Abstract 159 Table 1 Main results

All patients	
N	67 (100%)
Cancer types	
Ovarian	44 (65.7%)
Uterine	15 (22.4%)
Other	8 (11.9%)
Profiling test results	
No alteration detected	18 (26.9%)
Not enough specimen	1 (1.5%)
Alteration detected	38 (56.7%)
Ongoing	10 (14.9%)
Treatments	
Targeted therapy (off label)	11/38 (28.9%) +1/38 (2.6%)
Targeted therapy in patients with BRCA mutations within approved guidelines	5/38 (13.2%)
No therapy for progressive disease/DOD before starting	21/38 (55.3%)

Abstract 159 Table 2 Patients who actually started a FoundationONE® CDx off-label guided therapy.

Patient	Cancer type	Alteration detected	Treatment started (off-label)	Clinical outcome
#1	High grade serous ovarian cancer	CCND1 - E275*	Ribociclib	Stability of disease; Treatment ongoing (5 months)
#2	Endometrioid endometrial cancer	PIK3CA E545K	Everolimus Exemestane	Stability of disease; Treatment ongoing (6 months)
#3	Mixed endometrial cancer	KRAS - D33E	Trametinib	1 month treatment then clinical progression of disease
#4	Endometrioid ovarian cancer	PIK3CA - H1047L	Everolimus-Exemestane	Stability of disease; Treatment ongoing (5 months)
#5	Endometrioid endometrial cancer	CCND1 - amplification - equivocal	Palbociclib	1 month treatment then clinical progression of disease
#6	High grade serous ovarian cancer	BRCA1 - A1708E	Niraparib	3 months of stability of disease
#7	High grade serous ovarian cancer	BRCA1 - rearrangement intron 12	Talazoparib	4 months of stability of disease
#8	Cervical adenocarcinoma	ERBB2 – amplification	Trastuzumab	4 months of stability of disease
#9	High grade serous ovarian cancer	KRAS- Q22K NF1- W2317	Trametinib	9 months of stability of disease
#10	Endometrioid endometrial cancer	PIK3CA - E545K	Everolimus	Stability of disease; treatment ongoing (>12 months)
#11	High grade serous ovarian cancer	BRCA1 - splice site 787+1G>T	Niraparib	1 month treatment then clinical progression of disease

timing of the molecular test-guided therapies. Nevertheless, with the increasing use of target-based therapy, accessibility should be granted for all patients.

IGCS20_1146

160 THE IMPACT OF HYSTEROSCOPY ON THE DISEASE COURSE OF HIGH GRADE ENDOMETRIAL CARCINOMA

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Background With hysteroscopy, concerns have surfaced regarding intraperitoneal spread of endometrial cancer (EC); no studies have evaluated the effect of hysteroscopy on the disease course of a large series of patients with exclusively high risk histology.

Methods Patients who underwent hysterectomy for grade 3 EC at Mayo Clinic in Rochester, MN between January 2009-June 2016 were included, noting hysteroscopy within 6 months. Follow-up was restricted to five years. Cox proportional hazards models were fit to evaluate associations between hysteroscopy exposure and progression.

Results Among 831 patients, 133 underwent hysteroscopy. Patients with versus without hysteroscopy did not differ in mean age (67.7 vs. 67.8 years), BMI (31.6 vs. 31.3 kg/m2), ASA $\geq$3 (35.3% vs. 38.3%), or serous histology (47.4% vs. 48.7%). Advanced disease (III/IV) was less common among hysteroscopy patients (30.1% vs 43.8%, p=0.003). No difference was observed between those with hysteroscopy versus without (all p>0.05) in positive cytology (22.0% [26/118] vs. 29.7% [191/643]), stage IV disease (16.5% [22/133] vs. 21.9% [153/698]), any positive cytology OR adnexal invasion OR stage IV (28.6% [38/133] vs. 36.1% [252/698]), the aforementioned OR peritoneal recurrence within 2 years (30.8% [41/133] vs. 39.3% [274/698]). After stratifying by stage, hysteroscopy did not increase risk of progression (HR 1.06, 95% CI 0.59–1.92 for stage I/II; HR 0.96, 95% CI 0.62–1.48 for stage III/IV).

Conclusion In this retrospective study of high grade EC, we did not observe any significant association between pre-operative hysteroscopy EC and incidence of positive cytology, peritoneal disease, or progression.

IGCS20_1147

161 PREDICTION OF OVARIAN CANCER USING A MULTIVARIATE ASSAY: A RANDOMIZED CONTROLLED TRIAL TO IMPROVE DIAGNOSTIC STRATEGIES IN FILIPINO WOMEN (PRELIMINARY RESULTS OF THE OVERA STUDY)

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Introduction In our setting, conventional utilization of clinico-diagnostic, sonographic and single biochemical marker characteristics predominates the pre-operative evaluation of ovarian masses, while the value of multivariate assays has yet to be elucidated. In this study, a multivariate assay (OVERA®) was compared to singular and combined models for malignancy risk calculation.

Methods This is an ongoing randomized controlled trial using OVERA among Filipino women with ovarian masses in the

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University of the Philippines - Philippine General Hospital. A preliminary analysis comparing OVERA and other strategies for malignancy risk prediction was performed.

Results As of this report, 347 women have been enrolled in the study. Based on sonologic classifiers, high risk patients had higher predictive scores using LR1 (χ2[2]: 260.81, p<0.01), LR2 (χ2[2]: 271.57, p<0.01), Sassone (χ2[2]: 127.26, p<0.01), Lerner (χ2[2]: 153.98, p<0.01), IOTA-ADNEX (χ2 [2]: 215.22, p<0.01), and ROMA (χ2[2]: 144.48, p<0.01). Based on categorical classifiers, CA-125 (χ2: 34.59, p<0.01), OVERA (χ2: 54.25, p<0.01), and ROMA (χ2: 85.29, p<0.01) discerned well in the high-risk group, while HE4 (χ2: 105.10, p<0.01) discerned lower risk better. OVERA as a numerical variable appears to fare well in detecting the likelihood of malignant tumors (χ2[4]: 3.38, p: 0.50) as compared to sonologic models but was not as discerning as other models using the conventional cut-off value (5.0). A higher cut-off (6.9) would confer more optimal values of specificity across age (pre-menopausal or menopausal) and histopathologic types.

Conclusion The preliminary results stress the importance of population based studies in evaluating biochemical assays for ovarian cancer risk prediction.

IGCS20_1148

162 ABDOMINAL RADICAL TRACHELECTOMY VERSUS CHEMOTHERAPY FOLLOWED BY VAGINAL RADICAL TRACHELECTOMY IN STAGE 1B2 (FIGO 2018) CERVICAL CANCER. A SYSTEMATIC REVIEW ON FERTILITY AND RECURRENCE RATES

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Introduction There is currently no standard of care for women with cervical cancer stage IB2 (FIGO 2019, diameter 2–4 cm) who wish to preserve their fertility. Generally, two approaches are offered. Option 1: neoadjuvant platinum-based chemotherapy (NACT) to reduce the tumor size to ≤ 2 cm, followed by Vaginal Radical Trachelectomy (VRT) with Pelvic Lymph Node Dissection (PLND) either before chemotherapy or at the time of VRT. Option 2: Abdominal Radical Trachelectomy (ART) with PLND.

Objective To compare rates of fertility, pregnancy, life births as well as recurrence for women with cervical cancer stage IB2 treated with either NACT followed by VRT, or ART.

Methods A systematic review was performed using the PubMed database. Articles reporting the search term 'trachelectomy' as text word or as Medical Subject Headings (MeSH) were identified.

Results Ten studies were identified with a total of 338 patients. After NACT followed by VRT 39% of the women tried to conceive, 70% of these women got pregnant, of which 63% resulted in a life birth. The overall recurrence and death rate were 10% and 2.9% respectively. After ART 40% of the women tried to conceive, 21% of these women got pregnant, which resulted in a life birth rate of 42%. Recurrence and death rate after ART were 6.9%, and 3.4% respectively.

Conclusion Women with cervical cancer stage IB2 and a wish to preserve fertility treated with NACT followed by VRT have a significantly higher chance of pregnancy than women treated with ART, with comparative oncological results.

IGCS20_1150

164 ENGOT-CX11/GOG 3047/KEYNOTE-A18: A PHASE 3, RANDOMIZED, DOUBLE-BLIND STUDY OF PEMBROLIZUMAB WITH CHEMORADIOTHERAPY IN PATIENTS WITH HIGH-RISK LOCALLY ADVANCED CERVICAL CANCER

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Background High-risk locally advanced cervical cancer (CC) has a poor prognosis, and >50% of patients recur in 2 years. Concurrent chemoradiotherapy (CRT) may enhance the immunostimulatory activity of the PD-1 inhibitor pembrolizumab. After KEYNOTE-158, in which pembrolizumab demonstrated durable antitumor activity, pembrolizumab monotherapy was approved for patients with PD-L1–positive recurrent or metastatic CC who progressed during or after chemotherapy. ENGOT-cx11/KEYNOTE-A18 (NCT04221945) is a phase 3, randomized, placebo-controlled study evaluating pembrolizumab with concurrent CRT in locally advanced CC.

Trial design Approximately 980 patients with high-risk, locally advanced, histologically confirmed CC who have not received systemic therapy, immunotherapy, definitive surgery, or radiation will be randomized 1:1 to receive 5 cycles of pembrolizumab 200 mg Q3W + CRT (5 cycles [with optional 6th cycle] of cisplatin 40 mg/m2 Q1W + external beam radiotherapy [EBRT] followed by brachytherapy) followed by 15 cycles of pembrolizumab 400 mg Q6W or 5 cycles of placebo Q3W + CRT followed by 15 cycles of placebo Q6W. Randomization is stratified by planned EBRT type, cancer stage at screening, and planned total radiotherapy dose. Treatment will continue until patient receives ≤20 cycles of pembrolizumab (5 cycles 200 mg Q3W, 15 cycles 400 mg Q6W) vs placebo (~2 years) or until disease progression, unacceptable toxicity, or withdrawal. Primary endpoints are PFS per RECIST v1.1 by blinded independent central review and OS. Secondary endpoints include PFS at 2 years, OS at 3 years, complete response at 12 weeks, ORR, PFS and OS in PD-L1–positive patients, and safety. Enrollment is ongoing.

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