy number (CN) was quantified using ASCAT. Genomic heterogeneity was quantified as the estimated number of CN aberration events distinct between each pair of tumour deposits. Clonal diversity within a patient’s deposits was calculated using the difference between within-patient and between-patient heterogeneity.

**Results** Broad heterogeneity was detected in response to platinum treatment across cases at the phenotypic level in vitro (n=49), with higher variances in apoptosis induction observed in patients with platinum resistant disease. Genomic analysis revealed widespread variations in patterns of evolution for different patients’ tumours, including the relationship between primary tumours and relapsed disease. Extensive variations in CCNE1, MYC and PTEN CN were observed across multiple tumours in the same patients, and overall higher CCNE1 CN associated with poorer patient outcome (p=0.038).

**Conclusion** Vast intra-tumoural heterogeneity is observed at the phenotypic and genomic level in HGSOC patients. Extensive copy number variations in genes such as CCNE1, MYC and PTEN across multiple disseminated samples within patients, indicates that sampling of a single tumour site does not accurately represent overall disseminated HGSOC biology and has implications for overinterpretation of studies relating to outcome and platinum-resistance.

**Disclosures** CF: advisory boards and honoraria from Roche, Tesaro, Sequana, Olympus, Astra Zeneca. Other authors have no disclosures to declare.

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**Abstracts**

**550 NOVEL 3D MODEL SYSTEMS TO ASSESS HETEROGENEITY IN RESPONSE TO PLATINUM THERAPY IN HIGH GRADE SEROUS OVARIAN CANCER**

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10.1136/ijgc-2020-ESGO.172

**Introduction/Background** High-grade serous ovarian cancer (HGSOC) is the most common subtype of ovarian cancer, characterised by vast genomic instability and heterogeneity and acquired resistance to platinum-based chemotherapy. However, matching the most beneficial treatment options to patients is difficult to predict due to different platinum resistance mechanisms and limited effective predictive biomarkers. A study characterising intra-tumoural heterogeneity in HGSOC has identified variations in phenotypic responses to platinum treatment between different metastatic sites. In this study, we aim to develop novel clinically-relevant 3D ex-vivo models of HGSOC to investigate the effect of the local microenvironment on metastatic tumour cells’ response to treatment, and potential use as a screening tool to predict drug responses.

**Methodology** Three different ex-vivo models were developed: organotypic, organoid and tumour slice. For organotypic and organoid models, tumour cells were extracted from metastatic deposits obtained from defined anatomical regions during upfront radical debulking surgery of advanced stage HGSOC patients. Organotypic models were assembled using normal omental stromal cells embedded in Collagen-1 and tumour cells were added. Organoid models were propagated from tumour cells and embedded in basement membrane extract. For slice culture models, tumours were sliced into 350 μm sections using a vibratome and cultured on cell culture inserts. All models were treated with cisplatin and assessed for apoptosis and viability readouts.

**Results** Organotypic models showed that tumour cells cultured in 3D showed heterogeneity in response to cisplatin treatment, data showed a trend towards reduced response to treatment within 3D models compared to 2D (n=8). Changes in patterns of response to treatment between samples from 2D to 3D within the same patient was also demonstrated (n=5). Organoid models were successfully propagated from different metastatic sites and maintained long term growth (>15 passages). Histological read-outs for slice culture models demonstrated slices from different metastatic sites maintained viability in culture for up to 5 days.

**Conclusion** We have established growth, drug treatment conditions and assay read-outs for 3 different ex-vivo models of metastatic HGSOC. We have established that organoid culture must be generated within 24 hours of tumour cell extraction. Furthermore, both fresh and viable frozen tumours can be used to generate organotypic and organoid models. The broader implication of establishing clinically-relevant complex tumour models as routine methodologies for screening novel therapeutics and capturing the complex heterogeneity of individual patients, may lead to better development of therapeutic strategies including tumour/microenvironment combination strategies and also better personalisation of therapy for patients with HGSOC.

**Disclosures** CF: advisory boards and honoraria from Roche, Tesaro, Sequana, Olympus, Astra Zeneca. Other authors have no disclosures to declare.

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**393 A CLINICAL AUDIT OF MOLAR PREGNANCIES AND GESTATIONAL TROPHOBLASTIC NEOPLASIA CASES OVER 1YR IN A TERTIARY CARE HOSPITAL OF EASTERN INDIA WITH RESPECT TO THE INCIDENCE OF DISEASE, FACTORS RELATED TO ETIOPATHOGENESIS, DIAGNOSIS AND MANAGEMENT**

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10.1136/ijgc-2020-ESGO.173

**Introduction/Background** A Clinical Audit of molar pregnancies and gestational trophoblastic neoplasia cases over 1yr was conducted at Kolkata Medical College & Hospital, a tertiary care hospital of Eastern India with respect to the incidence of disease, factors related to etiopathogenesis, diagnosis and management and effects on maternal morbidity and mortality.

**Methodology** A total of 10000 patients attended this institution during 2017 June to 2018 June for pregnancy or its complication in department of gynaecology & obstetrics. 85 molar...
pregnancies and their sequelae were followed up in medical oncology. The data was collected from out patient & in patient tickets & admission registrars and was analysed by descriptive statistics.

**Results** Most cases were seen amongst the second gravida 40%, Hindus 53.3%, low socio-economic strata 72%. Predominant Blood group was B 53%. Hemoglobin below 10 mg/dl was seen in 94%. 21.33% of patients had haemoglobing was below 6 gm/dl. Most of the patients of Hydatiform Mole (50%) were diagnosed within a period of ammenorrhea of 8–12 weeks with 70% of cases diagnosed with amenorrhea of less than 16 weeks. 18% of patients were diagnosed after a period of amenorrhoea of greater than 20 weeks. The most common presenting symptom in cases of Hydatiform Mole was bleeding per vagina 74%. Features of Hyperthyroidism & respiratory distress were seen in 5% of patients. The most common signs were pallor 65%, pre-eclampsia were seen in 17.33% of patients.

Suction & evacuation 58.66% with Oxytocin infusion was the predominant mode of management in cases of Hydatiform Mole. Ligation was done in one patient considering the risk of repeat molar pregnancy in future conception.

Modes of diagnosis were clinical (74%), & USG in 68%.

Persistent Gestational Trophoblastic Disease and Choriocarcinoma were diagnosed during follow up by symptoms of irregular bleeding P/V, elevated beta HCG titre and abnormal USG pelvis and chest X-Ray.

Chemotherapy was the predominant mode of treatment of GTT. Hysterectomy was done in 2 patients of Invasive mole.

Single agent chemotherapy with Methotrexate in 20 patients 83.33% i.e low risk GTT. EMA-Co regimen was the preferred multiagent chemotherapy used in 4 patients 18% (upfront) and in 2 patients progressing on methotrexate, surgery in 1 patient not responding to EMACO or EMA-EP.

Toxicity of chemotherapy was predominantly, Nausea & vomiting (38.89%) mucositis (27.78%). Hepatotoxicity and infection was seen in 11.11% of patients. Grade 3/Grade 4 toxicity was nil.

**Conclusion** Though the proportion of molar pregnancies & gestational trophoblastic neoplasia is not much in comparison to the heavy attendees in the gynaecology and obstetrics OPD but they represent a highly curable one with minimally intense chemotherapy thus avoiding unnecessary hospital stay due to chemotoxicity.

**Disclosure** I do not have any conflict of interest with any person or organization.

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Seven months after treatment, she remains alive and well, with ongoing regular follow-ups. The importance of keeping a high index of suspicion in patients with a prior molar pregnancy who only have clinical presentations referable to metastatic sites to avoid delay in the diagnosis and treatment; as well as the curability of widespread disease with aggressive combined treatment modalities, is emphasized herein (figure 1 and 2).

Methodology NA
Results NA
Conclusion Cutaneous metastases in gestational CC is infrequent and one of its diverse atypical clinical manifestations that has the potential to delay diagnosis and affect the clinical outcome. It is also associated with disseminated disease. Nevertheless, remission through aggressive multi-modal therapeutic strategies like Etoposide-Cisplatin induction chemotherapy, high-dose EMACO with concurrent whole brain irradiation, and regular EMACO is still possible for Stage IV multi-metastatic gestational CC patients who have late presentations and already have advanced disease, as documented in the index case. Prompt identification and vigorous treatment as keys to ensure better prognosis in gestational CC is stressed.

Disclosures N/A
LONG TERM FOLLOW UP AFTER DIAGNOSIS OF GESTATIONAL TROPHOBLASTIC DISEASE

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Introduction/Background The spectrum of Gestational trophoblastic disease (GTD) ranges from pre-malignant conditions of complete (CHM) and partial (PHM) hydatidiform moles to the malignant invasive mole, choriocarcinoma (CC) and very rare placental site trophoblastic tumour/epithelioid trophoblastic tumour (PSTT/ETT). Gestational trophoblastic neoplasia (GTN) are highly responsive to chemotherapy (CT) and with appropriate diagnosis and management a high cure rate (>90%) is observed. In this study we reviewed the outcomes of long term follow up for GTN patients (pts) treated in our centre.

Methodology Update of outcomes (clinical records and phone contacts) of patients with GTN tumours treated in our centre between January 2005-December 2014.

Results Twenty three GTD pts between 2005–2014: 2 PHM (9%) and 9 CHM (39%), 8 CC (35%), 2 ETT (9%) and 2 PSTT (9%). Median age at diagnosis: 37 years (20–53). Staging: 12 stage I (52%), 9 stage III (39%) and 2 stage IV (9%). Most patients received CT as first treatment (20; 87%), according to prognostic risk score: 10 with metotrexate (MTX) monotherapy (50%) and 10 with EMA-CO (50%). Resistance to first line CT was observed in 5 patients (22%), 2 after MTX monotherapy and 3 after EMA-CO. For those pts, 2nd line CT was as follows: 1- ACT-D; 1 -EMA-CO (after MTX monotherapy) and 3-EMA-EP (after EMA-CO). Surgery was performed in 9 pts: 6 because of residual disease after CT and in 3 cases as the only treatment (1 patient with ETT and 2 patients with PSTT). One patient without criteria for treatment underwent clinical surveillance. Treatment related adverse reactions- Significant CT toxicity was observed in 2 pts (1-pneumonitis, 1- sarcoidosis), both with clinical resolution after specific care. One pt complained of late surgical sequelae (adhesions) and still hasn’t recovered. After a median follow up of 69 months, 2 patients died: 1 due to a second malignancy (glioblastoma), 1- due to acute respiratory failure (extensive lung metastasis in previous chronic lung disease). Five patients maintain FU at our centre and 17 were either referred to their primary care physician (9) or were lost to follow up (7). Second neoplasm was observed in 3 pts:1-glioblastoma, 1- thyroid papillary carcinoma, and 1- gallbladder polyps.

Conclusion GTD is a rare diagnosis and duration of follow is controversial. Our data suggests that prompt management of serious CT adverse reactions is important to prevent the late term impact of CT toxicities. Second neoplasm in survivors of GTD deserve further study.

Disclosures No disclosures to report.

Vaginal and vulvar cancer

CONTRALATERAL NON-SENTINEL NODE METASTASIS IN EARLY PRIMARY VULVAR CANCER WOMEN WITH POSITIVE UNILATERAL SENTINEL NODE

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Introduction/Background Since the introduction of the S2K AWMF guideline-based sentinel node biopsy technique in unifocal vulvar cancer (diameter of <4 cm) and unsuspicious groin lymph nodes, the morbidity rate of patients has significantly decreased in Germany. The groin recurrence rate after IFL is vary from 0% to 5.8%, in contrast to 2.3% (95% CI, 0.6% to 5%) in unifocal vulvar cancer vs 3% (95% CI, 1% to 6%) in multifocal vulvar cancer after SLNB only, as suggested in the GRoningen IInternational Study on Sentinel node in Vulvar cancer (GROINSS-V-V) in 2008. Current guidelines suggest that in cases of metastasis of unilateral sentinel lymph node (SLN) biopsy (B), groin node dissection, namely inguinosferominal lymphadenectomy (IFL), should be performed bilaterally. However, a publication by Woelber et al. in Germany and and Nica et al. in Canada contradicted the current guideline indication for bilateral IFL in case of unilateral SLNB metastasis.

Methodology Our research study consisted of a single-center analysis from the Department of Obstetrics and Gynecology in the University Hospital of Dusseldorf, evaluating vulvar cancer patients treated with SLNB retrospectively from 2002 to 2018.

Results

1. Twelve women (n=12/30; 40%) had ipsilateral IFL only, in accordance with patient desire to avoid morbidity and/or old age. Only one woman was diagnosed having positive metastatic IFL and 11 women were negative IFL.

2. Eighteen women (n=18/30; 60%) who received complete bilateral IFL were further divided into three subgroups:
   A. Thirteen women (n=13/30; 43.4%) had negative IFL results in both groins.
   B. One woman (n=1/30; 3.3%) had ipsilateral IFL metastasis.
   C. Four women (n=4/30; 13.3%) had contralateral IFL groin metastasis after unilateral SLNB metastasis initially.

Conclusion The depth of tumor cells infiltration is a significant factor in the prediction of contralateral metastasis (p=0.0038). According to our study results, radical bilateral IFL should be offered in treatment management of early primary vulvar cancer with anterior midline lesion and unilateral SLNB metastasis. However, the need for radical bilateral IFL in cases of localized tumor with positive ipsilateral SLNB should be further evaluated.

Disclosures The authors declare that there is no conflict of interest regarding the publication of this article. None of the authors received any funding for this study. This study is purely for scientific use and aimed to provide suggestions for current clinical guidelines and future research.
coverage. With the help of additive technologies, 3D-printed applicators can be tailored to the patient's tumour and anatomy.

**Methodology** In this report two cases of gynaecological cancer, one vaginal and one recurrent endometrial cancer are presented. The design of the applicator was based on MRI images of the patient with the standard Varian vaginal cylinder inserted. Parallel and oblique needles were virtually added to the planning system to get the best possible coverage of the tumour while respecting the dose constraints to the organs at risk (OARs). Individual applicators were made from biocompatible polyamide PA 12 with selective laser sintering (SLS) technology (figure 1). The next BT was performed with an individual applicator in situ. Rectal ultrasound was used for needle guidance. The dose-volume histogram (DVH) parameters for each patient were compared according to the planning aims. The planning aim for D90 high-risk clinical target volume (CTV-THR) was to reach physical dose >20.5 Gy per one BT fraction delivered in 24 pulses of pulsed dose rate (PDR) BT.

**Results** The DVH parameters for both cases per one BT fraction are presented in table 1. The procedure and the implantation of the needles was performed without complications in regional anaesthesia. The applicator was well tolerated, no adverse effect was reported during the treatment or removal of the applicator.

**Conclusion** The advantages of using an individually-designed multi-channel vaginal applicator are:

- better target coverage in advanced tumours extended in the vagina
- can be used in a narrow vagina
- implantation guidance of several oblique and parallel needles can be performed with minimized trauma to the surrounding tissue
- allows for the treatment of several tumour locations in the same BT fraction

**Disclosures** Helena Barbara Zobec Logar, Robert Hudej and Manja Kobav have nothing to disclose.
256 DIFFERENCES IN IMMUNE-RELATED ADVERSE EVENTS BETWEEN VULVOVAGINAL VS. CUTANEOUS MELANOMA: A RETROSPECTIVE COHORT STUDY

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10.1136/ijgc-2020-ESGO.180

Introduction/Background Few studies to date have comprehensively examined all immune-related adverse events (irAEs) in vulvovaginal and cutaneous melanoma patients on immune checkpoint inhibitors (ICIs).

Methodology We retrospectively analyzed 169 patients with advanced-stage vulvovaginal or cutaneous melanoma who received at least one dose of ICI between June 2012 to December 2018. Descriptive statistics were used to summarize the baseline characteristics, disease outcomes, and toxicity profiles. Chi-square statistical analysis was used to examine associations between irAEs and pre-existing conditions, as well as irAEs and treatment response. P-values <0.05 were considered statistically significant.

Results Overall, 53.8% of patients with vulvovaginal melanoma developed irAEs, compared to a similar percentage of 51.9% for patients with cutaneous melanoma. Yet the most common types of irAEs differed between patients. The most common irAEs for patients with vulvovaginal melanoma were gastrointestinal disorders (44.4%), hypothyroidism (22.2%), and renal and urinary disorders (22.2%). On the other hand, the most common irAEs for patients with cutaneous melanoma on ICIs were gastrointestinal disorders (21.7%), cutaneous adverse events (17.9%) and pneumonitis (18.75%). Cutaneous adverse events were overall the most common irAEs, and were significantly associated with patient response to ICIs (p = 0.01).

Conclusion Nuanced differences in the clinical presentation of irAEs in patients with vulvovaginal vs. cutaneous melanoma are important considerations for initiating ICIs in accordance with melanoma type. Furthermore, cutaneous adverse events were the most common irAEs overall, and were significantly associated with response to ICIs in patients with metastatic melanoma.

Disclosures I have no conflicts of interest.

282 THE EFFICACY OF FIBRIN SEALANTS IN REDUCING THE POST-OPERATIVE MORBIDITY AFTER INGUINO-FEMORAL LYMPHADENECTOMY IN MELANOMA AND VULVAL CANCER: BACK TO THE DRAWING BOARD?

Anastasios Tranoulis, Dimitra Georgiou, Bindiya Gupta, Omer Devaja, Stephen Attard-Montalto, Montalto. The Pan-Birmingham Gynaecological Oncology Centre, Sandwell and West Birmingham NHS Trust, Birmingham; Chelsea and Westminster NHS Foundation Trust, Imperial College; The Pan-Birmingham Gynaecological Oncology Centre, City Hospital; Panbirmingham Gynaecological Cancer Centre, Birmingham City Hospital; Gynaecological Oncology, Maidstone and Tunbridge Wells NHS Trust, Maidstone, UK

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Introduction/Background The inguino-femoral lymphadenectomy (IFL) and its associated morbidity remains to date a field of contention. Several intra-operative techniques have been advocated to intimidate the IFL-related complications. Despite the improvements in the IFL technique, apprehension towards operative complications still exists. The intra-operative application of collagen-fibrin sealants (CFS) has emerged as a promising intervention to reduce the IFL-related lymphorrhoea. To ascertain the clinical utility of CFS during IFL, we performed a meta-analysis to draw conclusions about their efficacy with the primary objective of reducing the volume and the duration of lymphatic drainage. A secondary objective was to elucidate its effectiveness in reducing other wound complications.

Methodology MEDLINE, Scopus and Cochrane Database were searched for relevant references from inception until August 2020 in line with PRISMA guidelines. Randomized controlled studies (RCTs) and observational studies (OSs) comparing the post-operative morbidity after IFL with or without the use of CFS were included. The modified Jadad score and the methodologic index for non-randomized studies were used to evaluate the quality of the included studies. Dichotomous variables were assessed using odds ratio (OR), whilst continuous variables were assessed using the standardised mean difference (SMD). Confidence intervals were set at 95%. The DerSimonian-Laird random-effects model was used due to the expected inter-study heterogeneity. Statistical analysis was performed using the RevMan software version 5.3. The level of statistical significance was set at p-value < 0.05.

Results Six RCTs and four OSs encompassing 305 and 221 patients respectively were included. The studies were of moderate quality and characterised by significant clinical heterogeneity. The meta-analysis of RCTs demonstrated that the application of CFS did neither decrease the length of drainage [SDM -0.55 (95% CI -1.34 to 0.23), p=0.17] nor the amount of drained output [SMD 0.46 (95% CI -0.29 to 1.20), p=0.23]. No significant difference was found regarding the incidence of lymphocele(s) formation [OR 0.96 (95% CI 0.56 – 1.65), p=0.88] or other wound complications. The safety profile of CFS was favourable. No severe adverse sequelae were reported.

Conclusion Our findings suggest that the use of CFS was not associated with difference in the incidence of IFL-related lymphorrhoea. Their safety profile was favourable. This evidence is constrained by the data available with an inevitable emphasis on short-term outcomes. In view of the lack of clinical equipoise, more high quality RCTs are warranted to draw firmer conclusions. An attempt should be made at standardising outcome measures, which will improve comparability between studies.

Disclosures None.

451 ROBOTIC INGUINOFEOMORAL GROIN NODE DISSECTION – MODIFICATIONS TO EXISTING ROBOTIC TECHNIQUE

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Introduction/Background Techniques to improve problems encountered during robotic Inguino-femoral node dissection and prevent muscle miss during surgery

Methodology Identification of muscles in the anterior upper half of the thigh is of paramount importance for approaching femoral triangle and femoral blood vessels. Sartorius and Vastus medialis are almost in the same spot in the anterior middle third of the thigh during dissection. Problems encountered in the initial five robotic groin node dissections with regards to anatomical muscle miss were addressed by
rearranging the position of the ports and bringing them closer to the tip of the femoral triangle. A 30 degree telescope helped in visualising the tip of the triangle better to remove the nodal tissue en bloc at completion of surgery.

Results Improved techniques led to easy identification of sartorius and standardization of the procedure.

Conclusion Issues and tips for improvement in surgical techniques especially in novel areas like robotic Inguino-femoral node dissection surgery are addressed.

Disclosures This surgical video was presented at IGCS Conference 2019.

INTRODUCTION ELECTRO-CHEMOTHERAPY (ECT) WITH BLEOMYCIN FOR PALLIATION OF CUTANEOUS RECURRENCE IN GYNECOLOGICAL MALIGNANCY

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Introduction/Background ECT utilises pulsed electrical current to transiently increase cell membrane permeability to the cytotoxic agent, bleomycin. We present the use of ECT in patients with recurrent gynaecological malignancy previously treated with a combination of surgery or radiotherapy, experiencing symptoms from cutaneous lesions. This report presents evidence of the role for ECT in second and third line treatment.

Methodology Between July 2017 and August 2019, 6 patients with cutaneous recurrence of gynaecological malignancy (3 vulvar SCC and 1 high grade serous ovarian cancer) were treated with intra-tumoural bleomycin (9000 iu or 15000 iu, dependent on tumour volume) and pulsed-probe electropropagation. Response was assessed clinically in routine follow up or post procedure pain scores were collated as part of the quality of life evaluation.

Results Median treated tumour diameter was 6 cm (range 2 – 12 cm). Pain scores peaked between day 2 and day 7 post-procedure. The median progression free interval was 3.6 months (range 0.8 – 6.7 months).

Following ECT treatment 2 patients continued to receive supportive care. Two patients underwent repeat treatment with ECT and reported symptom improvement with each treatment. Due to further progression two patients underwent radical surgery and one patient received palliative chemotherapy.

Conclusion ECT should be considered for patients with symptomatic cutaneous recurrence of gynaecological malignancy who have previously had multi-modal treatment. It can achieve symptom control and reduce the need for radical surgery in this palliative setting.

Disclosures The Authors have no conflicts of interest to disclose.

NEW VARIANT OF RECONSTRUCTIVE SURGERY FOR ADVANCED VULVAR CANCER TREATMENT

1Olha Bubliieva, 2Yevgeniy Kostuchenko, 3Igor Motuziuk, 3Valentyn Svintsitskiy, 1Sergiy Nespryadko, 1Alena Samokhvalova, 3Oleg Sydorchuk, 1National Cancer Institute; 2National Cancer Institute; D.O. Bogomolets National Medical University, 3D.O. Bogomolets National Medical University.

Introduction/Background Surgical treatment of advanced vulvar malignant tumors usually requires immediate reconstruction. Large defects after pelvis, vagina, vulva, groin and perineum wide excision require closure with the usage of difficult reconstructive techniques. In this case the most suitable myocutaneous flap for reconstruction is rectus abdominis muscle flap, which provides the biggest volume of tissues to cover those large defects.

Methodology Woman 67 y.o. initially presented with the combined treatment of cervical cancer stage IIIB. Within 5 month was diagnosed the lymphedema in the left lower extremity. Approximately 2 years she presented the vulvar tumor measured 15 × 10 cm. A biopsy was performed the lymphangiosarcoma.

Results In the National Cancer Institute of Ukraine we investigated a new variation of large defects reconstruction using rectus abdominis muscle flap. To collect a donor flap, we perform 3 arcuate incisions: one vertical by the medial line around the umbilicus, and two oblique incisions towards upper anterior iliac spine of one of the sides. In this way we use only one half of the abdomen, and in case of any complications with the flap or relapse of the disease we will have the second donor site for possible future re-operation. There is a narrow ‘bridge’ of tissues we leave between the excised donor and recipient sites. It is extremely important to preserve blood supply not only to the flap, but also to the ‘bridge’ to avoid complications. We perform a tunnel under the ‘bridge’ as small as possible to preserve all inferior epigastric vessels, but enough to transfer the flap and not to squeeze the pedicle. After the surgery we have a half-inverted Y-shaped scar on the sides of the abdomen, an inverted triangular scar at the pelvis area, circumumbilical scar and a short vertical scar on the flap to imitate pudendal cleft with central structures of vulva (urethra and vaginal tube).

Conclusion We consider our variation of this type of surgery the most safe and efficient, with the opportunity of re-operation if needed. Advanced vulvar malignancies are quite rare, so we will keep working on development and enhancement of the technique to help these patients.

Disclosures Authors declare no disclosures.
Results We presented two types of vulvar reconstructions at the time of primary treatment, using different types of flaps: medial thigh flap and rectus abdominal muscle flap. The histological types of tumors were vulvar squamous cell carcinoma and lymphangiosarcoma. The operation time was 320 and 420 minutes, the blood loss – 200 ml and 350 ml, the length of hospitalization was 12 and 14 days respectively. Both of patients suffered pain before surgery, and were relived after. There were no postoperative complications. None of patients had flap loss.

Conclusion The use of skin flap for reconstruction in treatment of advanced vulvar cancer can improve functional status. It is associated with the low rate of postoperative complications and decreasing pain, which significantly better the women’s quality of life.

Disclosures Authors declare no disclosures.
Impact of Tumour-Free Margin and Lymph Node Risk Factors Affecting Oncologic Outcomes in Vulvar Cancer - A Single Institute Experience

Chirnmooye Kalita, Shruti Bhatia, Renuka Gupta. Action Cancer Hospital; Gynaecological Oncology

Introduction/Background Vulvar cancers account for 3–5% of all gynaecological malignancies. Inguinal lymph node involvement and tumour-free margin are considered as significant prognostic factors for survival in patients with vulvar cancer. Surgery is the cornerstone of treatment. Lymph node ratio (LNR) is the ratio of the number of positive lymph nodes (LN) to the number of removed LN. This parameter incorporates not only the burden of nodal disease and cancer spread but also the extent and quality of surgical staging. Current data in the literature regarding a minimum oncologically safe tumour-free margin distance are contradictory. The objective of this study was to evaluate the association of tumour-free margin and LNR with oncologic outcomes in vulvar cancer.

Methodology Retrospective analysis evaluating 21 patients of vulvar squamous cell cancer who underwent primary surgery at our institution from January 2013 to December 2018. Patients were stratified into three risk groups according to tumour-free margin (<5 mm, ≥5 mm - <8 mm and ≥8 mm) and LNR (0%, >0-<20% and >20%) to compare oncologic outcomes. Follow up was done till August 2019. Qualitative variables were correlated using Chi-Square test/Fisher’s exact test. Overall survival (OS), disease free survival (DFS) and recurrence rate (RR) were estimated by Kaplan-Meier analysis and survival was calculated using Kaplan-Meier method. Log rank test was used for comparison among the groups.

Results Median age was 67 years. Median DFS and OS were 17.4 months and 27.7 months respectively. 11 patients (52.4%) developed recurrence of which 8 had local recurrence. RR in tumour-free margin <5 mm group was high (100%) as compared to ≥5 mm - <8 mm (50%) and ≥8 mm (30%) groups (p=0.037). DFS rates at the end of the study were increasing from 0.0% (in <5 mm group) to 66.7% (in ≥8 mm group) and as well OS rates also (50% to 65.6%). At the end of the study DFS rates in patients with LNR 0%, >0-<20% and >20% were 57.1%, 22.5% and 0.0% respectively (p=0.047). On applying Log rank test no significant difference was seen in the OS between the different groups of LNR.

Conclusion Prognosis of vulvar cancer patient is affected by tumour-free margin and high LNR in our study. DFS is significantly reduced in patients with tumour-free margin <5 mm even in the absence of LN metastasis. High LNR is associated with unfavourable DFS. Tumour-free margin ≥8 mm is a good prognostic factor in patients of vulvar carcinoma.

Disclosures None.

RISK FACTORS AFFECTING ONCOLOGICAL OUTCOMES IN VULVAR CANCER UNDERGOING PRIMARY SURGERY: CASE SERIES FROM A TERTIARY CANCER CENTRE

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Introduction/Background To evaluate risk factors associated with adverse oncological outcomes in women undergoing primary surgery for vulvar cancer.

Methodology Eighty-one patients who underwent primary surgery for SCC vulva and were registered at tertiary cancer hospital between January 2011- December 2018 were analysed retrospectively. Adverse risk factors such as age, stage, tumour free margins (TFM), depth of stromal invasion (DSI) and lymph node status were analysed using univariate analysis and survival was calculated using Kaplan-Meier curves.

Results Median age was 55 years. All patients underwent either wide radical excision/radical vulvectomy. Groins were addressed in 63 patients. Median follow up was 42 months. Overall survival and DFS at 3 years were 82% and 69% respectively. On univariate analysis of 81 patients, DSI, TFM (<10 mm) and stage III> had statistically significant effect on DFS, whereas DSI and stage III> had statistically significant effect on overall survival. Age >60 years did not have significant effect on oncological outcomes.

Following surgery, based on final histology report, 63 patients remained within stage I/II, whereas 18 patients were upstaged to Stage III & above (Stage III>). Stage migration was mainly due to lymph node positivity on histology.

On subgroup analysis of 63 patients in good prognostic group (stage I/II), DFS and TFM had statistically significant adverse effects on DFS and OS. Overall survival at 3 years was 86% and DFS 78% in this subgroup.

Of 18 patients in poor prognostic subgroup (post-surgical stage III and above), 1 in 3 developed recurrence and 1 in 2 died of disease.

Conclusion There is a positive correlation of DSI and lymph-node metastasis, hence lymphadenectomy is proposed based on DSI subcategory in FIGO stage I. Our study found DSI as an independent risk factor which affects both DFS and overall survival in early stage vulvar cancer with negative lymph nodes.

Disclosures None.
PRIMARY IMIQUIMOD TREATMENT VERSUS SURGERY FOR VULVAR INTRAEPITHELIAL NEOPLASIA – PITVIN STUDY. BASELINE RESULTS OF A RANDOMIZED CLINICAL TRIAL


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Usual type vulvar intraepithelial neoplasia (VIN) has been shown to be effective, but has not been compared to surgery. The aim of this study was to compare the effectiveness and acceptance of primary imiquimod treatment with surgical treatment of HSIL/VIN.

Methodology: This was a multicentre randomised controlled trial of women with histologically confirmed HSIL/VIN II-III. Exclusion criteria were clinical suspicion of microinvasion, a history of vulvar cancer, severe dermatosis, pregnancy, and active treatment for VIN within the previous three months.

Patients were randomized to primary topical treatment or surgery at a ratio of 1:1 and stratified by unifocal or multifocal disease. Treatment with imiquimod was self-administered for a period of 4 months with possible extension. Surgical treatment was performed according to the standard procedures of the trial site. Clinical assessment, colposcopy, vulvar punch-biopsy and HPV-test (cobas®, Roche) were performed at baseline and 6 months. Clinical follow-up, including questionnaires on health-related quality-of-life, was conducted at 12 months.

Results: Between June 2013 and January 2020 a total of 110 patients were enrolled at six hospitals in Austria. Mean age was 51 years (SD 16, range 19-82) with 57% being postmenopausal. 66 patients (61%) had a history of previous HPV related anogenital HSIL or genital warts, and 21 women (19%) had received previous treatment for VIN. 85 women (78%) presented with unifocal and 24 (22%) with multifocal VIN, and 56 women (51%) reported local symptoms. 40 women (37%) had a history of current or past smoking. 56 women were allocated to primary treatment with imiquimod, and 54 women to primary surgery. Surgical treatment was performed by local excision in 22 cases (14 cold-knife, 6 electro-surgical), by laser destruction (n= 27), or combined (n=3). 12-months follow-up will be completed in January 2021.

Conclusion: The results of this clinical trial will show whether imiquimod is a safe and effective alternative to surgery in women with HSIL/VIN-2-3.

Disclosures: The study was funded by the Austrian Science Fund (FWF) and the Austrian Association for Gynecologic Oncology (AGO). The study medication Aldara 5% cream was provided by Meda Pharma GmbH. The authors have no conflict of interest.

Organization of gynaecological cancer care

IMPLEMENTATION, PRACTISE AND EXPERIENCES OF AN INTERNATIONAL ONLINE MULTIDISCIPLINARY TUMOUR BOARD (IMDTB) WITH A CANCER CENTRE IN NORTHWEST REGION OF CAMEROON


Introduction/Background: Multidisciplinary tumour boards (MDTBs) are universally recommended. Nevertheless access to MDTBs, especially in low-income countries and rural areas, is limited. In order to gain insight in its effectiveness and in its impact on quality of cancer care this study has been performed on the international multidisciplinary (video-) online tumour board (iMDTB) established by Camofmedics e.V. and its partners Mephida e.V. and Global Health Catalyst Summit @ Harvard with a cancer centre in northwest region of Cameroon, the Mbingo Baptist Hospital.

Methodology: Patient’s data of all cases of 2019 of the Camofmedics-iMDTB have been collected and evaluated in regard of disease, age, sex, stage, recommendation and level of available care.

Furthermore an online survey among participants of the Camofmedics-iMDTB on their practises, experiences and satisfaction with the iMDTB has been undertaken.

Results: International multidisciplinary tumour board was scheduled monthly with online video meeting times of 60 to 90 mins. In 2019 during 12 meetings 95 tumour cases had been discussed. The majority of patients (75%) were female. 24% of all tumour cases were breast cancer followed by cervical cancer with 10%. Remarkably anorectal carcinomas and sarcomas occurred with a percentage of 7-8% each. Furthermore three women out of 72 suffered from high risk trophoblastic tumours.

66% of cases could be presented with a proper TNM-classification. More than half of these patients were already in a late stage of their disease (extended, metastatic or high risk). Pathology results were limited to microscopy for most cases. Additional diagnostics (such as hormone receptor status, HER2neu status) were available only in a minority of the cases. Treatment plans had been changed in up to 50% of cases.

The tumour board members describe their experience with the online conferences, data and documentation quality as satisfactory.

Conclusion: The iMDTB of Camofmedics is a helpful and effective way to improve cancer care in low income countries and rural areas such as the northwest region of Cameroon. The tumour board’s success very much depends on the charitable attendance of its specialists and the local (human) resources for time consuming preparation. Main challenges remain foremost the patients’ ability to afford expensive cancer care.
diagnostics and therapies, local availability of medical, surgical and radiological treatment as well as a stable online video connection. The iMDTB has a significant impact not only on multidisciplinarity of cancer management in the cooperating institutions but also on social values and education of the participants.

Disclosures None.

139 CENTRE OF HEREDITARY BREAST AND OVARIAN CANCER AT CHARITÉ – WHO PRESENTS FOR COUNSELING AND WHY?

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Introduction/Background Since the discovery of the BRCA-genes the knowledge about genetic risk factors for breast and ovarian cancer has multiplied. About 5–10% of all breast cancers and 15–20% of all ovarian cancers are caused by pathogenic mutations in different risk genes. Therefore, the Centre of Hereditary Breast and Ovarian Cancer at Charité offers as one of 20 centres in Germany genetic counseling. The extensive data of the counselees was now evaluated for the first time. The aim of this study was to ease the preparation for counseling sessions and gather information for more individualized counseling.

Methodology Data from 2531 counselees at the Charité-Centre from 2016 and 2017 were evaluated retrospectively. Special emphasis was laid on sociodemographic data and the results of genetic testing. Finally, the mutation frequencies were analyzed in different subgroups.

Results The 2531 counselees were almost exclusively female (n = 2493; 98.5%), 42.9 years old on average and came to the centre for the first time (n = 2198; 86.8%). 2287 (90.4%) counselees met the inclusion criteria for genetic testing. Of these, 863 (37.7%) were already diagnosed with breast or ovarian cancer. 1367 (59.8%) were genetically tested, 918 (67.2%) as index patients and 449 (32.8%) predictively. Mutations were detected in 545 (39.9%) tested persons. Most mutations were detected in BRCA1, BRCA2, CHEK2 and ATM. The highest mutation frequency was found among persons from families with both breast and ovarian cancer and in patients with TNBC. A significant correlation was found between mutation frequency in TNBC and age at first diagnosis (figure 1).

Conclusion In summary, the collective of counselees at the Charité- Center was described for the first time. The results provide doctors with a comprehensive overview of the counselees, enabling by that an even more individualized counseling and more focused preparation for the consultation.

The findings contribute to maintaining the high quality of the genetic counseling at the Centre for Familial Breast and Ovarian Cancer at the Charité (table 1).

Disclosures No conflict of interest.

Abstract 139 Table 1 Cancer specifics and age at first diagnosis

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>n=2287 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant tumor disease</td>
<td></td>
</tr>
<tr>
<td>No tumor</td>
<td>1387 (60.6%)</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>787 (34.4%)</td>
</tr>
<tr>
<td>ER/PR/HER2-positive</td>
<td>562 (24.6%)</td>
</tr>
<tr>
<td>Triple-negative</td>
<td>190 (7.9%)</td>
</tr>
<tr>
<td>DCIS</td>
<td>41 (1.8%)</td>
</tr>
<tr>
<td>male breast cancer</td>
<td>4 (0.2%)</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>76 (3.3%)</td>
</tr>
<tr>
<td>Other malignest tumor disease</td>
<td>37 (1.6%)</td>
</tr>
<tr>
<td>Age at first diagnosis, mean in years</td>
<td></td>
</tr>
<tr>
<td>Breast cancer</td>
<td>44.4 (24.83 years)</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>56.8 (17.75 years)</td>
</tr>
</tbody>
</table>

Abstract 139 Figure 1 Flow chart of the results of the genetic testing

241 WHEN MDT INTERDISCIPLINARITY ENHANCES STRINGENCY AND PROFESSIONAL QUALITY; AN ANALYSIS OF MULTI-DISCIPLINARY TEAM CONFERENCES

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10.1136/ijgc-2020-ESGO.193

Introduction/Background In 2016 the Danish Multidisciplinary Cancer Group’s (DMCG) national Multidisciplinary Team (MDT) working committee established recommended quality standards in Danish healthcare.

This current study investigates the status of implementation of the guideline published in 2016 amongst the clinicians who
now manages and carry out the developed guideline at the MDT conference. The aims are to identify challenges and successful initiatives based on individual experiences and to point out areas of development within the MDT conference.

Methodology The study is conducted as a social scientific questionnaire using the complexity theoretic model by Ralph Stacey, designed using MSC (Most Significant Change technique) which focus on development and dynamics in organizations that are constantly and rapidly changing. 618 participants were identified and invited by either their own MDT leader or by a contact person appointed by the chairman of the cancer group.

Results Answers were calculated using selective coding resulting in themes leading to the following outcome: The MDT conference is a well-established part of clinical practice, and are perceived as significant, qualified and qualifying; Measures that can further qualify the conference decision include more time for the task; A spinoff effect is identified on the conference participants’ social and professional relationship, which are developed, valued and supported in relation to the meetings.

Conclusion Multiple opportunities for improvement and future development potentials are presented in this article.

Disclosures The authors have nothing to disclose. ICMJE forms signed.

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Abstracts

334 TESTING PREDICTION ACCURACY OF IDEAL AND PROLONGED LENGTH OF HOSPITAL STAY FOLLOWING OVARIAN CANCER CYTOREDUCTION USING MACHINE LEARNING METHODS

1Alexandros Laios, 2Camilo De Lelis Medeiros-de-Moras, 1Yong Tan, 3Gwendolyn Saalmink, 1Mohamed Otify, 1Amudha Thangavelu, 1Richard Hutson, 1David Nugent, 4Kassio Michell Gomes de Lima, 1George Theophilou. 1St James’s University Hospital; Teaching Hospitals; Gynaecologic Oncology; School of Pharmacy and Biomedical Science; University of Central Lancashire; 2St James’s University Hospital; Research and Innovation Centre; 4Federal University of Rio Grande Do Norte; Chemistry

Introduction/Background Cytoreductive surgery for advanced high grade serous ovarian cancer (HGSOC) patients to achieve complete removal of all visible disease often requires prolonged surgical time and possible multi-visceral resection potentially necessitating HDU support and prolonged hospitalisation. Length of stay (LOS) has been suggested as a marker of quality or effectiveness of short-term care. Identifying modifiable risk factors at admission predicting LOS could lead to appropriately targeted interventions to improve the delivery of care. Modern data mining technologies such as Machine Learning (ML) could be helpful in monitoring hospital stays to improve standards of care. We aimed to improve the accuracy of predicting both ideal and prolonged LOS, by use of ML algorithms.

Methodology A cohort of 176 HGSOC patients, who underwent surgical cytoreduction, from Jan 2014 to Dec 2017 was selected from the ovarian database. They were randomly assigned to ‘training’ and ‘test’ subcohorts. ML methods including Linear Discriminant Analysis (LDA), Support Vector Machine (SVM), Decision-Tree-Analysis, and K-Nearest Neighbors were employed to derive predictive information for LOS from selected variables including age, BMI, Surgical Complexity Score (SCS), operative time, preoperative albumin and morbidity score (Clavien-Dindo 3–5). These methods were tested against conventional linear regression. The accepted ‘ideal’ LOS was deemed to be 5 days or fewer. Prolonged LOS was defined as time spent in the hospital beyond the 90th percentile. Through the introduction of the Enhanced Recovery after Surgery (ERAS) pathway in 2015, effort was made to shorten the LOS for patients following major surgery, whilst still assuring they received effective treatment and high-quality care.

Results Mean and median LOS was 4.6 and 4.0 days (IQR 0–38), respectively. The delayed LOS group consisted those staying 10 days or longer. The rate of ideal LOS continuously improved for every year from 32% in 2016 to 73.5% in 2019 despite increasing mean SCS. For ideal LOS prediction accuracy, ML slightly outperformed conventional logistic regression, with no bowel resection and operative time been the most predictive variables. For prolonged LOS, LDA and SVM were more accurate to predict prolonged LOS than conventional regression. Bowel resection and Clavien-Dindo complications were most importantly contributing to the improved accuracy of the model (figure 1).

Conclusion Predictive ML algorithms may facilitate quality improvement of modern care by improving prediction accuracy for ideal and prolonged LOS. They more accurately identify potentially modifiable factors delaying hospital discharge, which may further inform services performing root cause analysis of LOS.

Disclosures No disclosures.

Abstract 334 Figure 1
TESTING PREDICTION ACCURACY OF HDU ADMISSION FOLLOWING HIGH GRADE SEROUS ADVANCED OVARIAN CANCER CYTOREDUCTIVE SURGERY USING MACHINE LEARNING METHODS

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Introduction/Background Advanced high grade serous ovarian cancer patients (HGSOC) frequently require extensive procedures including bowel resections and upper abdominal surgery potentially necessitating HDU/ICU support and prolonged hospitalisation. HDU/ICU admission is a measurable outcome that can be used as a benchmark of surgical care. Modern data mining technologies such as Machine Learning (ML), a subfield of Artificial Intelligence, could be helpful in monitoring HDU/ICU admissions to improve standards of care. We aimed to improve the accuracy of predicting HDU admission in that cohort of patients by use of ML algorithms.

Methodology A cohort of 176 HGSOC patients, who underwent surgical cytoreduction from Jan 2014 to Dec 2017 was selected from the ovarian database. They were randomly assigned to ‘training’ and ‘test’ subcohorts. ML methods including Classification and Regression Trees (CART) and Support Vector Machine (SVM), were employed to derive predictive information for HDU/ICU admission from a list of selected preoperative, intraoperative, and postoperative variables. These methods were tested against conventional linear regression analyses.

Results There were 29 out of 176 (16.4%) HDU/ICU admissions; 23 admissions were elective whilst six were unplanned admissions. For the outcome of HDU/ICU admission, both ML methods outperformed conventional regression by far (table 1). Bowel resection and operative time were the most predictive variables (figure 1). HDU/ICU admission was not associated with increased length of stay, increased number of postoperative complications, and increased risk of readmission within 30 days.

Conclusion We refined risk-adjusted predictors for HDU admission and we tested the feasibility of ML models allowing the adjustment for case mix when auditing the HDU admission as a proxy indicator of the quality of care. Predictive ML algorithms may facilitate quality improvement of modern care by improving prediction accuracy for HDU/ICU admission. For this inherently high-risk population, this information is critical when counseling patients about peri-operative risks in cytoreductive surgery.

Disclosures No disclosures.

Trials in progress abstract

MIRRORS TRIAL: MINIMALLY INVASIVE ROBOTIC SURGERY, ROLE IN OPTIMAL DEBULKING OVARIAN CANCER, RECOVERY & SURVIVAL

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Introduction/Background MIRRORS is a UK based prospective feasibility study opened June 2020, following ethics approval. Its purpose is to establish the feasibility of launching a randomised control trial (RCT) of Robotic interval debulking surgery for ovarian cancer (including cancer of the fallopian tube & peritoneum) MIRRORS-RCT in the future.

MIRRORS will focus on the feasibility of obtaining consent from women and the acceptability of Robotic interval debulking surgery for advanced ovarian cancer.

Methodology Women will be identified through the Gynaecological Oncology multi-disciplinary team meeting.

Inclusion Criteria

- adult women ≥18 years with stage IIIc–IVb ovarian cancer (including cancer of the fallopian tube & peritoneum)
- undergoing neo–adjuvant chemotherapy
- considered suitable for interval debulking surgery (IDS)
- ≤8 cm pelvic mass on CT
Exclusion Criteria

- Pelvic Mass >8 cm
- open surgical approach considered necessary following MDT review.
- Women lacking capacity to the extent they are unable to understand or complete trial documentation/questionnaires will be excluded from the trial.

MIRRORS inclusion criteria are intentionally wide, not restricting by Body Mass Index (BMI), patient comorbidity or Ca125 values.

Surgery will commence with an initial laparoscopic assessment followed by a decision to proceed to robotic or open interval debulking surgery. The aim of surgery is to remove all visible disease safely by whichever route. If conversion to open surgery is required to complete this, then it will be done.

Results All women recruited to MIRRORS, whether eventually undergoing robotic or open surgery, will be followed up to assess recovery, complication rate, pain and quality of life.

If the following Success Criteria are met, we will progress to MIRRORS-RCT:

- >20% of women eligible for the study accept inclusion in MIRRORS.
- Robotic IDS Complication rate is not higher than for open interval debulking surgery
- Conversion to open surgery rate not greater than 50% in patient group deemed suitable for Robotic IDS following initial diagnostic laparoscopy.

Conclusion Robotic surgery is unlikely to be suitable in all cases of ovarian cancer, particularly those with large pelvic masses or extensive disease around the upper part of the abdomen, however, it has the potential to provide significant recovery and quality of life benefits. Ultimately we would like to determine whether, in selected women, robotic surgery offers improved quality of life and recovery with equivalent overall and progression free survival.

Disclosures

Anil Tailor: Proctor for Intuitive Surgical
Jayanta Chatterjee: paid-lectures on behalf of pharmaceutical companies
Agnieszka Michael: Educational-grants: Clovis, GSK, Ipsen, Novartis, Pfizer, and Tesaro
Simon Butler-Manuel: Proctor for Intuitive Surgical, Plasma Surgical & Ethicon

Background

Carboplatin-paclitaxel is standard systemic anti-cancer therapy for recurrent or advanced EC for which surgery and/or radiation are not curative. Dostarlimab (TSR-042) is an anti-programmed cell death (PD)-1 humanised monoclonal antibody that has demonstrated antitumour activity and an acceptable safety profile in patients (pts) with recurrent or advanced EC in the GARNET trial. The RUBY trial will evaluate the efficacy and safety of dostarlimab in combination with carboplatin-paclitaxel in recurrent or primary advanced EC compared with carboplatin-paclitaxel alone.

Trial Design

This is a global, randomised, double-blind, multicenter, placebo-controlled study. Eligible pts must have first recurrent or primary stage III or stage IV EC with a low potential for cure by radiation therapy or surgery alone or in combination. Pts with carcinosarcoma are eligible for enrolment. 470 pts will be enrolled from approximately 160 sites in the ENGOT countries, United States, and Canada. Stratification factors are DNA mismatch repair status (proficient [p], or deficient [d] MMR), prior external pelvic radiotherapy (yes or no), and disease status (recurrent, primary stage III or primary stage IV). Pts will be randomised 1:1 to receive combination dostarlimab 500 mg or placebo + carboplatin AUC 5 + paclitaxel 175 mg/m2 every 3 weeks for 6 cycles followed by dostarlimab 1000 mg or placebo monotherapy every 6 weeks for up to 3 years in the absence of progressive disease, death, unacceptable toxicity, or patient/physician decision to withdraw from the study. The primary endpoint is progression-free survival (PFS) as assessed by the investigator in the all-comers population and the dMMR population per RECIST version 1.1. Secondary efficacy endpoints are PFS assessed by blinded independent central review per RECIST version 1.1, overall survival, objective response rate, duration of response, disease control rate, safety and tolerability, and patient-reported outcomes.

Disclosures

Sponsor: GlaxoSmithKline, Waltham, MA, USA
NCT number: NCT03981796

Encore statement: This data is presented on behalf of the original authors with their permission. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, May 29–31, 2020, Virtual.

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Drs. Harker and Valabrega have nothing to disclose.

Drs. Im, Walker, and Guo are employees of GlaxoSmithKline.
Introduction/Background Tumor Treating Fields (TTFields) are a non-invasive, antimitotic cancer therapy. The Phase 2 INNOVATE study demonstrated safety of TTFields/weekly paclitaxel in 31 PROC (platinum-resistant ovarian cancer) patients (Vergote Gyn Onc 2018); efficacy: median PFS 8.9 months, 25% partial response, ≥71% clinical benefit and 61% 1-year survival rate. This phase 3 ENGOT-ov50/GOG-329/INNOVATE-3 study [NCT03940196] investigates TTFields plus weekly paclitaxel in PROC patients.

Methodology Patients (N=540) will have PROC (RECIST V1.1) within 6 months of platinum therapy with maximum of 2–5 prior lines of systemic therapy, ECOG 0–1 and no peripheral neuropathy >grade 1. Patients with primary refractory disease will be excluded. Patients will be randomized 1:1 to weekly paclitaxel alone or weekly paclitaxel (starting of dose 80 mg/m² weekly for 8 weeks, and then on Days 1, 8, and 15 for subsequent 28-day cycle ) plus TTFields (200 kHz for 18 hours/day and continued if no progression in the abdominal or pelvic regions; [in-field region] per RECIST V1.1. Clinical follow-up will be performed q4w, with radiological follow-up (CT or MRI scans of the abdomen and chest) q8w. The primary endpoint is overall survival. Secondary endpoints: PFS, objective response rate, AEs, and quality of life (EORTC QLQ-C30 with QLQ-OV28). Sample size (n=540) will detect an increase in median OS from 12 to 16 months (HR 0.75). Data Monitoring Committee (DMC) meeting (March 2020) concluded that data to-date showed no safety issues and recommended trial continuation.

Results TIP N/A

Conclusion TIP N/A

Disclosures
generation sequencing (NGS) and to determine their associations with clinical features. DNA from 35 uterine lavage fluid from ovarian cancer, uterine cancer and benign ovarian mass patients and 20 ovarian tissue samples were analysed using NGS. The sequencing libraries were prepared using Ion AmpliSeq™ On-Demand Panel targeting 10 OC related genes: BRCA1, BRCA2, PIK3CA, PTEN, KRAS, TP53, CTNNB1, PPP2R1A, ARID1A and FBXW7. Variant uncertain significance (VUS) pathogenicity predicted with Var-Some database.

Results Technique of lavage from uterine cavity was successfully performed in all patients. We were able to detect 37 SNP (22 of these known to be pathogenic) in 20/35 uterine lavage samples, of these 19 (10 known pathogenic mutations) matched SNP found in tissue samples. 4/15 VUS predicted to be pathogenic: ARID1A c.5548delG, c.6628C>T, c.3606delG and BRCA1 c.3871delT. We were able to detect 62.5% (10/16) known pathogenic mutations in both matched samples (n = 17). Most mutations found in patients with serous OC and metastases.

Conclusion Cell-free DNA samples obtained from uterine lavage could be used for molecular profiling of OC patients. Uterine lavage is a simple procedure which can be performed in a physician’s office-based setting and it holds great potential and significant promise for earlier diagnosis of OC and suggest the future possibility of this approach for screening women for gynecological cancers.

Disclosures This study is supported by NCI research fund.

Late breaking abstracts
Breast cancer

611 EFFECT OF SENTINEL LYMPH NODE BIOPSY ON UPPER LIMB FUNCTION IN WOMEN WITH EARLY BREAST CANCER: A SYSTEMATIC REVIEW OF CLINICAL TRIALS
Taynara Louisi Pilger, Daniely Franco Francisco, Francisco Jose Candido Dos Reis. Ribeirão Preto Medical School/University of São Paulo, Ribeirão Preto

10.1136/ijgc-2020-ESGO.201

Introduction/Background Axillary surgery is essential in the management of early breast cancer. Conservative surgeries like sentinel lymph node biopsy (SLNB) are less invasive than the traditional axillary dissection. However, some extent of ipsilateral upper limb dysfunction might still occur. The aim of this systematic review was to describe the incidence of lymphedema, pain, sensory, and motor disorders after SLNB in women with breast cancer.

Methodology We conducted a systematic review of randomized controlled trials. The search was performed on Pubmed, EMBASE, CINAHL, and Web of Science. The search was based on the following concepts: breast cancer, sentinel lymph node biopsy, axillary dissection, upper limb complications. The risk of bias was evaluated using the Cochrane Rob 2.0 toll.

Conclusion SLNB is associated with postoperative complications that persist up to at least two years after the surgical procedure. The burden of complications, although lower when compared to axillary dissection, should not be ignored.

Disclosures The authors have no conflict of interest to disclose.

Cervical cancer

576 CLINICAL CHARACTERISTICS, TREATMENT RESPONSE AND PROGNOSIS OF LOCALLY ADVANCED ADENOCARCINOMA OF THE CERVIX, A LOCAL STUDY
Marilou Yu, Jonalyn Bagadiong, Jose R. Reyes Memorial Medical Center; Dr. Jose Fabella Memorial Hospital; Obstetrics and Gynecology Section of Gynecologic Oncology and Trophoblastic Diseases

10.1136/ijgc-2020-ESGO.202

Introduction/Background Treatment of locally advanced cervical carcinoma regardless of histology, either, squamous, adenocarcinoma or adenosquamous carcinoma is the same, concurrent chemoradiotherapy. Nevertheless, studies have different and contradictory results regarding the impact of tumor histology in relation to treatment response. The current study sought to determine the clinical characteristics, treatment response and prognosis of locally advanced adenocarcinoma of the cervix in comparison to squamous cell carcinoma.

Methodology Records of the cervical cancer patients from the outpatient department of the Section of Gynecologic Oncology of a tertiary hospital were retrospectively reviewed.

Results Among the 979 charts reviewed, only 278 patients were included in the analysis. Seventy-five percent of the patients had squamous cell carcinoma and only 20% had adenocarcinoma. Baseline characteristics were comparable. Ninety-eight percent had Cisplatin-based concurrent chemoradiotherapy. Median follow up was 17 months, with 75.30% of the patients had complete response, 7.97 had partial response and 16.73% had recurrent disease. Patients having squamous cell carcinoma had higher percentage of being alive at the time of follow up, better response to treatment, lesser recurrence and lower mortality rate as compared to adenocarcinoma, however, there was no sufficient evidence to demonstrate a difference in disease free survival and overall survival.

Conclusion Patients with locally advanced adenocarcinoma of the cervix who underwent concurrent chemoradiaion had the same treatment response and prognosis to patients with squamous cell carcinoma.

Disclosures None.

583 PROGNOSTIC IMPACT OF SERUM INFLAMMATORY BIOMARKERS COMBINED WITH IL-6 EXPRESSION IN CERVICAL CANCER PATIENTS

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10.1136/ijgc-2020-ESGO.203

Introduction/Background Increasing evidences demonstrated a crucial role of inflammation in inducing and promoting several cancers. Cancer-related inflammation is an essential process in malignant disease by stimulating tumour cells proliferation, invasion mechanisms, metastasis, neoangiogenesis and by activating pathways of apoptosis’s resistance. Cells and mediators of inflammation (as cytokines) represent a major part of tumour milieu. Particularly, IL-6 has been linked with cervical
cancer development and progression by inducing upregulation of vascular growth factors (as VEGF), by modulating apoptosis, by fostering platelet production, activation and aggregation. An elevated platelet to lymphocyte ratio (PLR) has been recognised as markers of inflammation and also linked to poor prognosis in several malignancies. The aim of the study was to evaluate prognostic impact of inflammatory biomarkers (high platelet count, PLR) in combination with IL-6 tumour expression in cervical cancer patients.

**Methodology**
Between 2016 and 2019, 108 out of 159 patients with cervical cancer presented to the Department of Gynecological, Obstetrical and Urological Sciences of “Sapienza” University of Rome and to the Division of Obstetrics and Gynecology at Department of Experimental and Clinical Medicine, University of Pisa have been enrolled. Study project was made in collaboration with National Research Council of Italy, Institute of Clinical Physiology (CNR-IFC) of Pisa. Cut off level of pre-treatment platelet count and PLR were identified by using ROC curve. IL-6 tumoural and peri-tumoural expression was analysed and stratified as low and high (low expression: 0, +1; marked expression:+2, +3).

**Results**
Median follow up duration was 30 months (range 16–44). Patients with higher platelet counts showed worse OS and DFS (OS p < 0.001 and DFS p < 0.001, respectively figure 1A). Cumulative rates of OS and DFS in patients with lower PLR were higher than in patients with higher values of PLR (OS p < 0.001 and DFS p = 0.032; figure 1B). Survival analysis showed a better prognosis in patients with lower IL-6 tumoural expression (PFS p < 0.001; OS p < 0.001; figure 2).

Patients’ characteristics were stratified according to platelet count, PLR, and IL-6 tumoural expression then compared using Pearson’s correlation. Significant correlations were observed between negative cervical cancer-related prognostic factors (advanced stage of disease, tumor size, high grading, positive LVSI, lymph nodes and parametrical involvement) and pro-inflammatory patient’s status. **Conclusion**
Nowadays causal relationship between inflammation, innate immunity and cancer is more widely accepted; however, many of the molecular and cellular mechanisms mediating this relationship remain unresolved.

Ongoing inflammatory response was associated with poor outcomes in cervical cancer patients. A higher pre-treatment platelet count and PLR value associated with higher IL-6 tumoral expression could be used to predict poor prognosis in cervical cancer patients. Further investigations about inflammatory markers in prognostic models could contribute in early cervical patients’ stratification and consequent management. **Disclosures**
None.

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**592 SENTINEL LYMPH NODE MAPPING IN EARLY-STAGE CERVICAL CANCER USING NEAR-INFRARED FLUORESCENCE IMAGING: A PROSPECTIVE PILOT STUDY**

Anastasios Tranoulis, Hebatallah Awad, Christina Thompson, Amy Fisher, Jeremy Twigg.

1The Pan-Birmingham Gynaecological Oncology Centre, Sandwell and West Birmingham NHS Trust, Birmingham; 2Jane’s Cook University Hospital, Middlesbrough

**Introduction/Background**
The aim of this pilot study was to ascertain the feasibility of sentinel lymph node (SLN) mapping in early-stage cervical cancer (CC) and evaluate factors affecting bilateral SLN detection.

**Methodology**
This was a prospective cohort study spanning the period from January 2015 to March 2019. Women with early-stage CC (FIGO 2018 stage IA2 to IB2) scheduled to undergo robot-assisted laparoscopic radical hysterectomy or trachelectomy and SLN mapping with the Da Vinci Si Surgical System were included.
Introduction/Background
Organized screening programs reduce cervical cancer incidence and mortality. However, in many low-middle income countries, the screening programs are opportunistic. In this work, we investigated the trends in cervical cancer mortality, advanced-stage at diagnosis, and screening coverage in an opportunistic setting.

Methodology
In this large retrospective cohort, we analyzed data on invasive cervical cancer diagnosed between January 2000 and December 2014. Cancer data were provided by Fundação Oncocentro de São Paulo (FOSP) and screening coverage by the Instituto Brasileiro de Geografia e Estatística (IBGE). Five-year cervical mortality was calculated using the Fine and Gray regression model. Joinpoint regression analysis was used to estimate annual percentage changes (APC) for five-year mortality, the proportion of advanced stage, and screening coverage.

Results
From 18,206 cases, we identified 6,479 deaths in five years of follow up due to cervical cancer. The leading risk factor was the advanced stage ($hHR = 6.48$, 95% CI $5.75$ to $7.30$). The rate of cervical cancer mortality was stable from 2000 to 2014 (APC=$-0.106$; 95%CI $-0.730$ to $0.522$; $P=0.720$). The estimated proportion of women screened (in the last three years) was 81% in 2003, 83% in 2008, and 85% in 2013 (APC=$0.443$; 95%CI $-4.913$ to $6.102$; $P=0.492$). The proportion of advanced stage reduced from 77% in 2000 to 71% in 2006 (APC=$-1.294$; 95%CI $-2.322$ to $-0.256$; $P=0.020$) and increased to 76% in 2014 (APC=$0.924$; 95%CI $0.248$ to $1.605$; $P=0.012$).

Conclusion
Opportunistic screening strategies fail to achieve a similar proportion of early-stage diagnosis and reduced mortality in invasive uterine cervix cancer compared to organized screening programs.

Disclosures
The authors have no conflict of interest to disclose.

Disclosures
The authors have no direct interest in the results of the research and that no benefit will be conferred to us or any organisation with which we are associated.
LONG-TERM RESULTS OF NEOADJUVANT DOSE-DENSE PLATINUM-BASED CHEMOTHERAPY IN PATIENTS WITH LOCALLY ADVANCED CERVICAL CANCER

1Olga Smirnova, 2Elena Ulrikh, 3Alina Abramova, 1Maria Yakovleva, 1Anna Petrova, 1Nikolay Mikaya, 1Olga Latynovich, 1Nikolay Bondarenko, 1Adel Urmarchenova, 1Igor Beriev, 1N.N. Petrov National Medical Research Center of Oncology; 2Almazov National Medical Research Centre; North-Western State Medical University, N.N.Petrov National Medical Research Centre of Oncology; Oncology

10.1136/ijgc-2020-ESGO.207

Abstract 608 Table 1

<table>
<thead>
<tr>
<th>Group</th>
<th>CIN 2 (N/total N (%))</th>
<th>CIN 3 (N/total N (%))</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Imiquimod)</td>
<td>17/21 (81.0)</td>
<td>12/19 (63.2)</td>
<td>0.366</td>
</tr>
<tr>
<td>Group 2 (LLETZ)</td>
<td>10/22 (45.5)</td>
<td>27/33 (81.9)</td>
<td>0.288</td>
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</tbody>
</table>

Abstract 608 Table 2

<table>
<thead>
<tr>
<th>Group</th>
<th>Presence of side effects and the highest grade of side effects in patients treated with imiquimod (group 1) and LLETZ (group 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Imiquimod)</td>
<td>Group 2 (LLETZ)</td>
</tr>
<tr>
<td>Significant effects</td>
<td>p-value</td>
</tr>
<tr>
<td>Significant effects</td>
<td>p-value</td>
</tr>
<tr>
<td>Grade 1 (CIN 2)</td>
<td>18/52 (34.6)</td>
</tr>
<tr>
<td>Grade 2 (CIN 3)</td>
<td>7/52 (13.5)</td>
</tr>
<tr>
<td>Grade 3 Other (CIN 3)</td>
<td>3/52 (5.8)</td>
</tr>
</tbody>
</table>

Abstract 608 Table 3

<table>
<thead>
<tr>
<th>Group</th>
<th>Success of treated in patient treated with imiquimod (group 1) and LLETZ (group 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Imiquimod)</td>
<td>Group 2 (LLETZ)</td>
</tr>
<tr>
<td>Significant effects</td>
<td>p-value</td>
</tr>
<tr>
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<td>p-value</td>
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<tr>
<td>Group 1 (Imiquimod)</td>
<td>17/21 (81.0)</td>
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<td>Group 2 (LLETZ)</td>
<td>10/22 (45.5)</td>
</tr>
</tbody>
</table>

Introduction/Background In our study, we evaluated the long-term results of neoadjuvant dose-dense platinum-based chemotherapy in patients with locally advanced cervical cancer FIGO IB2, IIB stage.

Methodology A cohort of 119 consecutive patients with median age of 43 (range 27–68) years was studied. All patients had verified locally-advanced (cT1b2Nx,0M0; cT2bNx,0M0) cervical cancer and received 3 dose-dense intravenous neoadjuvant AP (cisplatin 75 mg/m2, doxorubicin 35 mg/m2; n=75) or TP (cisplatin 60 mg/m2 and paclitaxel 60 mg/m2; n=30) chemotherapy cycles.

Results The median follow-up was 28 (4–48) months for AP and 17 (3–30) months for TP group, accordingly. The overall survival rates in FIGO IB2 stage for AP and TP groups were 100%. For FIGO IIB stage the overall survival rate in AP group was 94%, in TP group - 97%.

The disease-free survival rate in FIGO IB2 stage for AP group was 78%, for TP group - 100%. For FIGO IIB stage the disease-free survival rate in the AP group was 87%, in TP group - 100%.

Conclusion The dose-intensive chemotherapy is an effective treatment modality for locally-advanced cervical cancer and may be a feasible alternative for standard treatment approach. It deserves further study in larger patient cohort with evaluation of the long-term results.

COMPARISON OF TOPICAL TREATMENT OF CERVICAL SQUAMOUS INTRAEPITHELIAL LESIONS WITH IMIQUIMOD WITH STANDARD EXCISIONAL TECHNIQUE USING LLETZ: A RANDOMIZED CONTROLLED TRIAL

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10.1136/ijgc-2020-ESGO.208

Introduction/Background Standard treatment of cervical squamous intraepithelial lesions (SIL) is large loop excision of transformation zone (LLETZ), which is associated with increased risk of preterm delivery, higher subfertility rate, and higher spontaneous abortions rate. Our aim was to determine whether topical treatment of high-grade SIL (HSIL) with imiquimod is comparable to standard treatment in terms of efficiency and side effects occurrence.

Methodology We performed a randomized controlled study. Patients with HSIL aged 18–40 years were included and treated with either imiquimod, 3 times per week for 16 weeks (experimental arm), or with LLETZ (control arm). Treatment success was evaluated by regression to low-grade SIL (LSIL) 20 weeks after initiation of the treatment in the experimental arm and by negative cytology 6 months after LLETZ in the control arm. Secondary outcome was occurrence of the side effects during and after treatment. Statistical analysis was performed using SPSS Statistics Programme. Statistical significance was set at p-value<0.05.

Results We included 104 patients. In the experimental arm, 43 out of 52 patients (82.7%) completed treatment, while in the control arm, all of the 52 patients received the planned treatment (100%). Treatment with imiquimod was successful in 62.8% and treatment with LLETZ in 75.0%, the difference was not statistically significant (p-value=0.288). When evaluating treatment success in the intermediate risk subgroup (patients with cervical intraepithelial neoplasia grade 2 – CIN 2), there were also no statistically significant differences between groups (p-value=0.366). However, LLETZ was significantly more successful in patients with CIN 3 lesions (p-value=0.012). We did not observe any cases of progression of the precancerous disease to cancer. Side effects and severe side effects were significantly more prevalent in the imiquimod than in the LLETZ group (88.5% vs. 44.2% (p-value<0.001) and 51.9% vs. 13.5% (p-value<0.001), respectively). The most prevalent side effects were vaginal inflammation, flu-like and lower urinary tract symptoms. Over the course of the treatment with imiquimod, overall occurrence and the severity of side effects decreased.

Conclusion Topical imiquimod has a potential of becoming an alternative treatment for HSIL, especially in younger women with intermediate risk HSIL. However, its use is associated with higher occurrence of side effects, which can affect patients’ quality of life. In the future, larger studies evaluating the long-term effects of this treatment are needed, especially in the view of disease progression and recurrence.

Disclosures The authors declare no competing interests. This research was financially supported by UMC Maribor.
Abstract 619 Table 1 Results of FRD staining, PAP smear, HPV test, colposcopy and histology in 10 patients.

<table>
<thead>
<tr>
<th>Case</th>
<th>FRD</th>
<th>PAP</th>
<th>HPV</th>
<th>Colposcopy</th>
<th>Histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+</td>
<td>H-SIL</td>
<td>+</td>
<td>5</td>
<td>CIN 1</td>
</tr>
<tr>
<td>2</td>
<td>+</td>
<td>H-SIL</td>
<td>+</td>
<td>8</td>
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</tr>
<tr>
<td>3</td>
<td>+</td>
<td>H-SIL</td>
<td>-</td>
<td>4</td>
<td>No dysplasia</td>
</tr>
<tr>
<td>4</td>
<td>+</td>
<td>ASC-H</td>
<td>+</td>
<td>6</td>
<td>CIN 2</td>
</tr>
<tr>
<td>5</td>
<td>+</td>
<td>H-SIL (Dx)</td>
<td>/</td>
<td>8</td>
<td>Acute cervicitis</td>
</tr>
<tr>
<td>6</td>
<td>-</td>
<td>H-SIL</td>
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<td>7</td>
<td>+</td>
<td>PAP B (Dx)</td>
<td>+</td>
<td>4</td>
<td>CIN 1</td>
</tr>
<tr>
<td>8</td>
<td>+</td>
<td>PAP A</td>
<td>+</td>
<td>3</td>
<td>CIN 1</td>
</tr>
<tr>
<td>9</td>
<td>+</td>
<td>L-SIL (Dx)</td>
<td>+</td>
<td>3</td>
<td>CIN 1</td>
</tr>
<tr>
<td>10</td>
<td>-</td>
<td>ASC-US</td>
<td>L-SIL</td>
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</table>

Introduction/Background MicroRNAs are short molecules that regulate gene expression. The microRNA expression profile changes in cells during neoplastic transformation. In particular, characteristic changes in microRNA are observed in the cells of the cervical epithelium during the development of intraepithelial neoplasia. These changes are compounded in invasive cervical cancer cells. Accordingly, microRNAs can serve as diagnostic or prognostic biomarkers in patients with cervical dysplasia of varying severity.

In this study, we analyzed microRNA in patients with low grade squamous intraepithelial lesions (LSIL) and compared the data obtained with the clinical course of the disease.

Methodology Total RNA was isolated from the epithelium of patients with low grade squamous intraepithelial lesions and divided into two pools: “persistence” (n=10) and “recovery” (n=10), depending on the data of repeated cytological examination conducted after 6–9 months. In the obtained samples, we performed a comprehensive screening analysis of 85 microRNA expression (Cancer focus miRCURY RT-PCR panel, Exiqon, Denmark).

Results The results of microRNA profiling showed different levels of expression of 9 molecules in the compared groups. In cases of persistent cervical epithelial atypia during dynamic observation, miR-126-3p, Mir-16-5p, miR-182-5p, miR-200c-3p, miR-205-5p, miR-223-3p, and miR-24-3p molecules were expressed significantly more actively than in the group of samples obtained from patients whose cervical epithelium condition normalized during observation. The reverse situation was observed for miR-192-5p and miR-let-7f-5p.

Conclusion MicroRNA molecules whose expression level correlates with the prognosis of cervical epithelial dysplasia can serve as useful biomarkers and be used to personalize the treatment of this common gynecological disease. Validation of the microRNA estimation method requires more extensive research.

Disclosures The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

Endometrial cancer

580 SURGICAL MANAGEMENT OF GYNECOLOGIC CANCERS DURING THE COVID-19 PANDEMIC

Nazila Shokri, Yeka Parsa, Hamidreza Niazyar, Zahra Naeli, Atfeh Moridi. Shahid Beheshti University of Medical Sciences, Obstetrics And Gynecology

Introduction/Background The COVID-19 pandemic brings about various challenges for surgeons in different fields. They should assess the risk-benefit of each surgery prior to the operation, and decide whether the surgery is beneficial for the patient or the surgery is delayable due to the risk of COVID-19 infection. In this regard, gyneco-oncology surgeries are no exception. If the treatment is deferred, it may lead to the progression of the disease, affect the quality of life and patient’s survival.

Case Reports In this article, we report and discuss three cases of gynecologic cancer including two cases of endometrial cancer and one case of cervical cancer in situ that referred to Mahdiyeh hospital, Tehran, Iran, during the COVID-19 pandemic.
Conclusion According to the centers for disease control and prevention (CDC) guidelines, the COVID-19 Polymerase Chain Reaction (PCR) must be performed for each patient before surgery. If the patient was positive for COVID-19, the surgery should be postponed for at least two weeks. If the test is negative and the patient is candidate for surgery, delay in surgery should be minimized and efforts should be made to discharge the patient earlier to reduce the contact of patient with health worker and other patients. All of these processes are to protect the cancer patient from COVID-19 infection. For the current situation of COVID-19 pandemic, risk assessment should be done carefully to identify whether the role of surgery is curative or palliative and how it may impact the life expectancy of the patient. Every cancer patient should be screened for possible infection before the surgery. During the surgery, measures should be taken to reduce the time of surgery and complications that my lead to ICU (intensive care unit) admissions. Discharging patients earlier after the surgery could also reduce the risk of infection.

Disclosures There is not any conflict of interest to be declared regarding the manuscript.

A PILOT STUDY FOR THE VALIDATION OF SENTINEL LYMPH NODE BIOPSY WITH INDOCYANINE GREEN FLUORESCENCE METHOD IN EARLY ENDOMETRIAL CANCER AT FUNDACIÓN JIMÉNEZ DÍAZ UNIVERSITY HOSPITAL

José García Villayzan.
10.1136/ijgc-2020-ESGO.212

Introduction/Background Sentinel Lymph Node Biopsy is a technique developed to predict lymphatic involvement in patients with early endometrial cancer, decreasing the morbimortality associated with routine systematic lymphadenectomy and improving quality of life.

Methodology Main Objective: To determine the detection rate and negative predictive value of the Sentinel Lymph Node Biopsy by Immunofluorescence in patients with early endometrial cancer.

Secondary Objective: To determine the morbidity and mortality associated with Sentinel Lymph Node Biopsy in comparison to systematic lymphadenectomy

To determine the quality of life of the patients who only underwent Sentinel Lymph Node Biopsy in comparison to systematic lymphadenectomy

Method A descriptive observational study in patients with early endometrial cancer (FIGO stage I-II) for all histological types and grades, who underwent the Sentinel Lymph Node by immunofluorescence Technique and/or systematic lymphadenectomy between June 2019 and March 2020 at the Fundación Jiménez Díaz University Hospital.

We used indocyanine green powder for injection, with a concentration of 25 milligrams (mg). We proceeded to dissolve it in 10 cubic centimeters (cc) of distilled water to avoid precipitation of the marker; obtaining a final concentration of 2.5 mg. After which, we injected 2 cc of the prepared solution into the cervix at the 3 and 9 o’clock positions at a depth of 1 cm through Abbocath N° 12G (figure 1).

Results Eighteen patients were included, analyzing a total of 26 sentinel nodes: 24 pelvic and 2 paraaortic; and a total of 273 lymph nodes (sentinel and non-sentinel nodes): 83 right pelvic, 86 left pelvic and 104 paraaortic. All nodes were negative for metastasis.

Global and bilateral detection rates were 77.78% and 50% respectively. The Negative Predictive Value and sensitivity were 100%. No significant difference in morbimortality was found between performing only Sentinel Lymph Node technique or systematic lymphadenectomy; but the association with quality of life was significant, with better results for those who only underwent the sentinel lymph node technique versus systematic lymphadenectomy (0% vs 77%).

However, we observed at the beginning of the study bilateral detection was very limited. This could have been due to a failure in the tracer injection technique in our first 10 patients. Since the standardization of the technique we
obtained a considerable improvement in bilateral detection; 87.5% (before technical standardization 20%). This supports the theory that technique is the most important factor in detection (Rossi, 2019). On the other hand, it is important to assess the learning curve, considered an independent factor that can influence the quality of the technique (table 1).

Conclusion The global and bilateral detection rates of the Sentinel Lymph Node Technique by immunofluorescence were 77.78% and 50% respectively, obtaining a Negative Predictive Value and Sensitivity of 100%. Sentinel Node Biopsy is a valid technique to predict lymphatic affection in early endometrial cancer, with lower morbimortality than systematic lymphadenectomy (figure 2).

Disclosures No conflict of interest to disclose.

EARLY STAGE, LOW GRADE ENDOMETRIAL ADENOCARCINOMA IN REPRODUCTIVE AGED WOMEN. AN EVALUATION OF PATIENT PERSPECTIVES OF DIAGNOSIS, TREATMENT DECISION MAKING, MANAGEMENT, FERTILITY AND SURVIVORSHIP: A QUALITATIVE STUDY

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Background Endometrial cancer is rare in reproductive aged women. Standard surgical treatment can impact fertility. Non-standard conservative management with progestins can be used in very specific populations to give women an opportunity for childbearing. The treatment experiences of this cohort have not been well studied, and unmet needs not identified or explored. This study aims to explore the experiences of reproductive aged women with early endometrial cancer across diagnosis, decision making, treatment, fertility and survivorship.

Methodology A mixed methods retrospective cohort study was undertaken utilising an online survey and semi-structured interviews addressing themes of diagnosis, management decision making, treatment, fertility and survivorship. Women aged 18–40 years with early EAC, treated at the Royal Women’s Hospital (RWH), Melbourne, Australia were identified. Seventy-five women were invited to participate. Online survey links were distributed via mobile text message along with an invitation for interview. Survey responses were collated, and interview transcripts were thematically analyzed using a grounded theory approach.

Results Twenty-six surveys and 14 interviews were completed. Medical management: 20 surveyed 7 interviewed (mean age 33ys) Surgical management: 6 surveyed 7 interviewed (mean age 38 yrs). Responses highlight the shock of the diagnosis and improvements which could be made when communicating the diagnosis. Common themes also included a strong desire for women to be presented with treatment options, suboptimal information provision around treatment options and implications for fertility and long term survivorship as well as the significant emotional burden across all aspects of the treatment journey. Women consistently expressed they did not identify with the wider EAC cohort or other reproductive aged women with cancer and had a strong desire for specific cancer support services. Overall 20 themes across 5 domains were identified. Examples in figure 1.

Conclusion This study examines the experience of young women diagnosed with early EAC. It highlights unmet needs, particularly around available supports and provision of information. These needs should be considered in the future management of these cancer patients.

Acknowledgements To the participants for sharing their experiences.

Disclosures No authors have disclosures to report.

597 MISMATCH REPAIR PROTEIN EXPRESSION DEFECTS IN ENDOMETRIOID ENDOMETRIAL ADENOCARCINOMA

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Introduction/Background Endometrial cancer has been shown to be the sentinel cancer in over half the female patients with heritable mismatch repair (MMR) mutations as part of Lynch syndrome. Immunohistochemical testing for MMR protein expression in endometrial cancer is the first screening test identifying cases that potentially harbour familial cancer syndrome-related mutations. MMR has also become a biomarker to predict response to targeted therapeutics such as in immune-checkpoint blockade. This is the first study to describe the prevalence of MMR protein expression defects in Maltese endometrial carcinoma patients and the correlation with patient age at diagnosis.

Methodology 200 endometrioid endometrial cancer cases were retrospectively identified from the Mater Dei Hospital laboratory information system and categorized into three arms: the first consisting of 151 cases over the age of 50 at diagnosis, the second consisting of 49 cases at or under the age of 50 at diagnosis and a control group consisting of 30 patients who underwent endometrial tissue sampling for benign conditions. H&E slides for these cases were re-examined by an independent pathologist to confirm the diagnosis as well as to identify the block best representing the tumour. Four new slides per case were recut and immunohistochemistry performed for MLH1, PMS2, MSH2, and MSH6 MMR proteins. Protein expression was analysed semiquantitatively using Allred score.

Results In the overall cohort 69% of cases were MMR proficient while 31% of cases were deficient for one or more MMR proteins. Dual loss of the MLH1 and PMS2 heterodimer protein expression was the most common deficiency and occurred in 24.5% of the EEC population. Loss of MSH2-MSH6 heterodimer protein expression was less common and represented 3.2% of MMR-deficient cases. Well differentiated tumours had a 76.5% proficiency rate as opposed to grade 2/3 disease with 53.2% and 52.9% proficiency rate respectively. There was no statistically significant difference in overall MMR status when age 50 was used as a hypothetical testing threshold. After correcting for tumour grade as a confounding variable it was shown that MLH1 and PMS2 expression were negatively correlated with increasing age while MSH6 expression was positively correlated with increasing age at diagnosis (figures 1 and 2).

Conclusion There is no statistically significant difference in overall immunohistochemical MMR status when using the age of 50 as a threshold for tumour analysis. Such a threshold would have missed 82.3% of cases with tumoral MMR deficiency and should not be included in lab protocols for EEC IHC analysis. Reflex testing of all EEC cases is highly advised as IHC testing is no longer solely about diagnosis of Lynch syndrome. Prospective evidence is required to clarify the role IHC scoring and semi-quantitative analysis should play in MMR status interpretation and patient management especially in the ever-evolving field of targeted therapeutics.

Disclosures This study was self-financed. Authors declare they have no conflict of interest, financial or otherwise.

598 RECURRENCE AND SURVIVAL AFTER LAPAROSCOPY VERSUS LAPAROTOMY IN EARLY STAGE ENDOMETRIAL CANCER: FOLLOW-UP FIVE YEARS AFTER A RANDOMISED TRIAL

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Introduction/Background Laparoscopic hysterectomy has been proven to be a safe surgical procedure and is globally accepted as the standard treatment for early-stage endometrial cancer, despite insufficient data on long-term survival. Aim
was to provide the five-years outcomes of a randomised Dutch trial on total laparoscopic hysterectomy (TLH) versus total abdominal hysterectomy (TAH) in early-stage low-risk endometrial cancer.

**Methodology** Follow-up of a multi-centre, randomised controlled trial on TLH versus TAH without routine lymphadenectomy. A total of 279 women with stage I endometrial cancer were enrolled between 2007–2009 in a 2:1 randomisation to undergo either TLH (n=185) or TAH (n=94). Primary outcome was disease-free survival. Secondary outcomes were primary site of recurrence, overall and disease-specific survival. The Kaplan-Meier survival curves and Cox proportional hazard ratios were applied.

**Results** Follow-up data of 253/279 patients are available. At a median follow-up time of 5.0 years, disease-free survival was 90.4% after TLH and 83.3% after TAH, HR 0.68 (95% CI 0.31–1.49). There were no port-site metastases and local recurrence rates were comparable. After adjustment for the covariates, overall survival outcomes were comparable between groups HR 0.64 (95% CI 0.33–1.26). Disease-specific survival was comparable between both groups.

**Conclusion** This is the first study reporting on survival among women with early-stage endometrial cancer randomised to TLH or TAH, without routine lymphadenectomy. No significant differences were found in disease-free, overall and disease-specific survival five-years postoperatively. This supports the widespread use of laparoscopic hysterectomy as primary treatment procedure for early-stage, low-grade endometrial cancer.

**Disclosures** None.

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**Abstracts**

**613 PREDICTING LYMPHEDEMA ASSOCIATED WITH LYMPH NODE DISSECTION IN PATIENTS WHO UNDERGO SURGERY FOR ENDOMETRIAL CANCER: ROLE OF DEMOGRAPHIC AND CLINICAL CHARACTERISTICS**

1Nazila Shokri, 1Atfeh Monidi, 1Yekta Parsa, 1Shahin Reazadeh, 1Maryamaadat Hosseini, 1Farah Farzaneh, 1Masoumeh Raoufi. 1Shahid Beheshti University of Medical Sciences; Obstetrics And Gynecology; 1Imam Khomeini Hospital Urooncology Research Center; 1Preventive Gynecology Research Center, Oshandyn Dep; Shahid Beheshti University of Medical Sciences

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**Introduction/Background** Multimodal treatments have significantly improved oncological outcomes in patients with endometrial cancer. Therefore most of the patients are long-term survivors and may experience adverse effects related to treatment. Lymph node dissection in patients who undergo total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAH+BSO) may be associated with adverse effects such as lymphedema. Several factors including number of removed lymph nodes and extent of lymph node dissection have been postulated to be associated with adverse events. However, in most studies the definition of the complications is poorly described and contradicting findings exist. In this prospective study we aim to assess the complications related to lymph node dissection in patients who undergo TAH+BSO and potential factors that predict adverse events.

**Methodology** We conducted this prospective study to assess the complications related to lymph node dissection in patients who underwent TAH+BSO for endometrial cancer. Patients with prior history of lower limb surgery, pelvic radiation and prior history of cancer treatment were excluded from study. Additional exclusion criteria were heart failure, uncontrolled thyroid abnormalities and other disorders associated with impaired lymphatic drainage and/or lower limb edema. Demographic and clinical characteristics including age, body mass index, pathologic stage, and extent of lymph node dissection were recorded. We also assessed complications related to lymph node dissection i.e. lymphedema, lymphatic leakage and lymphocele. Lymphedema was defined based on American Physical Therapy Association criteria. We applied Gynecologic Cancer Lymphedema Questionnaire to evaluate severity of symptoms related to lymphedema. Written informed consent was obtained from all patients and institutional review board approved the study.

**Results** A total of 135 patients with a mean age of 57.6±11.5 underwent TAH+BSO during the study period. Lymph node dissection was performed in 83 (61.4%) patients. The extent of lymph node dissection was limited to pelvis in 18 (33.3%) patients, whereas, 3 (2.2%) patients underwent pelvic and para-aortic lymph node dissection. Median number of dissected lymph nodes was 11 (interquartile range: 5–21.2). Among patients who underwent lymph node dissection, 14 (16.3%) patients showed lymph node involvement. Stage I, II and III were recorded in 97(71.9%), 13 (9.6%), and 25 (18.5%) patients respectively. We did not observe lymphedema in our study participants. Other complications related to lymph node dissection were low grade and were not associated with age, BMI, extent of lymph node dissection, total number of dissected lymph nodes, lymph node involvement and disease stage.

**Conclusion** Complications related to lymph node dissection including lymphedema are rare after TAH+BSO for endometrial cancer and the extent of lymph node dissection or disease stage is not associated with higher risk of such complications.

**615 CLINIC-PATHOLOGICAL FEATURES OF MIXED ENDOMETRIAL CARCINOMA; EVALUATION OF 29 PATIENTS IN A SINGLE TERTIARY CENTER**

Mete Suçu, Ömer Faruk Geckil, Ulum Kucukgaz Gulec, Ahmetbaris Guzel, Ghanim Khatib, Mehmet Ali Vardar. Cukurova University Faculty of Medicine; Obstetrics and Gynecology

10.1136/ijgc-2020-ESGO.217

**Introduction/Background** Mixed endometrial carcinoma (MEC) refers to a tumor that is comprised of two or more distinct histotypes. Each component histotype by definition has to represent more than 5% of the tumor. Although it is relatively rare, both diagnosis and management can be troublesome. Molecular and histopathologic features have become important in the identification and more importantly the precise management of the MEC’s.

In our study, we aimed to evaluate the clinical and pathological characteristics of the MEC

**Methodology** The clinical and pathological records of the 29 MEC patients who were operated on and regularly followed up in the clinic between January 2000–December 2019 were reviewed. Clinical features, operation characteristics, pathologic findings, myometrial invasion degree (MI), lymph node involvement (LNI), lymphovascular space invasion (LVS), adjuvant therapies, and follow-up data of the patients and their effects on survival were investigated.
**Results** During the study period, 29 out of 1110 patients with endometrial cancer had MEC (2.6%). Eighteen of the cases had endometrioid + serous, 7 had endometrioid + clear, 3 had endometrioid + serous, and 1 had clear + serous histopathology. The mean age of the patients was 63.2±12.1. Laparoscopic surgery was performed in 8 of the cases (27.6%). Sixteen of the cases were in stage 1 (55.1%), 4 were in stage 2 (13.8%), and 9 were in stage 3 (31%). LVSI was positive in 17 cases (58.6%). LNI was detected in 7 cases (24.1%). Approximately 80 percent of cases received adjuvant therapy. While 80% of the cases received chemotherapy, this rate was 55% for radiotherapy.

**Conclusion** MECs are tumors that can be difficult to diagnose and manage. In addition to histopathological features, revealing and evaluating their molecular properties will help us to better understand this group of tumors.

**Disclosures** None

**Miscellaneous**

**594** IMPACT OF THE COVID PANDEMIC ON GYNAECOLOGICAL CANCER SURGERY – RESULTS FROM THE COVIDSURG GYNAECOLOGICAL CANCER INTERNATIONAL STUDY

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**Introduction/Background** Covid-19 has resulted in significant number of elective surgeries being delayed or cancelled worldwide with an estimated 28 million patients being affected.1

Studies show that perioperative Covid-19 infection has a high perioperative mortality of 23.8%. (2) Complications increase with any additional treatment burden such as cytotoxic chemotherapy, radiotherapy or immunotherapy.3 In an effort to reduce treatment related morbidity and mortality during the Covid-19 pandemic, many elective anticancer treatments have been postponed or modified.4

**Methodology** We investigated the impact of the Covid-19 pandemic on gynaecological cancer surgery in an international prospective multi-centre study. Participating centres entered consecutive patient’s data into a customized electronic database for 12 weeks from the first COVID positive patient managed in their hospital between March and June 2020. Patients were
eligible for enrollment if they were planned to undergo surgery during the study duration, regardless of COVID-19 status and whether they underwent surgery as recommended or not. Patients who did not undergo their planned surgery were followed up for 12 weeks to observe outcomes. Descriptive analysis of outcomes is presented.

4490/4472 (95%) patients received surgery; of these 17% (n=758) experienced change or adaptation of surgery. The main impact was on surgical timing; 11% (n=483) experienced delay in surgery, 3% (n=119) a change in choice of operation, 10% (n=452) received surgery in alternative hospital.

Patients in this study had confirmed resolved COVID-19 prior to surgery in 0.95% (n=45) patients with an additional 0.34% (n=16) with probable resolved COVID-19 infection. A post-operative COVID-19 rate of 2.27% (n=25) and pulmonary complication rate of 1.8% (n=20) was found in the initial analysis of the Covidsurg cancer data, analysing outcomes for 1102 gynaecological cancer patients. The overall 30-day mortality rate in this cohort was 1.18% (n=13).5

Conclusion The largest multi-centre analysis of gynaecological cancer surgery during the Covid-19 pandemic has demonstrated significant adjustments of timing, indications and radicality of surgery in an effort to reduce COVID-19 related complications and has exposed constraints, even in high income countries. Nevertheless, perioperative pulmonary complications and death rates of COVID-19 affected operated women were overall low compared to data reported for other cancers. Failsafe systems are urgently needed to ensure continuity of high standard oncologic care to preserve cancer survival.

Disclosures

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### Abstract 600 Figure 1

**RETROPERITONEAL METASTATIC PELVIC ADAMANTINOMA: A NOVEL LOCATION MIMICKING OVARIAN MALIGNANCY AND REVIEW OF THE CURRENT LITERATURE**

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10.1136/ijgc-2020-ESGO.219

Introduction/Background Adamantinoma is a rare primary low-grade malignant tumour of the appendicular skeleton. It primarily affects the long bones and is most commonly found in the tibia. The disease process has an indolent course and histogenic origin has not been clearly defined, however there have been several suggestions pertaining to a vascular origin in the literature. Local recurrences and lung metastases occur over a protracted duration. Less frequently, they have also been reported elsewhere; including four documented cases of soft tissue and five of pelvic bony adamantinoma. There is only one documented case of adamantinoma of the ovary and one of concurrent unrelated primary tumour. There are also no reports available regarding surgical management of a retroperitoneal adamantinoma of the pelvis within a gynaecological oncology surgical setting. Clinical guidelines have not yet been established.

Results We present the case of a 65-year-old female with known recurrent and metastatic right tibial disease. On further investigation, a Positron Emission Tomography scan identified a primary breast lesion and an 11 cm mass in the right iliac fossa of suspected ovarian malignancy amenable to surgical resection (figure A). The patient underwent total abdominal hysterectomy, bilateral salpingo-oophorectomy and resection of a retroperitoneal mass arising from the pelvic sidewall encompassing the iliac vasculature. The tumour was cleaved from the external iliac artery successfully, however the external iliac vein perforated during dissection. A Satinsky clamp was placed and a small cuff of vein wall was removed alongside adherent tumour. The vein defect was closed with 5–0 prolene, ensuring a patent lumen (figure B). The patient made an uneventful recovery with histology confirming metastatic disease.

Conclusion We present an overview of adamantinoma and highlight a previously undocumented gynaecological oncology surgical approach to this novel location of metastatic disease mimicking possible ovarian malignancy. We further explore disease histogenesis and also comment on an incidental finding or primary breast cancer. Particularly in uncommon locations, its heterogeneous nature presents radiological and histological challenges regarding diagnosis and treatment. Such cases warrant a full complement of MDT specialist knowledge and expertise; with advanced surgical skills and experience regarding retroperitoneal and pelvic sidewall anatomy. We also highlight a paucity of recommendations for surveillance and follow up and propose an individualised approach. We report on this unusual case to assist clinicians in the building of a consensus opinion for optimal adamantinoma case management under current circumstances where formal guidelines do not exist.

Disclosures None
NIRAPARIB IN PATIENTS WITH NEWLY DIAGNOSED ADVANCED OVARIAN BRCAM CANCER: A POST HOC ANALYSIS OF THE PRIMA/ENGOT-OV26/GOG-3012 TRIAL

Introduction/Background
The PRIMA/ENGOT-OV26/GOG-3012 trial showed that niraparib significantly improves progression-free survival (PFS) in patients with newly diagnosed advanced ovarian cancer (aOC) that responded to front-line platinum-based chemotherapy (hazard ratio, 0.62; 95% CI, 0.50–0.76). Based on these results, niraparib has been approved in the United States and the European Union for front-line maintenance treatment in patients with aOC. In this post hoc analysis, we report the efficacy of niraparib in patients with BRCA-mutated (BRCAm) aOC with an emphasis on efficacy and safety of fixed vs. individualized starting doses (FSD vs. ISD).

Methodology
In this double-blind, placebo-controlled, randomised phase 3 trial, patients with newly diagnosed, high-grade aOC who responded to platinum-based chemotherapy were randomised 2:1 to receive FSD of niraparib 300 mg orally once daily (QD) or placebo. The trial was amended to incorporate an ISD of 200 mg orally QD for patients with a body weight <77 kg or platelet count <150,000/μL, and 300 mg QD in patients with a body weight ≥77 kg and platelet count ≥150,000/μL. Patients were stratified by best response to first-line chemotherapy (complete/partial response), receipt of neoadjuvant chemotherapy (yes/no), and homologous recombination status (deficient/proficient and not determined). BRCA status was determined in tumour samples at screening via the myChoice test (Myriad®). The post hoc BRCAm subgroup PFS analysis was performed using a stratified Cox proportional hazards model and Kaplan-Meier methodology. Safety and patient-reported outcome analyses were also performed.

Results
The intention-to-treat population comprised 733 randomised patients, of which 223 (30%) had BRCAm tumours. Of those, 144 (65%) received FSD and 79 (35%) received ISD. Niraparib provided a comparable PFS benefit over placebo in patients receiving both FSD (hazard ratio, 0.44; 95% CI 0.26–0.73) and ISD (hazard ratio 0.29; 95% CI 0.13–0.67). A PFS subgroup analysis by patient characteristics is shown in table 1. A summary of grade ≥3 selected adverse events is shown in table 2.

Conclusion
Niraparib significantly improved PFS when utilised as maintenance treatment after front-line therapy in patients with BRCAm aOC. Patients receiving FSD or ISD derived similar PFS benefit, while the ISD group showed an improved safety profile.

Disclosures
Dr. Graybill reports personal fees from GlaxoSmithKline.
Dr. Redondo reports institutional research funding from PharmaMar, Roche, and Eisai; and advisory roles at PharmaMar, AstraZeneca, Tesaro, Roche, and Eisai.

Abstract 571 Table 1

<table>
<thead>
<tr>
<th></th>
<th>Niraparib</th>
<th>Placebo</th>
<th>Hazard ratio (95% CI)</th>
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<tbody>
<tr>
<td>Starting dose cohort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSD</td>
<td>99</td>
<td>45</td>
<td>0.44 (0.26–0.73)</td>
</tr>
<tr>
<td>ISD</td>
<td>53</td>
<td>26</td>
<td>0.29 (0.13–0.67)</td>
</tr>
<tr>
<td>Age category</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65 years</td>
<td>109</td>
<td>54</td>
<td>0.45 (0.27–0.74)</td>
</tr>
<tr>
<td>≥65 years</td>
<td>43</td>
<td>17</td>
<td>0.20 (0.08–0.48)</td>
</tr>
<tr>
<td>Neoadjuvant chemotherapy</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>102</td>
<td>48</td>
<td>0.43 (0.26–0.73)</td>
</tr>
<tr>
<td>No</td>
<td>50</td>
<td>23</td>
<td>0.35 (0.17–0.72)</td>
</tr>
<tr>
<td>BRCAm, BRCA mutation; FSD, fixed starting dose; ISD, individualised starting dose; PFS, progression-free survival.</td>
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</table>

Abstract 571 Table 2

<table>
<thead>
<tr>
<th>Adverse event, no (%)</th>
<th>Niraparib</th>
<th>Placebo</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FSD</td>
<td>ISD</td>
<td>FSD</td>
<td>ISD</td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia events*</td>
<td>49 (99)</td>
<td>10 (53)</td>
<td>2 (2)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Anaemia</td>
<td>32 (32.3)</td>
<td>16 (30.2)</td>
<td>1 (2.2)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Neutropenia events†</td>
<td>18 (18.2)</td>
<td>7 (13.2)</td>
<td>1 (2.2)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hypertension events‡</td>
<td>9 (9.1)</td>
<td>1 (1.9)</td>
<td>0</td>
<td>2 (8.0)</td>
<td></td>
</tr>
<tr>
<td>aOC, advanced ovarian cancer; BRCAm, BRCA mutation; FSD, fixed starting dose; ISD, individualised starting dose.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Thrombocytopenia events include thrombocytopenia and platelet count decreased.
†Neutropenia events include neutrophil count decreased, neutropenia, and febrile neutropenia.
‡Hypertension events include hypertension and blood pressure increased.
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primary debulking surgery and group 2 (G2), patients who underwent primary chemotherapy with platinum salt followed by cytoreductive surgery (interval surgery).

The anatomo-clinical aspect, the histological type, the intra-operative finding, the procedures performed, the results after surgery, the morbidity and mortality and the survival curves were analysed prospectively.

**Results**
The mean age of patients in G1 was 50.05 years (30–80) and in G2 55.90 years (23–80), the majority of patients were classified ASA I in both groups (51, 2%), the mean body mass index (BMI) was 29.16 in the G1 and 27.29 in the G2, the most frequent histological type was serous carcinoma in both groups (69.5%) of patients. The main procedure performed is a total hysterectomy, bilateral adnexectomy, infra colic or infra gastric omentectomy, pelvic and lumbar aortic dissection and resection of any macroscopically visible lesion.

In some cases, an associated procedure has been performed such as digestive resection, cholecystectomy, peritoneectomy, caudal pancreatectomy. Rate of actions performed in G1: 65.8%; G2: 34.1%. Rate of R0 obtained (41.4%) or 51.5% in G1 and 48.4% in G2. The operative morbidity was 20.7% with a rate of 14.6% in G1 and 6% in G2.

**Conclusion** Complete cytoreductive surgery has become a fundamental principle in surgery for peritoneal carcinomatosis. The gold standard for treating advanced ovarian cancer is complete surgery combined with chemotherapy with platinum salt. The sequence of treatment is still debated, but primary surgery seems to be preferred in terms of recurrence-free survival and overall survival when complete resection (R0) is obtained.

**Disclosures**
Pr Chemseddine CHEKMAN: I declare that I have no conflict of interest.
Dr Fatiha GOUAREF: I declare that I have no conflict of interest.
Pr Kamel BENTABAK: I declare that I have no conflict of interest.
Pr Fatiha HADJARRAB: I declare that I have no conflict of interest.
Pr Kamel BOUZID: I declare that I have no conflict of interest.

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**Abstract 596**

**A RANDOMISED PHASE II STUDY OF NINTEDANIB (BIBF1120) COMPARED TO CHEMOTHERAPY IN PATIENTS WITH RECURRENT CLEAR CELL CARCINOMA OF THE OVARY OR ENDOMETRIUM. (NICCC/ENGOT-OV36)**

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**Introduction/Background** Clear cell carcinoma (CCC) is a rare subtype of ovarian and endometrial cancer. It carries a poor prognosis and response to chemotherapy in recurrent disease is low. As angiogenesis pathways are activated in CCC, we performed a trial comparing nintedanib (BIBF1120), an orally available, triple kinase inhibitor targeting VEGFR, PDGFR and FGFR with physician’s choice of chemotherapy. As the first randomised trial in relapsed CCC, it gives important information on the efficacy and toxicity of both nintedanib and chemotherapy. Here we report the ovarian cancer (OC) results.

**Methodology** This was an international, multi-centre, randomised, open label phase II, 3 outcome design. Patients were randomised to nintedanib 200 mg PO twice daily or chemotherapy (paclitaxel (80 mg/m2 IV Day 1,8,15), pegylated liposomal doxorubicin (40 mg/m2 IV) or topotecan (4 mg/m2 IV Day 1,8,15) every 28 days). Treatment was given until disease progression or unacceptable toxicity. The primary endpoint was progression free survival (PFS) in the ovarian cohort. Secondary objectives included overall survival (OS), response rate (RR), disease control rate (DCR) and patient reported outcomes. With 90 OC patients, the study was powered to detect an improvement in median PFS from 3 to 5 months (HR=0.6) with >90% power, 20% 1-sided significance. A statistically significant PFS difference at the 1-sided 10% level (Nintedanib superior) would give a clear signal that a phase III study is warranted. A statistically significant
result at the 1-sided 20% level would require other supportive evidence. EudraCT Ref:2013-002109-73. ISRCTN No: ISRCTN50772895.

Results 91 OC patients were included in the analysis. Median age was 54 years. Median number of previous lines was 2. After a median follow up of 20.7 months the median PFS was 2.3 months with nintedanib and 1.9 months with chemotherapy (hazard ratio=0.79, 80% CI=(0.58,1.06), p(1-sided) =0.1521. Median OS was 9.0 and 4.9 months, respectively. Difference in OS estimates at 6 and 12 months were 19.7% and 8.9% demonstrating non-proportional hazards. RR was 2.1% and 0%, and DCR at 16 weeks was 23.4% and 9.1% (odds ratio=5.81, 80%CI=(1.79,18.89), p(1-sided) =0.0276) with nintedanib and chemotherapy, respectively.

Conclusion The study failed to demonstrate sufficient activity of nintedanib as a monotherapy to support a phase III trial. However, the benefit in PFS, DCR and OS suggests it may be interesting to combine nintedanib with other agents in OCCC. Chemotherapy is ineffective and the outcomes for women with OCCC are extremely poor confirming the need for continued research into novel targets and therapies. Translational research is on-going (figures 1 and 2).

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Isabelle Ray-Coquard: Honoraria (self) from Abbvie, Agenus, Advaxis, BMS, PharmaMar, Genmab, Pfizer, AstraZeneca, Roche, GSK, MSD, Deciphera, Meserna, Merck Sereno, Novartis, Amgen, Tesaro and Clovis; honoraria (institution) from GSK, MSD, Roche and BMS; advisory/consulting fees from Abbvie, Agenus, Advaxis, BMS, PharmaMar, Genmab, Pfizer, AstraZeneca, Roche/GeneTec, GSK, MSD, Deciphera, Meserna, Merck Sereno, Novartis, Amgen, Tesaro and Clovis; research grant/funding (self) from MSD, Roche and BMS; research grant/funding (institution) from MSD, Roche, BMS, Novartis, AstraZeneca and Merck Sereno; and travel support from Roche, AstraZeneca and GSK.

Prevention of gynaecologic cancer

577 EARLY SALPINGECTOMY (TUBECTION) WITH DELAYED OOPHORECTOMY AS AN ALTERNATIVE FOR RISK-REDUCING SALPINGO-OOPHORECTOMY TO IMPROVE QUALITY OF LIFE IN WOMEN WITH A BRCA1/2 PATHOGENIC VARIANT (TUBA STUDY): A PROSPECTIVE MULTICENTER PREFERRENCE TRIAL

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to women with a BRCA1/2 pathogenic variant (PV). To prevent premature menopause, risk-reducing salpingectomy (RRS) is considered, because recent data indicate the Fallopian tube instead of the ovary as origin of high grade serous ovarian carcinoma (HGSC). Based on this hypothesis, the TUBA study (NCT02321228) compares quality of life (QoL) between the novel RRS with delayed oophorectomy (RRO) and standard RRSO.

Methodology Within this national multicenter preference trial, BRCA1/2-PV carriers chose between the novel strategy (RRS) upon completion of childhood and RRO at age 40–45 (BRCA1) or 45–50 (BRCA2)) and the standard strategy (RRSO at age 35–40 (BRCA1) or 40–45 (BRCA2)). The primary outcome is menopause-related QoL, measured by the Greene climacteric scale (GCS). A higher sum of the GCS represents more menopausal complaints.

Results A total of 577 women were included, 51.5% carried a BRCA1-PV, and 72% chose the novel RRS with delayed RRO. Until now, 394 women underwent RRS and 154 RRSO of which 30% did not start hormone replacement therapy (HRT). Without HRT, the adjusted mean increase from baseline on the GCS was 0.6 points (95% confidence interval (CI) 0.0;1.1) one year after RRS and 7.7 points (95% CI 6.2;9.9) one year after RRSO. Thus, the adjusted mean difference between the treatment groups was 7.2 (95% CI 5.4;9.0, P<0.001). In women with HRT and RRSO, a difference of 3.4 points (95% CI 2.2;4.6, P<0.001) was found compared to RRS. For sexual functioning, women without HRT had an increase of 0.4 points (95% CI -0.3;1.1) one year after RRS and a decrease of 5.7 points (95% CI -8.7;-3.7) one year after RRSO. A decrease of 1.6 points (95% CI -3.2;0.0) was found one year after RRSO with HRT. A decrease represents a worsening of sexual functioning. No differences in cancer worry, decisional conflict or decisional regret were found between groups. No HGSC has occurred during follow-up.

Conclusion Menopause-related QoL is better after novel RRS when compared to RRSO in women with a BRCA1/2-PV, regardless of HRT use. Moreover, sexual functioning is better at one year after RRS. No cancers have occurred since RRS, but follow-up is too short to draw conclusions on safety. An international follow-up study is currently recruiting to evaluate the oncological safety of RRS with delayed RRO (TUBA-WISP II, NCT04294927).

Disclosures Nothing to disclose.

Quality of life after treatment

612 VAGINAL RADIOFREQUENCY FOR THE TREATMENT OF GENITAL ATROPHY IN PATIENTS WITH ONCOLOGICAL HISTORY IN A PUBLIC HOSPITAL. LIFE AFTER CANCER

Rocio Garcia Berrio, Alvaro Zapico Górriz, Aldina Couso Gonzalez, Patricia Lopez Arribas, Beatriz Moya Esteban, Altea Reyes Ibóna. Hospital Príncipe DE Asturias; Hospital Universitario Príncipe de Asturias; Gynaecology and Obstetrics
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Introduction/Background Menopausal symptoms can impact quality of life. The goal of this prospective research is the clinical improvement on vulvovaginal sphere with vulvovaginal radiofrequency in cancer survivors.

Methodology Between June 2019 and February 2020 we apply vulvovaginal radiofrequency to 11 menopausal patients unresponsive to standard treatments. Symptoms are checked 6 months later.

Requirements Benign cytology and normal examination Non active vaginal infection Stable oncological process for at least 5 years

Materials Monopolar vulvovaginal radiofrequency generator Dermatology Life Quality Index (DLQI) before and after (figure 1) Record of the mean main symptom and photo shooting.
Method Specific and approved by Hospital protocol and Informed consent Number of sessions depends on response
Maximum power applied: 3000 ms in two rounds in vulva and vagina Clinical control at 3,6 and 12 months

Results The mean age is 55 years with ages between 43 and 71. Natural or medical mean menopause age is 48.87 ± 8.17 years.

Clinical history of patients: 63.6% (n=7) breast cancer, 27.3% (n=3) early stage endometrial cancer and 9.1% (n=1) of benign metastasizing leiomyomatosis.

When consulted, 63.6% (n=7) of the patients complained mainly of dyspareunia, 18.2% (n=2) of itching and 18.2% (n=2) of dryness. The average time of previous treatment had been 13.3 months. 54.5% (n=6) had received treatment with moisturizers, 36.3% (n=4) with steroids and 9.1% (n=1) did not tolerate any topical treatment. Patients with a history of endometrial cancer receive radiofrequency exclusively in external genitalia.

The average power used is 2491 ms (1700–3000)

They have received radiofrequency every 25.93 days with an average of 6 sessions per patient.

Qualitative evaluations According to the DLQI scale, patients presented symptoms before/after the treatment

- No effect on patient’s life: (n=0)/36.4% (n=4)
- Small effect: 45.4% (n=5)/54.5% (n=6)
- Moderate effect: 27.3% (n=3)/9.1% (n=1)
- Very large effect: 27.3% (n=3)/(n=0)

Of the 11 patients, not all of them have been followed for a year, so the assessment of their condition is presented after 6 months. In these the DLQI scale has varied clinically > 4 in 6 of them. In those that have not, however, the clinical range has changed in 8 of them (figure 2).

The improvement in quality of life is significant in this group (p < 0.008, Wilcoxon signed rank test) until treatment is well tolerated by 100% of patients. Immediately, 18.2% (n=2) of the patients showed slight discomfort but it disappeared spontaneously (figures 1 and 2).

Conclusion While we wait more cases and more time for their evolution, radiofrequency is presented to us as a good alternative for genital atrophy in those patients who are symptomatic, who do not respond to usual therapies and in whom treatment with local oestrogens may not be ideal. Well tolerated and with good clinical response.

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Translational research

**428 GENOMIC INSTABILITY METRIC CONCORDANCE BETWEEN ONCOSCAN™, CYTOSNP AND AN FDA-APPROVED HRD TEST**

Razvan Cristescu, Xiao Qiao Liu, Gladys Areaza, Cai Chen, Andrew Albright, Fing Qu, Matthew Marton. Hospital Merck and Co., Inc

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Introduction/Background Various biomarkers have been investigated to identify patients likely to respond to PARP inhibition. PARP inhibitor olaparib plus bevacizumab is approved by the US FDA as maintenance therapy for homologous recombination deficiency (HRD)-positive advanced ovarian cancer; the FDA contemporaneously approved a commercial assay as a companion diagnostic for HRD assessment that includes a genomic instability biomarker. Other genomic platforms measuring HRD are available or in development, including single-nucleotide polymorphism (SNP) genotyping arrays designed to measure tumour-related copy number changes. We evaluated the performance of OncoScan™ (ThermoFisher) and Infinium CytoSNP-850K (CytoSNP; Illumina) for assessing HRD genomic instability.

Methodology DNA extracted from pretreatment archival tumour samples (N=126 across 20 indications) was evaluated with Oncoscan™, CytoSNP and an FDA-approved HRD test. ASCAT (v2.5.1), using log R ratio and B-allele frequency of autosomal markers with GC wave correction, was used to evaluate copy number variation (CNV) and loss of heterozygosity (LOH). The genomic metrics were further generated with default parameters using previously reported algorithms for LOH,2 number of telomeric-allelic imbalance (NTAI)3 and large-scale state transition (LST)4; the aggregate HRD metric was the sum of the three components. The association between genomic metrics (with BRCA deleterious alterations) and an FDA-approved HRD test metric (dichotomised at clinical cutoff) was calculated using AUROC. Correlations among continuous metrics were assessed using Spearman rank correlation coefficients.

Results CNV segmentation and genomic metrics were successfully calculated for 120 (Oncoscan™), 106 (CytoSNP) and 126 (FDA-approved test) samples. Assessed by SNP genotyping arrays, the genomic metric as a continuous variable demonstrated good association with deleterious BRCA alterations.
and the FDA-approved test at cutoff 42 (AUROC of HRD: Oncoscan™, 0.87; CytoSNP, 0.75) (table 1) and the FDA-approved test at cutoff 42 (AUROC of HRD: Oncoscan™, 0.92; CytoSNP, 0.91) (table 2). The genomic metric as a continuous variable showed good correlation with the FDA-approved HRD test metric (Spearman correlation of HRD: Oncoscan™, 0.82; CytoSNP, 0.81). The Spearman correlation of genomic metrics with the FDA-approved HRD test metric was 0.68 (LOH), 0.76 (TAI), 0.78 (LST) and 0.82 (HRD) for Oncoscan™ and 0.59 (LOH), 0.77 (TAI), 0.82 (LST) and 0.81 (HRD) for CytoSNP.

Conclusion HRD as a continuous variable assessed by SNP genotyping arrays showed good correlation with an FDA-approved HRD test metric; SNP assays may potentially be able to identify most HRD-positive tumours if appropriate clinically relevant cutoffs can be determined.

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Razvan Cristescu is an employee of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, and has stock ownership interests in Merck & Co., Inc., Kenilworth, NJ, USA.

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Ping Qiu is an employee of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, and has stock ownership interests in Merck & Co., Inc., Kenilworth, NJ, USA.

Matthew Marton is an employee of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, and has stock ownership interests in Merck & Co., Inc., Kenilworth, NJ, USA.

CIRCULATING TUMOUR CELLS IN BREAST AND OVARIAN CANCER: SIZE-BASED ISOLATION AND EX VIVO EXPANSION

Bashir Mohamed, Mark Ward, Mark Bates, Cathy Spillane, Tanya Kelly, Cara Martin, Michael Gallagher, John Kennedy, Fees Abu Saadeh, Noreen Gleeson, Doug A Brooks, Robert D Brooks, Stavros Selemidis, Sean Hannify, Eric P Dixon, Sharon O’toole, John O’Leary, Trinity College Dublin; Trinity St James’s Cancer Institute, Dublin 8, Ireland; Hope Directorate, St. James’s Hospital, Dublin 8, Ireland; Trinity St James’s Cancer Institute, Dublin 8, Ireland; Trinity College Dublin; Cancer Research Institute, University of South Australia; Cancer Research Institute, University of South Australia; School of Health and Biomedical Sciences, Rmit University, Bundoora, Victoria, Australia, 3083; Bd Research Centre Ireland, Limerick, Ireland; Bd Technologies and Innovation, Research Triangle Park, Nc, USA. 10.1136/ijgc-2020-ESGO.229

Introduction/Background Circulating tumour cells (CTCs) play a crucial role in cancer dissemination and cellular
extravasation leading to metastasis. There are only a limited number of CTCs per clinically/ethically allowed cancer patient’s blood draw and expanding this population of cells in vitro is crucial in order to provide a reliable number of cells to analyse CTC biology. CTCs can grow in a hypoxic environment and the activation of hypoxia-inducible factor (HIF-1α) results in increased cell survival and cellular proliferation, leading to cancer progression. Our aim was to optimise cell culture conditions using cobalt chloride (CoCl2) as a chemical inducer of hypoxia that would allow us to examine growth of cells in real time. Primary ovarian cancer cells would be used for the hypoxia optimisation and conditions adapted ovarian/breast CTC cultures in vitro.

**Methodology** Primary ovarian cancer cells were cultured in modified media supplemented with various concentrations of CoCl2 for HIF1α induction (50, 100, 150 and 200 uM). Cell viability and the expression of HIF-1α, PHH3, EpCAM and HER2 were examined in these cells using either ELISA, Immunoblotting or Immunofluorescence techniques. CTCs were isolated from breast and ovarian cancer patients using the ScreenCell® Cyto R device and cultured in specially modified media optimised for CTC culture supplemented with 20% FCS, growth factors and additives including: FGF-2, FGF-10, Nicotinamide, Y-27632, Primocin and CoCl2. EpCAM and HER2 were examined in cultured and expanded CTCs using Immunofluorescence techniques.

**Results** HIF-1α expression was induced and cell proliferation and viability were maintained in the primary ovarian cancer cells at a concentration of 100 µM of CoCl2. Subsequently this concentration was used for the culturing of isolated CTCs. Using this condition, CTCs were successfully cultured and expanded for more than nine weeks. Based on the morphological and phenotypical characterisation, two phenotypes of CTCs were isolated from a breast cancer patient: epithelial-like expressed EpCAM and quasi-mesenchymal express HER2.

**Conclusion** We demonstrated the feasibility of culturing cancer patient blood derived CTCs under hypoxic conditions. We also demonstrated the presence of heterogenous CTC populations; classical epithelial-like CTCs and quasi-mesenchymal subtypes in a breast cancer patient and their corresponding molecular phenotypes. Our work also demonstrated the suitability of size-based isolation for this culturing approach.

**Disclosures** The authors have no conflict of interest.

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**REFERENCES**


### Vaginal and vulvar cancer

**606 ANGIOMYOFIBROBLASTOMA VULVAR: CASE REPORT AND LITERATURE REVIEW**

Sandra Marcela Buitrago, Carolina Morante Caicedo, Luis Orlando Puentes. Gynecology and Obstetric department. Pontificia Universidad Javeriana. Hospital Universitario San Ignacio, Bogotá (Colombia)

**Introduction/Background** Angiomyofibroblastoma is part of the benign mesenchymal tumors of the genital tract and was first described by Fletcher in 1992. The vulva represents the main presentation site, but cases have been described at the level of the vagina, cervix, fallopian tubes, the scrotum and the ischiorectal fossa. It presents as a mass, generally painless, with well-defined edges and without compromising the overlying skin. It is normally less than 5 cm, but cases of up to 37 cm have been described.

**Methodology** A 45-year-old woman with a 1 month history of painful vulvar mass of progressive growth. Physical examination reveals a stony, mobile mass of 5×5 cm in right labia majora. Initial immunostaining suggested an AMFB, so she was taken to vulvectomy. A review was made of all articles in English or Spanish, published until March 10, 2019, related to the diagnosis and treatment of vulvar AMFB. The search included the PubMed, Embase, Cochrane, LILACS and Scielo databases, with the keywords "Vulvar Angiomyofibroblastoma" OR "Angiomyofibroblastoma of the vulva with sarcomatous transformation".

**Results** A total of 69 reported cases were found. In our knowledge, the case presented is the first report of AMFB in Colombia. The age of the patients ranged between 16 and 82 years, with an average of 43 years. The main presenting symptom was the presence of a non-painful vulvar mass, although some of the patients in the reported cases reported pain and dyspareunia (8/69). The evolution time varied between 1 month and 9 years with an average of 21 months, and the size between 1 and 37 centimeters with an average of 7 centimeters. Of the cases taken to immunohistochemical study, 86% were positive for estrogen receptors and 80% for progesterone receptors, 88% were positive for desmin and 98% for vimentin, 92% were negative for S100 and the cases that were positive corresponded to the lipomatous variant, 43% were positive for α-SMA and 34% for CD 34. Definitive diagnosis is based on histological findings. In this reviewed cases, only one relapse was reported. The universal treatment is excision and only one case of relapse was reported, which corresponded to the only reported case of malignant transformation.

**Conclusion** Vulvar AMFB is a rare mesenchymal tumor, with exclusive surgical treatment and excellent prognosis, although it may have malignant transformation. The reported case could represent the second case of AMFB with malignant transformation.
ANGIOMYOFIBROBLASTOMA VULVAR: CASE REPORT AND LITERATURE REVIEW

Sandra Marcela Buitrago, Carolina Morante Caicedo, Luis Orlando Puentes. Gynecology and Obstetric department. Pontificia Universidad Javeriana. Hospital Universitario San Ignacio, Bogotá (Colombia)

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Conclusion Vulvar AMFB is a rare mesenchymal tumor, with exclusive surgical treatment and excellent prognosis, although it may have malignant transformation. The reported case could represent the second case of AMFB with malignant transformation.

Disclosures

Organization of gynaecological cancer care

INTRODUCTION/BACKGROUND Complete cytoreductive surgery and platinum-based chemotherapy is standard of care in the United Kingdom (NICE, 2011), yet studies indicate substantial variation in the utilization of both (Kumar et al, 2016, Hall et al). Recent work from the Netherlands shows variations in treatment for ovarian cancer across regions; however, contribution to survival was unclear (Timmermans et al, 2019). Care that
Abstracts

Abstract 604 Figure 2  A) Variation across 19 Cancer Alliances in England for patients with advanced OC receiving surgery: women diagnosed 2016–2018
B) Survival analysis from 19 Cancer alliances in England women diagnosed 2013–2017

Interpretation - Stressing differences in the time coverage & cohort definitions, cross-referencing treatment variation & survival analyses suggests Cancer Alliances less likely to undertake surgery had generally lower than average five year survival

is not compliant with guidelines is also seen in other countries, including the USA (Warren et al, 2017).

As part of the Ovarian Cancer Audit Feasibility Pilot, geographic variation in treatment was investigated with the objective of informing improvements in treatment and outcomes for all women diagnosed with ovarian cancer in England.

Methodology Ovary, fallopian tube and primary peritoneal carcinomas (‘ovarian cancers’) diagnosed between January 2016 and December 2018 were audited using data extracted from the national cancer registry (Henson et al,). Borderline tumours were excluded. Data is routinely collected for every patient with cancer in England through a national dataset; Cancer outcomes and Services Dataset (COSD). This information was supplemented with relevant data from the Systemic Anti-Cancer Therapy (SACT) dataset for patients receiving chemotherapy and Hospital Episode Statistics (HES) for admitted patients. Linear probability models were constructed adjusting for tumour morphology, stage at diagnosis, patient age at diagnosis; Charlson comorbidity index, area income deprivation. Tumours with stage 1 disease at diagnosis were excluded from analysis of variation in treatment. Treatment variations across the 19 cancer alliances (units of geography) were evaluated. Survival analyses were extracted from a previous cohort diagnosed 2013–2017.

Results Treatment received in 13,889 ovarian cancers was analysed. The weighted average probability (range for cancer alliances) of a stage 2–4 ovarian cancer receiving any treatment, any surgery, and any chemotherapy across England was 73.8% (70.4% - 79.3%), 51% (37.2% - 58.9%) and 66.5% (61.8%-73.6%) respectively (figure 1). One-year net survival for the 19 Cancer Alliances in England varied between 62.9% and 73.6%) respectively. One-year net survival for the 19 Cancer Alliances in England varied between 62.9% and 73.6% respectively. One-year net survival for the 19 Cancer Alliances in England varied between 62.9% and 73.6% respectively.

Conclusion Significant variation in treatment and survival across England are demonstrated in this audit. The population-based nature of this robust audit indicates that our findings are likely to be relevant to international settings. Efforts to understand and reduce variation in treatment decision making and reducing the proportion of women not receiving treatment are critical to improving survival in ovarian cancer.

Ongoing audit of treatment will be key to driving and monitoring progress.

622 APPLICABILITY OF DUKE ACTIVITY SCALE INDEX (DASI) IN PERIOPERATIVE PREDICTION OF POSTOPERATIVE COMPLICATIONS FOR GYNAECOLOGY PATIENTS

Introduction/Background Cohort of patients with multiple comorbidities, obesity and frailty requiring gynaecological interventions is continuously increasing and because of that there is an unmet need for an accurate perioperative risk prediction. The Duke Activity Scale Index (DASI) is a 12 item self-reported questionnaire based around commonly performed activities. DASI score determines functional capacity through conversion to Metabolic Equivalent of task (METs), which have been shown to indicate fitness for surgery. In our study we continue to investigate the accuracy of DASI in prediction of postoperative outcomes in the context of gynaecology.

Methodology A retrospective data for 290 patients was collected using a dedicated gynaecology database or patients' notes at a tertiary oncology centre. All of the patients had filled the DASI questionnaire prior to surgery, which we used for the analysis. Actual postoperative complications which occurred within 30 days of the surgery were also recorded. The DASI score was then compared with the occurrence of postoperative complications.

Results According to our preliminary analysis of 141 patients DASI score has not found to be a statistically significant model for prediction of postoperative complications in the general population of the gynaecology patients (AUC=0.433). However we were able to show that a 25 point higher DASI score is predicted to deliver 1 day less in hospital. We also found that DASI score could be promising for...
patients with ovarian and cervical malignancy (AUC-0.634 and AUC 0.750 respectively), but there were not enough patients to validate the findings in the analysed cohort (figures 1 and 2).

Conclusion DASI is an uncomplicated and straightforward tool that could be useful in perioperative estimation of postoperative complications for ovarian and cervical cancer patients. Further analysis with a larger sample size and multicentre prospective study are currently underway to validate the findings.

Disclosures There are no disclosures to be made.

Introduction/Background Accurate postoperative surgical risk assessment is essential for surgeons and patient for assessment of potential post-operative complications especially with increasing numbers of patients with multiple comorbidities and frailty. Currently the most widely used risk scoring tool for post-operative risk prediction in the UK is P-POSSUM. Published data suggests that P-POSSUM overestimates risk causing undue patient anxiety.

We continue to explore the accuracy of the ACS-NSQIP (American College of Surgeons National Surgical Quality Improvement Program) surgical risk calculator which is a validated web-based tool based on 21 preoperative risk factors to predict 8 post-operative outcomes and compare it with P-POSSUM.

Methodology R&D approved retrospective study on 1200 patients undergoing robotic, laparoscopic and open surgery between 2009–2020. Data collection done through a dedicated gynaecology database at a tertiary referral cancer centre by both anaesthetic and gynaecology team. Data collated on 540 patients undergoing robotic, 71 laparoscopic and 350 open surgery for suspected or confirmed gynaecological malignancy. Missing data collected from patient notes. Following data lock with actual post-op event that occurred in this retrospective cohort, the risk calculators were used to calculate predictive scores. Mortality and morbidity predictions using the Portsmouth modification of the POSSUM and ACS algorithm were compared to the actual outcomes separately.

Baseline analysis of 153 patients undergoing robotic surgery was undertaken to explore possible co-relation between both two tools and to understand if they could be used to enhance patient understanding of risk in a subsequent prospective study. Data analysis evaluating P-POSSUM and ACS-NSQIP to assess its validity and relevance in gynaecological oncology patients undergoing robotic surgery performed.

Results P-POSSUM reports on mortality and morbidity only; ACS-NSQIP reports individual complications as well. ACS-NSQIP risk prediction was most accurate for VTE(AUC-0.793), pneumonia(AUC-0.657) and it showed 90% accuracy in prediction of 5 major complications (Brier score 0.01). Morbidity was much better predicted by ACS-NSQIP than by P-POSSUM (AUC-0.608 vs AUC-0.551) with same result in mortality (Brier score 0.0000). Moreover a statistically significant overestimation of morbidity has been shown by P-POSSUM calculator (p=0.018).

Conclusion The ACS-NSQIP risk calculator appears to be better predictor of major complications and mortality and it may be used by surgeons as an informed consent tool. Preliminary data suggests further validation needs to be performed to evaluate if the risk scores may be used to inform patients preoperatively of their risk of complications and is currently being rolled out in a multi-centre model.

Disclosures There are no disclosures to be made.
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