IGCS 2024 Annual Global Meeting DUBLIN
OCTOBER16-18, 2024

IGCS 2024 Abstracts:

Regular Submission Short Oral Presentations (IGCS Poster Talk Sessions)

Short oral abstract presentations are included in the below sessions. The sessions will be recorded for on-demand viewing via the IGCS 360 Educational Portal.

IGCS POSTER TALKS 01
Wednesday, October 16, 2:00 – 3:15 PM | The Liffey B

IGCS POSTER TALKS 02
Friday, October 18, 2:30 – 3:30 PM | The Liffey B

PT001 / #646

IGCS POSTER TALKS 01

Topic: *AS03. Cervical Cancer*

POSTOPERATIVE CHEMOTHERAPY FOR EARLY-STAGE, INTERMEDIATE-RISK CERVICAL CANCER NOT MEETING SEDLIS CRITERIA: A PRELIMINARY ANALYSIS OF A RANDOMIZED CONTROLLED CLINICAL TRIAL

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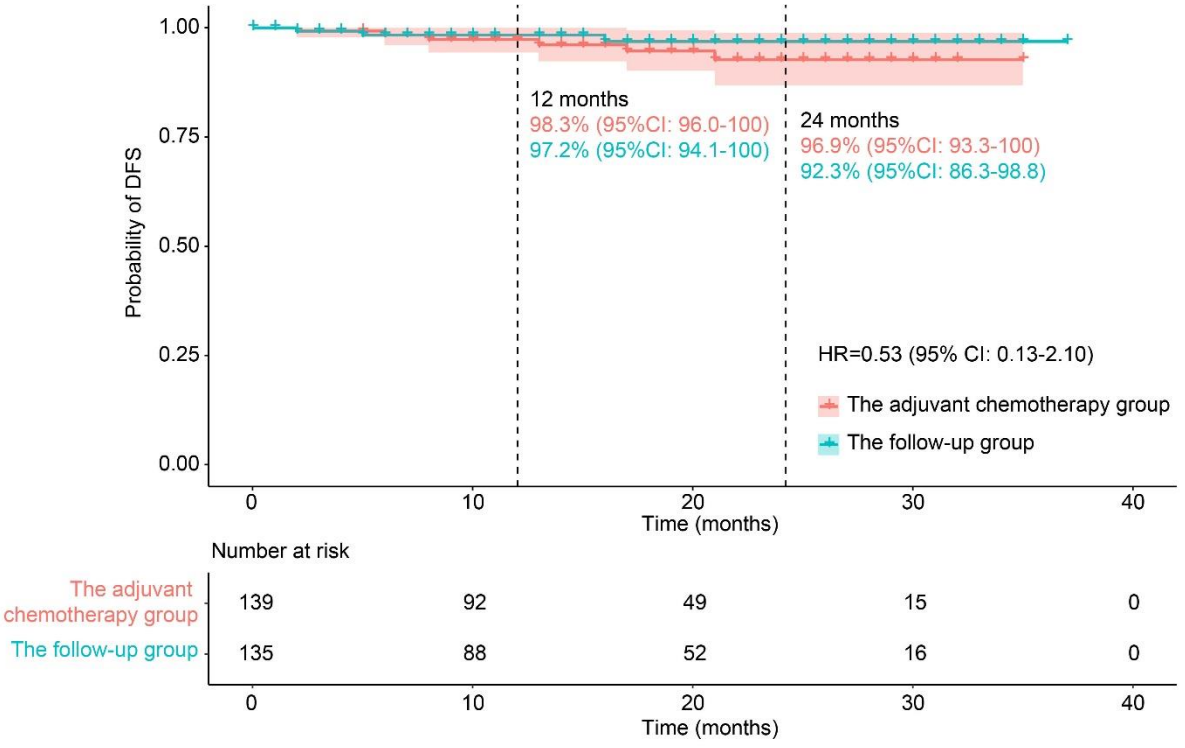
Introduction: There is debate regarding the necessity of adjuvant therapy in early-stage cervical cancer with intermediate-risk factors that do not meet the Sedlis criteria. This study aimed to assess the efficacy of postoperative adjuvant chemotherapy for these patients.

Methods: This trial involving patients with stage IB1, IB2, and IIA1 cervical cancer who had postoperative risk factors not meeting the Sedlis criteria but included invasion depth ≥2/3, moderate to poorly differentiated tumors, lymph-vascular space invasion, adenocarcinoma or adenosquamous carcinoma, or tumor size ≥2cm. Patients were randomly assigned to receive postoperative adjuvant chemotherapy or undergo follow-up observation. The primary endpoint was disease-free survival (DFS).

Results: From January 7th, 2021, to February 29th, 2024, 288 patients underwent randomization, of whom 274 (135 patients in the adjuvant chemotherapy group and 139 patients in the follow-up group) were included in this preliminary analysis, with a median follow-up time of 16 months (IQR: 6-24). Details of risk factors in both groups are presented in Table 1. Three DFS events occurred in the adjuvant chemotherapy group, and 6 events occurred in the follow-up group. The corresponding one-year DFS rates were 98.3% (95% CI: 96.0-100) and 97.2% (95% CI: 94.1-100), respectively (unadjusted HR for adjuvant chemotherapy was 0.53 [95% CI: 0.13-2.10], Fig 1; HR adjusting for stage and tumor size was 0.45 [95% CI: 0.11-1.88]). One death occurred in the adjuvant chemotherapy
group.

	Adjuvant chemotherapy group (n=135)	Follow-up group (n=139)	p-value
FIGO Stage			0.001
IB1	63 (46.67)	92 (66.19)	
IB2	37 (27.41)	33 (23.74)	
IIA1	35 (25.93)	14 (10.07)	
Histologic subtype			0.754
SCC	112 (82.96)	113 (81.29)	
AC or ASC	23 (17.04)	26 (18.71)	
Differentiation grade			0.334
G1	3 (2.22)	6 (4.32)	
G2-G3	127 (94.07)	123 (88.49)	
Not reported	5 (3.70)	10 (7.19)	
Tumor Size			0.112
< 2cm	71 (52.59)	87 (62.59)	
≥2cm	64 (47.41)	52 (37.41)	
Depth of invasion			0.009
< 2/3	99 (73.33)	120 (86.33)	
≥2/3	35 (25.93)	18 (12.95)	
Not reported	1 (0.74)	1 (0.72)	
LVSI			0.424
Yes	26 (19.26)	21 (15.11)	
No	109 (80.74)	118 (84.89)	



Conclusion/Implications: Our short-term analysis did not demonstrate the benefit of postoperative adjuvant chemotherapy for intermediate-risk cervical cancer not meeting Sedlis criteria. Further follow-up is needed to ascertain the findings.

PT002 / #568

IGCS POSTER TALKS 01

Topic: *AS03. Cervical Cancer*

CADONILIMAB IN COMBINATION WITH DISITAMAB VEDOTIN OR NAB-PACLITAXEL IN THE TREATMENT OF RECURRENT OR METASTATIC CERVICAL CANCER: A PROSPECTIVE, DOUBLE-COHORT, MULTI-CENTER, OPEN-LABEL, PHASE II CLINICAL STUDY (AK001)

Haifeng Gu[1], Jian Zhou[1], Jianwei Wang[1], Lili Liu[1], Yun Zhou[1], Baoyue Pan[1], Weijun Ye[1], Li Zhou[2], Yan Ding[3], Jinxin Bei[1], Xinping Cao[1], Min Zheng[4]
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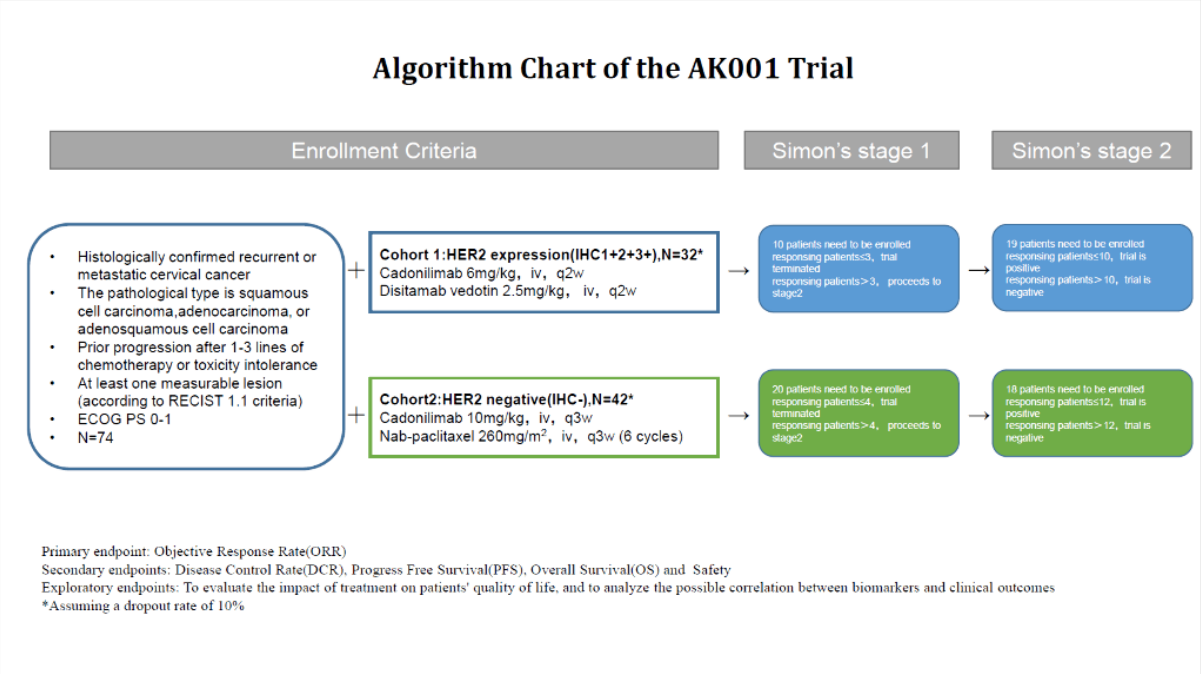
Introduction: Introduction: The aim of AK001 trial (ChiCTR2300076740) is to investigate the efficacy of cadonilimab in combination with disitamab vedotin or nab-paclitaxel in the treatment of recurrent or metastatic cervical cancer. Here, we report the preliminary results of AK001.

Methods: Patients with recurrent or metastatic cervical cancer who had progressed after 1-3 lines of chemotherapy were eligible in this study. The included patients were divided into two independent cohorts according to the HER2 immunohistochemistry (IHC) expression: cohort I with a HER2 IHC 1+~3+ and cohort II with HER2 0. Patients in Cohort I were treated with cadonilimab and disitamab vedotin biweekly while those in cohort II were treated with cadonilimab and nab-paclitaxel triweekly. The primary endpoint of the study was objective response rate (ORR). A Simon 2-stage design was

utilized.(see Chart 1)



Results: Presently 17 patients have been enrolled in this study including 10 evaluable patients (4 in cohort I and 6 in cohort II), the median follow-up was 4.1 (95%CI 3.2-5.2) months. Baseline characteristics were shown in table 1. For cohort I, the ORR and DCR were 50% (2/4) and 75% (3/4). For cohort II, the ORR and DCR were 66.7%(4/6) and 88.3% (5/6). Toxicity was tolerable in both cohorts.

Table 1.Baseline characteristics

	Cohort I	Cohort II
Age		
<60	1	4
⩾60	3	2
Histologic type		
squamous cell carcinoma	1	6
adenocarcinoma	1	0
other	2	0
Prior lines of systemic therapy		
1	1	5
2~3	3	1
Prior immunotherapy		
Yes	2	2
No	2	4
HER2 expression		
1+	3	0
2+	1	0
3+	0	0

Conclusion/Implications: Our preliminary results provide an encouraging solution for the second-line treatment of recurrent or metastatic cervical cancer based on HER2 expression. Cadonilimab plus disitamab vedotin may emerge as a novel effective combination for the treatment of HER2 positive cervical cancer in the future. Data will be updated further.

PT003 / #255

IGCS POSTER TALKS 01

Topic: *AS16. Rare Tumors*

CLINICAL OUTCOMES WITH TRASTUZUMAB EMTANSINE OR IPATASERTIB PLUS PACLITAXEL FOR PERSISTENT/RECURRENT RARE EPITHELIAL OVARIAN CARCINOMAS: ENGOT-GYN2/GOG-3051/BOUQUET PHASE 2 BIOMARKER-DIRECTED STUDY

David Gershenson[1], Andrés Redondo[2], Thibault De La Motte Rouge[3], Rowan Miller[4], David O'malley[5], Sandro Pignata[6], Ali Ayhan[7], Philipp Harter[8], Intidhar Labidi-Galy[9], Beatriz Pardo[10], Elsa Kalbacher[11], Jae-Weon Kim[12], Charlie Gourley[13], Robert Coleman[14], Luis Manuel Manso Sanchez[15], Dominique Berton[16], Yong Man Kim[17], Anais Malpica[18], Lauren Yauch[19], Max Dieterich[20], Ophélie Caras-Zeroug[21], Venkatesh Krishnan[22], Jung-Yun Lee[23], Jubilee Brown[24], Isabelle Ray-Coquard[25]
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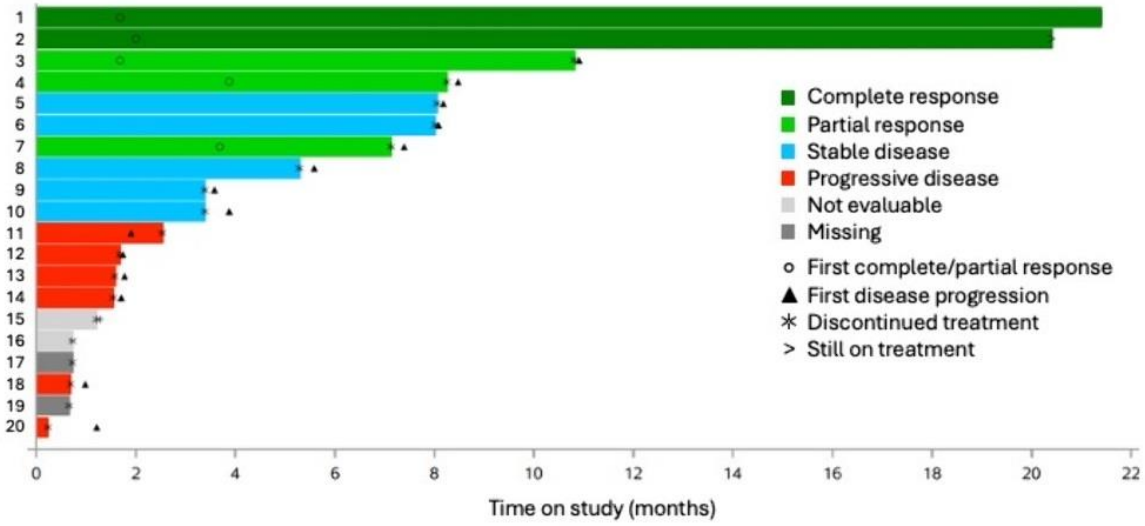
Introduction: The BOUQUET study (NCT04931342) is evaluating biomarker-directed regimens for rare epithelial ovarian carcinomas (OCs). We report results for trastuzumab emtansine (T-DM1) and ipatasertib+paclitaxel.

Methods: Eligible patients had measurable persistent/recurrent platinum-resistant non-high-grade serous/non-high-grade endometrioid OC confirmed by central pathology review and had received 1–4 prior lines of non-hormonal systemic therapy. Tumour samples were tested centrally (FoundationOne CDx NGS assay). Patients with *ERBB2* amplification and/or mutation received T-DM1 3.6 mg/kg IV day 1 q21d. Patients with *PTEN/PIK3CA/AKT1* alterations received oral ipatasertib 400 mg/day days 1–21 plus IV paclitaxel 80 mg/m^2 days 1, 8 and 15 q28d. The primary endpoint was investigator-assessed confirmed objective response rate (cORR) per RECIST v1.1.

Results: Among 21 patients treated with T-DM1 (11 clear cell [CC], 8 mucinous, 2 low-grade serous OC; 18 *ERBB2* amplifications, 3 *ERBB2* mutations), 1 with *ERBB2*-amplified CC OC had a partial response (5% cORR). By the data cut-off, 2 patients (both with *ERBB2*-amplified mucinous OC) remained on treatment and 13 had died. In the ipatasertib+paclitaxel arm (n=20), the cORR was 25% (3/17 with CC OC, 2/3 with low-grade endometrioid OC; 3 *PIK3CA* alteration, 1 *PTEN* alteration, 1 both). By the data cut-off, 1 patient remained on ipatasertib+paclitaxel and 11 had died. Two complete responses were ongoing after >20 months' treatment. There were no treatment-related deaths with either regimen. The table and figure provide further efficacy and safety results.

Parameter	T-DM1 (n=21)	Ipatasertib+paclitaxel (n=20)
Data cut-off date	25 Nov 2023	15 Jan 2024
Median follow-up, months (range)	5.3 (0–15)	6.8 (1–22)
cORR, n (%) [95% CI]	1 (5) [0–24]	5 (25) [9–49]
Complete response, n (%)	0	2 (10)
Partial response, n (%)	1 (5)	3 (15)
Median duration of response, months (range)	9.1	9.3 (4–18[a])
Disease control rate, n (%) [95% CI][b]	7 (33) [15–57]	7 (35) [15–59]
6-month PFS rate, % [95% CI]	23 [4–42]	41 [18–65]
Median PFS, months [95% CI]	2.8 [2.0–4.7]	3.9 [1.7–8.2]
Median treatment duration, months (range)	2.1 (0–11)	Ipatasertib: 3.0 (0–21) Paclitaxel: 2.7 (0–21)
Adverse events, n (%)		
Grade 3/4	10 (48)	17 (85)
Leading to treatment interruption	7 (33)	Ipatasertib: 12 (60) Paclitaxel: 13 (65)
Leading to dose reduction	4 (19)	Ipatasertib: 5 (25) Paclitaxel: 5 (25)
Leading to any treatment discontinuation	0	1 (5)

[a]Censored observation. [b]Complete/partial response or stable disease ≥16 weeks.
PFS = progression-free survival.



Conclusion/Implications: Minimal clinical activity was observed with T-DM1 in *ERBB2*-amplified or -mutated tumours. Ipatasertib+paclitaxel demonstrated more encouraging activity. The tolerability of both regimens was consistent with previous experience.

PT004 / #583

IGCS POSTER TALKS 01

Topic: *AS10. Ovarian Cancer*

SUCCESSFUL CARBOPLATIN DESENSITIZATION PROTOCOL IN PATIENTS WITH PROVEN OR INCREASED RISK OF CARBOPLATIN HYPERSENSITIVITY REACTION

Mariateresa Lapresa[1], Giuseppe Caruso[1], Gabriella Parma[1], Camilla Ottomano[2], Costantino Jemos[3], Martina Milani[4], Silvia Derio[1], Marta Mongillo[1], Sara Gandini[5], Emanuela Omodeo Salè[2], Nicoletta Colombo[1]
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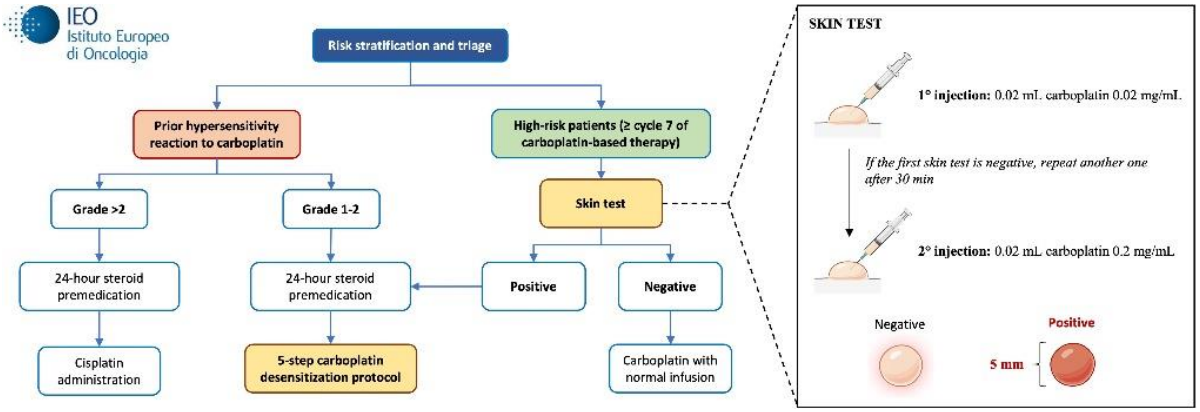
Introduction: Carboplatin-based chemotherapy remains a cornerstone of treatment for patients with gynecologic cancers; however, hypersensitivity reactions occur in 12-33% of patients retreated with carboplatin. We aimed to assess the efficacy of a carboplatin desensitization protocol to manage patients with proven or increased risk of carboplatin hypersensitivity reactions.

Methods: Patients with gynecologic cancer who underwent a carboplatin desensitization protocol at the European Institute of Oncology (Milan, Italy) between 2014 and 2021 were identified. Patients with a documented hypersensitivity reaction to carboplatin or with a positive skin test before receiving ≥cycle 7 of carboplatin-based therapy were triaged to carboplatin desensitization after steroid premedication (**Figure 1** and **Figure 2**). Descriptive statistics were used to assess the negative predictive value of carboplatin skin test and the number of successful carboplatin infusions.

Results: A total of 621 patients with a mean age of 57 years were included: 469 (76%) ovarian cancer, 87 (14%) endometrial cancer, and 65 (10%) cervical cancer. The number of positive skin tests was 4%, with a higher rate (14%) between the 8th-9th cycles. The negative predictive value of skin testing was 98%. Carboplatin infusion was not initiated in 18% of patients due to severe skin test reactions. A hypersensitivity reaction was reported in 20% of carboplatin desensitization infusions. Reactions were mild in 86% of cases, and the number of completed desensitization infusions was 95%.



IEO
Istituto Europeo
di Oncologia

Premedication in the 24 hours before carboplatin infusion	
h 2pm	NS 0.9% 100 cc + dexamethasone 12 mg* + PPI 40 mg IV in 30 min
h 8pm	NS 0.9% 100 cc + dexamethasone 12 mg* + PPI 40 mg + chlorphenamine 10 mg* IV in 30 min

Standard premedication on the day of carboplatin infusion	
h 8am	NS 0.9% 100 cc + dexamethasone 12 mg* + granisetron 3 mg*+ PPI 40 mg + chlorphenamine 10 mg* IV in 30 min

*Or equivalent.

5-step carboplatin desensitization protocol

Carboplatin solution (NS 0.9% or D5W)	Dilution factor	Volume (mL)	Infusion time (min)	Rate (mL/h)	% of total dose infused
Solution 1	1:10000	50	15	200	0.01%
Solution 2	1:1000	50	15	200	0.1%
Solution 3	1:100	50	15	200	1%
Solution 4	1:10	50	15	200	10%
NS 0.9% 100 cc + hydrocortisone 500 mg					
Solution 5	1:1	Remainder	180	Variable	88.89%

Abbreviations: D5W, dextrose 5% in water; IV, intravenous; NS, normal saline; PPI, proton-pump inhibitor.

Conclusion/Implications: A 5-step carboplatin desensitization protocol after 24-hour steroid premedication is an effective strategy to complete platinum-based chemotherapy in gynecologic cancer patients with proven or increased risk of carboplatin hypersensitivity reaction.

PT005 / #1267

IGCS POSTER TALKS 01

Topic: *AS10. Ovarian Cancer*

CASP8 IN OVARIAN CANCER: INSIGHTS ON PARP INHIBITOR RESISTANCE THROUGH MENDELIAN AND SINGLE-CELL ANALYSIS

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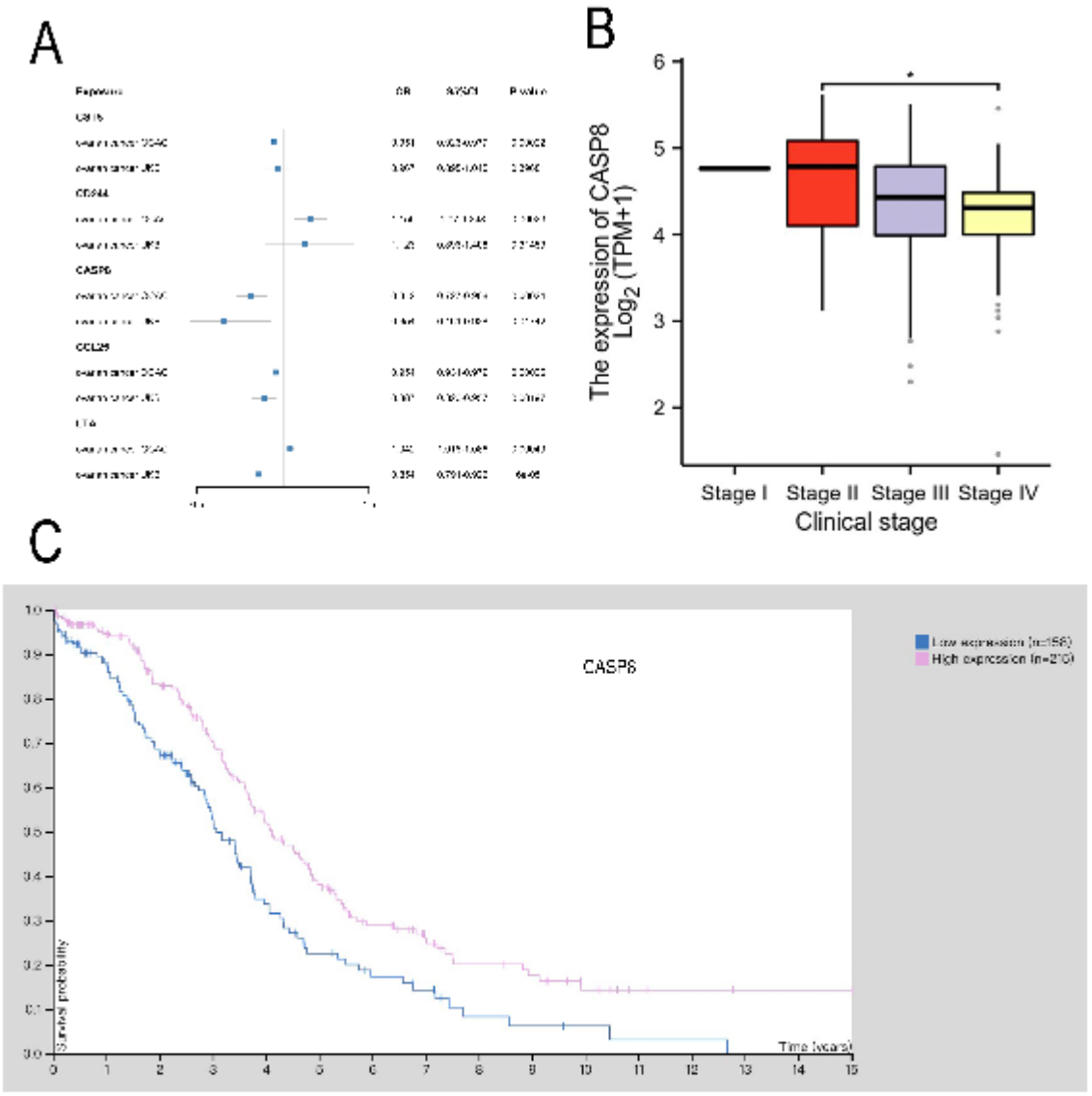
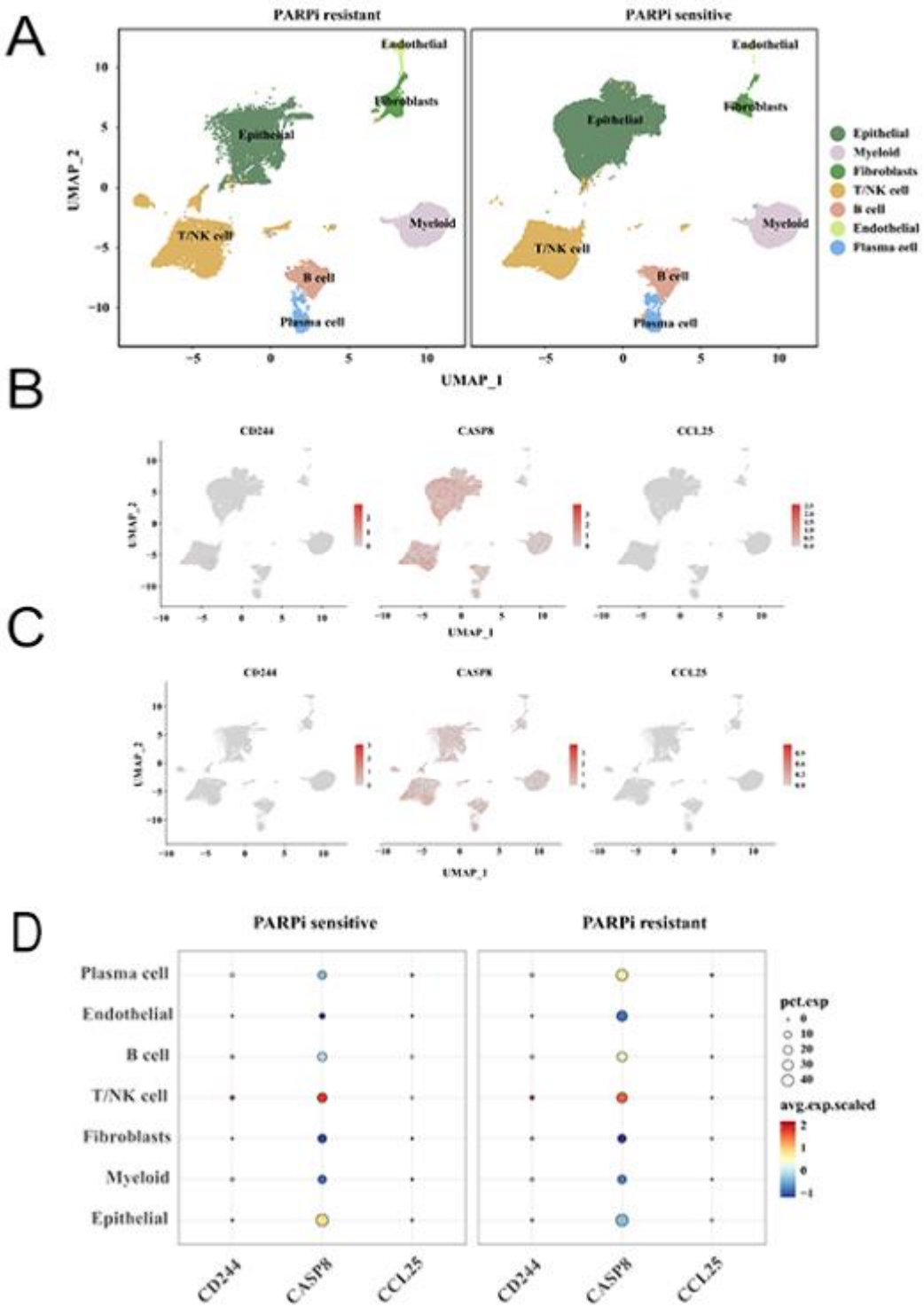
Introduction: The causal link between inflammatory proteins and ovarian cancer, particularly in PARP inhibitor (PARPi) resistance, remains elusive.

Methods: We systematically interrogated circulating inflammatory proteins associated with ovarian cancer via Mendelian randomization (MR) analysis. Genetic associations were derived from a large-scale GWAS meta-analysis that enrolled 14,824 predominantly European participants, the Ovarian Cancer National Alliance (OCAC) cohort (25,509 cases and 40,941 controls), and the UK Biobank (1147 cases and 207,089 controls). Colocalization and summary-data-based MR (SMR) analyses validated candidate proteins' causal implication. Single-cell RNA sequencing data from PARPi-resistant and responsive ovarian cancer cohorts were provided by the Cancer Hospital affiliated with Chongqing University. Single cell-type expression analysis, protein-protein interaction (PPI), and druggability evaluation were further conducted to detect the specific cell type with enrichment expression and prioritize potential therapeutic targets. Clinical significance utilized data from The Cancer Genome Atlas (TCGA).

Results: Genetically inferred levels of 5 proteins were associated with ovarian cancer risk. Elevated CD244 and LTA levels, and decreased CST5, CASP8, and CCL25 levels, were linked with heightened ovarian cancer susceptibility. CASP8, notably, were prioritized with the most convincing evidence and correlated robustly with prognosis and disease stage. Diminished CASP8 expression in advanced-stage ovarian cancer indicated poorer clinical outcomes. CASP8 expression was predominant in T/NK cells and epithelial cells within PARPi-resistant ovarian tumor
tissues.


A
B
The expression of CASP8
Log2 (TPM+1)
Stage I
Stage II
Stage III
Stage IV
Clinical stage
C
CASP6
Survival probability
Time (years)



Conclusion/Implications: This study underscores CASP8's association with ovarian cancer and PARPi resistance, offering insights into disease etiology and therapeutic avenues for managing ovarian cancer and resistant phenotypes.

PT006 / #314

IGCS POSTER TALKS 01

Topic: *AS10. Ovarian Cancer*

STEREOTACTIC ABLATIVE RADIOTHERAPY FOR OLIGOMETASTATIC OVARIAN CANCER LYMPH NODE DISEASE: THE MITO-RT3/RAD PHASE II TRIAL

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Introduction: MITO-RT3/RAD(NCT04593381) is a prospective multicenter Phase II trial designed to assess the effectiveness and safety of stereotactic radiotherapy(SBRT) in patients diagnosed with oligometastatic ovarian cancer(oligo-MPR-OC).In this report, we provide the results of the trial in the setting of lymph node disease.

Methods: The primary endpoint was the complete response(CR) rate,secondary endpoints included local control(LC), progression-free survival(PFS), overall survival(OS), treatment-free interval(TFI),and toxicity rates.Sample size was based on a previous study reporting an average 70.0% CR with SBRT.The study was powered to detect an improvement in the CR rate from 70.0% to 85.0%, with an α error of 0.05 (two-sided) and a β error of 0.1.

Results: The study met its primary endpoint of a statistically significant improvement of CR.135 patients with 249 lesions were enrolled across fifteen Institutions from May 2019 to November 2023. CR were observed in 194 lesions(77.9%), PR in 40(16.1%), SD in 14(5.6%), and Progressive Disease(PD) in one lesion(0.4%).The ORR was 94%, with an overall clinical benefit rate of 99.6%. CR lesions exhibited a significantly higher LC rate than partial or not responding lesions(12-month LC: 92.7% vs. 63.1%, $p<0.001$).The 12-actuarial rates for PFS and for OS were 36.6% and 97.2%,respectively.The 12- actuarial rate for Treatment Free Interval was 52.7%.Twenty-three patients (17.0%) experienced mild acute toxicity. Late toxicity was reported in 9 patients (6.7%), mostly Grade 1.

Conclusion/Implications: This trial confirms the efficacy of ablative SBRT, with minimal toxicity observed. SBRT offered a high CR rate, promising long-term outcomes and systemic-therapy-free survival rate for complete responders.

PT007 / #746

IGCS POSTER TALKS 01

Topic: *AS05. Fertility/Pregnancy*

THE PROGNOSTIC IMPACT OF MOLECULAR CLASSIFICATION IN ENDOMETRIAL CANCER UNDERGOING FERTILITY-SPARING TREATMENT

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Introduction: In 2020, 8.6% of endometrial cancer (EC) occurred in women <45 years of age, when fertility preservation is crucial. No biomarkers are available to predict treatment response in EC undergoing fertility-sparing treatment (FST). Therefore, we aimed to evaluate the prognostic role of molecular classification.

Methods: Patients with EC who underwent FST with progestins at the European Institute of Oncology, Milan between 2005-2021 were retrospectively identified. POLE, TP53/p53, mismatch repair (MMR) proteins were assessed to assign patients to a molecular group: POLE mutated (POLEmut), MMR deficient (MMRd), no-specific molecular profile (NSMP), p53 abnormal (p53abn). Treatment response was classified as complete (CR), partial (PR), stable disease (SD), or progressive (PD). Response at 6 months, best response, and recurrence after CR were compared between molecular classes.

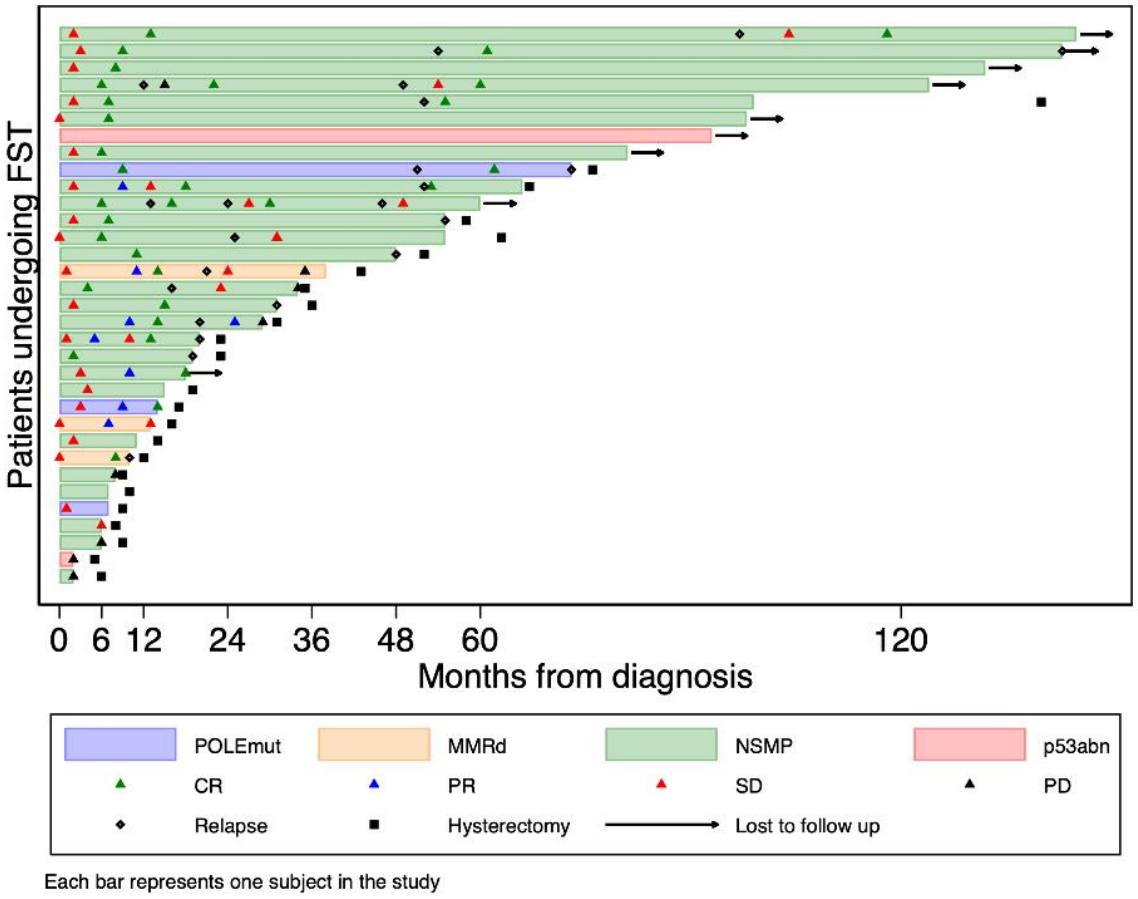
Results: Molecular analysis identified 3(9%) POLEmut, 3(9%) MMRd, 25(76%) NSMP, 2(6%) p53abn (Table

Table 1. Characteristics of endometrial cancer patients undergoing fertility-sparing treatment according to molecular class

	Total	POLEmut	MMRd	NSMP	p53abn
N	33	3	3	25	2
Age at diagnosis, median (IQR)	34.8 (31.5, 38.9)	39.2 (30.0, 39.4)	35.6 (33.7, 41.5)	34.3 (31.5, 38.2)	30.2 (22.9, 37.6)
BMI (kg/m2), median (IQR)	24.8 (22.0, 31.3)	22.8 (22.3, 23.3)	20.8 (19.5, 22.0)	26.7 (22.3, 31.5)	31.3 (31.3, 31.3)
Personal history of cancer?	4 (12%)	1 (33%)	1 (33%)	1 (4%)	1 (50%)
Family history of cancer	10 (45%)	2 (100%)	3 (100%)	5 (31%)	0 (0%)
Synchronous Ovarian Cancer	5 (16%)	0 (0%)	2 (67%)	2 (8%)	1 (50%)
Hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Diabetes	2 (6%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Polycystic ovary syndrome	8 (25%)	1 (33%)	0 (0%)	7 (29%)	0 (0%)
Endometriosis	5 (16%)	0 (0%)	1 (33%)	4 (17%)	0 (0%)
Type of therapy					
IUD + GnRH analogue	15 (45%)	1 (33%)	1 (33%)	12 (48%)	1 (50%)
IUD + Megestrol	10 (30%)	2 (67%)	1 (33%)	6 (24%)	1 (50%)
IUD + Megestrol + Metformin	8 (24%)	0 (0%)	1 (33%)	7 (28%)	0 (0%)
Oncologic outcome at 6 mo					
Complete Response	7 (21%)	0 (0%)	0 (0%)	6 (24%)	1 (50%)
Partial Response	1 (3%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Stable Disease	22 (67%)	3 (100%)	3 (100%)	16 (64%)	0 (0%)
Progressive Disease	3 (9%)	0 (0%)	0 (0%)	2 (8%)	1 (50%)
Best overall response					
Complete Response	23 (70%)	2 (67%)	2 (67%)	18 (72%)	1 (50%)
Partial Response	1 (3%)	0 (0%)	1 (33%)	0 (0%)	0 (0%)
Stable Disease	5 (15%)	1 (33%)	0 (0%)	4 (16%)	0 (0%)
Progressive Disease	4 (12%)	0 (0%)	0 (0%)	3 (12%)	1 (50%)
Recurrence after Complete Response					
No	6 (26%)	1 (50%)	0 (0%)	4 (22%)	1 (100%)
Yes	17 (74%)	1 (50%)	2 (100%)	14 (78%)	0 (0%)
Hysterectomy					
No	9 (27%)	0 (0%)	0 (0%)	8 (32%)	1 (50%)
Yes	24 (73%)	3 (100%)	3 (100%)	17 (68%)	1 (50%)
Surgical indication					
Treatment failure	20 (83%)	3 (100%)	2 (67%)	14 (82%)	1 (100%)
Completed family planning	3 (12%)	0 (0%)	0 (0%)	3 (18%)	0 (0%)
Ovarian cancer	1 (4%)	0 (0%)	1 (33%)	0 (0%)	0 (0%)
Vital status at follow up					
No evidence of disease	31 (97%)	3 (100%)	3 (100%)	23 (96%)	2 (100%)
Alive with disease	1 (3%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)

1).

0/3(0%) POLEmut, 0/3(0%) MMRd, 6/25(24%) NSMP, and 1/2(50%) p53abn achieved CR within 6 months. In terms of best response during the entire treatment period, 2/3(67%) POLEmut, 2/3(67%) MMRd, 18/25(72%) NSMP, and 1/2(50%) p53abn showed CR. After achieving CR, 1/2(50%) POLEmut, 2/2(100%) MMRd, 14/18(78%) NSMP, and 0/1(0%) p53abn had a recurrence (Figure 1).



Each bar represents one subject in the study

At the last follow-up, 1/25(4%) NSMP was alive with disease, all others showed no evidence of disease.

Conclusion/Implications: Most EC undergoing FST were NSMP. Although the low number of patients limits our findings, MMRd showed a poorer response to progestins compared to NSMP (0 vs. 24% CR at 6 months and 100 vs. 78% relapsed after CR), similar to previous studies.

PT008 / #908

IGCS POSTER TALKS 02

Topic: *AS20. Survivorship*

THE MENOPAUSE AFTER CANCER (MAC) STUDY – MULTIMODAL, TECHNOLOGY-ASSISTED INTERVENTION FOR THE MANAGEMENT OF MENOPAUSE AFTER CANCER IMPROVES INSOMNIA SYMPTOMS

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Introduction: Sleep disturbance is commonly experienced by cancer survivors, with rates ranging from 25-59%. Often this can be due to vasomotor symptoms (VMS), particularly in women who are ineligible for menopause hormonal therapy.

Methods: The MAC Study ((NCT04766229) was a prospective, single arm, phase 2 trial examining the impact of a composite intervention consisting of -Non-hormonal pharmacotherapy to manage VMS -Digital CBT for insomnia (dCBT-I) through Sleepio (BigHealth) -Self-management strategies for VMS, -Nominated support person. The trial met its primary endpoint, improvement cancer-specific global quality of life (QOL), here we present data on sleep outcomes as a secondary end point.

Results: 204 women (82% history of breast cancer). were recruited, with a median age of 49, (range 28 – 66). 93% met diagnosis criteria for insomnia (SCI<16) at baseline, which reduced to 45.2% at 6 months ($p<0.001$). The mean SCI score increased from 8.5 (SEM 0.4) to 17.3 (SEM0.5) at 6 months ($p<0.0005$). Clinically relevant changes were seen in sleep parameters, with sleep onset latency reducing by 13.6 minutes after completion of dCBT-I ($p<0.001$). A 35 minute reduction in wakefulness after sleep onset was also seen ($p<0.001$) alongside a 29.1% improvement in sleep quality ($p<0.001$). Comparison of breast cancer and non-breast cancer patients demonstrated the intervention was equally effective in both groups.

Conclusion/Implications: The MAC study demonstrated that a targeted composite intervention can improve sleep and self-reported insomnia symptoms for women with troublesome VMS after a cancer diagnosis, which contributed to an improvement in cancer specific global QOL.

PT009 / #845

IGCS POSTER TALKS 02

Topic: *AS19. Surgical Techniques and Perioperative Management*

SHORT TERM V/S EXTENDED COURSE OF LMWH FOLLOWING MAJOR GYNECOLOGICAL SURGERIES : A RANDOMIZED CONTROLLED TRIAL.

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Introduction: Incidence of post-operative venous thromboembolism (VTE), in the absence of any prophylaxis, in patients undergoing gynecological surgeries is 15-40%. The guidelines for VTE prophylaxis recommend the use of LMWH for 28 days in women undergoing gynecologic oncological surgery, but, these recommendations have not been clearly validated. The primary objective of this study was to assess the incidence of VTE in high risk women, receiving seven v/s twenty-eight-day LMWH for thromboprophylaxis and secondary objective was to compare the incidence of major bleeding episodes following 3 months of surgery.

Methods: It was a Randomized Controlled trial including patients undergoing major gynecological surgeries and at high risk of VTE (Caprini score ≥ 4). The patients were randomized into short course (7 days) and extended course (28 days) of post-operative LMWH therapy. The incidence of VTE and bleeding complications was assessed in both groups at the end of three month follow up.

Results: A total of 256 women were assessed, 134 of them received short course of LMWH while 122 received long course. There was no VTE event in the short-course group while one patient had pulmonary embolism on day 4 of surgery in the long arm group. There was no incidence of any major bleeding episode in both the groups while the incidence of minor bleeding episodes was significantly higher in the long-course group (6.7% v/s 17.2%).

Conclusion/Implications: The study concludes that the post-operative use of short course LMWH is as effective as long-course thromboprophylaxis in preventing VTE and its sequelae.

PT010 / #827

IGCS POSTER TALKS 02

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

DNA DAMAGE RESPONSE ALTERATIONS WITHIN MOLECULAR SUBGROUPS OF ENDOMETRIAL CANCER AND ASSOCIATION WITH PLATINUM CHEMOTHERAPY RESPONSE: AN ENDOMETRIAL CANCER MOLECULARLY TARGETED THERAPY CONSORTIUM STUDY

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Introduction: To describe alterations in DNA damage response (DDR) genes within distinct molecular subtypes of endometrial cancer and to evaluate the relationship between DDR gene mutations, platinum chemotherapy response, and overall survival.

Methods: Data was extracted from the national Endometrial Cancer Molecularly Targeted Therapy (ECMT2) Consortium. Next-generation sequencing and molecular profiling was used to define molecular subtypes and DDR alterations. The association between DDR gene mutations and platinum sensitivity (defined as partial or complete response) and survival was analyzed using Kaplan-Meier curves and risk estimates.

Results: 769 patient tumors across 14 institutions were analyzed (Table 1). The most common DDR gene mutations were *ARID1A*, *ATM*, *BRCA2*, and *BRCA1*. *ARID1A* mutations were higher in POLE-mutated, MMR-D, and p53wt than p53mut tumors *(P*<0.001). In p53wt tumors, *BRCA1* mutation was predictive of platinum chemotherapy sensitivity (RR=1.71, *P*=0.001*)*. In p53wt tumors, *AKT* mutation was predictive of improved overall survival (median OS months 20.9 vs. 32.7 *P*=0.004*.)*.

Table 1. Most common DDR Mutations within endometrial cancer molecular subgroups.

	All (n=769)	POLE-mutated (n=18)	MMR-D (n=157)	p53wt (n=351)	p53abn (n=243)
ARID1A (%)	34.9	76.5	86.1	8.7	45.9
ATM (%)	6.6	29.4	13.8	1.8	8.3
BRCA1 (%)	4.0	5.9	8.2	2.2	4.6
BRCA2 (%)	5.7	17.7	14.4	3.0	6.6
CHD4 (%)	2.4	0	4.5	0.9	2.8
RAD51 (%)	2.3	0	1.5	4.5	1.4
TMB-High (%)	16.8	66.7	67.0	0	2.5

Conclusion/Implications: The rates of DDR alterations adiffers amongst endometrial cancer molecular subgroups and are associated with platinum chemotherapy response and survival. Our findings provide a foundation for precision medicine in endometrial cancer.

PT011 / #872

IGCS POSTER TALKS 02

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

LAPAROSCOPIC OR LAPAROTOMIC SURGICAL APPROACH IN ENDOMETRIAL CARCINOMA IS STILL A MATTER OF DEBATE? RESULTS FROM THE TOTEM RANDOMIZED TRIAL.

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Introduction: Laparoscopic approach (LPS) is recommended by the ESGO/ESTRO/ESP guidelines over laparotomic surgery (LPT) for the treatment of endometrial carcinoma (EC), even if there is still interest in comparing long term overall survival (OS), especially in high-risk patients. The large and pragmatic TOTEM trial, designed to compare intensive versus minimalist follow-up after surgery for EC, was analyzed to evaluate the impact of LPS vs LPT approaches on OS.

Methods: We included all randomized patients with complete surgical data. The association between surgical approach and OS was estimated with Cox models adjusted for age, risk class, histology, adjuvant therapy, follow-up type and stratified by center. Moreover, we evaluated if LPS effect was different according to risk class adding an interaction term.

Results: Out of 1840 patients, 926 underwent LPS (50.3%). The two groups (LPS and LPT) were well balanced by age, histology, and type of follow-up. In the LPS group, a lower proportion of patients were at high risk (32.1% vs 47.5%) and received an adjuvant treatment (25.4% vs 41.1%). Overall, we did not observe a clear difference between LPS vs LPT in terms of OS (HR=0.85 95%CI [0.60,1.20], p=0.352). Moreover, we observed a similar LPS effect in low-risk (HR=0.99; 95%CI=0.60-1.62 p=0.956) and in high risk patients (HR=0.76; 95%CI=0.49-1.18 p=0.224) (p for interaction=0.400).

Conclusion/Implications: A secondary analysis of the TOTEM trial confirmed that OS was very similar between LPS and LPT approaches for EC surgery, both in low and high-risk patients. On behalf of TOTEM Collaborative Group.

PT012 / #560

IGCS POSTER TALKS 02

Topic: *AS03. Cervical Cancer*

ASSOCIATION OF SURGICAL APPROACH WITH ONCOLOGIC OUTCOMES IN LOW-RISK CERVICAL CANCER: POPULATION BASED COHORT STUDY

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Introduction: To determine whether the association between minimally invasive surgery (MIS) and oncologic outcomes varies by cervical cancer risk group.

Methods: We performed a population-based cohort study of all cervical cancer patients undergoing primary radical hysterectomy by a gynecologic oncologist from 2006-2017 in Ontario, Canada. Overlap weighted survival models were used to examine the association between surgical approach and oncologic outcomes, adjusting for clinical and pathological characteristics. We tested for an interaction between surgical approach and disease risk group, with patients classified as low- or high-risk based on CCTG CX.5-SHAPE criteria (low risk: depth of invasion <10mm and maximum tumour diameter ≤20mm).

Results: We identified 903 patients (MIS 450, open 453, low-risk 621, high-risk 282) with median age 44 years (IQR 38-53) and median follow-up 9 years (IQR 6-11). Compared to open surgery, MIS was associated with significantly increased rates of cervical cancer death (HR 3.27, 95% CI 1.29-8.31, p=0.01) but not all-cause death (HR 1.65, 0.90-3.04, p=0.11) or recurrence (HR 1.57, 0.89-2.77, p=0.12). This association varied based on disease risk group: MIS was associated with increased all-cause death in high-risk patients (HR 2.93, 1.22-7.03, p=0.02), but not in low-risk patients (HR 0.83, 0.34-2.06, p=0.69; p-interaction=0.05). Similar patterns were observed for cervical cancer death and recurrence.

Conclusion/Implications: Oncologic outcomes after MIS may vary according to disease risk group. MIS does not appear to be associated with increased all-cause mortality in patients with low-risk disease. Additional studies are required to confirm whether MIS may remain safe in a low-risk population defined by strict SHAPE criteria.