IGCS 2025 CAPE TOWN

Annual Global Meeting, November 5–7, 2025

IGCS 2025 Abstracts:
Regular Submission Oral Presentations

Oral abstract presentations are included in the sessions listed below. Some sessions will be recorded for on-demand viewing via the IGCS 360 Educational Portal as indicated.

Plenary: High-Impact Oral Abstract Presentations
Wednesday, November 5, 08:30 - 09:30 | Hall A&B | in-person & on-demand

Plenary: Endometrial Cancer Oral Abstract Presentations
Wednesday, November 5, 09:35 - 10:35 | Hall A&B | in-person & on-demand

Endometrial Cancer Master Session
Wednesday, November 5, 11:20 - 12:50 | Hall A&B | in-person & on-demand

Plenary: Ovarian Cancer Oral Abstract Presentations
Thursday, November 6, 08:00 - 09:25 | Hall A&B | in-person & on-demand

Pathology Workshop Part II: Endometrial Cancer Pathology
Thursday, November 6, 17:00 - 18:00 | The Verve | in-person only

Plenary: Cervical Cancer Oral Abstract Presentations
Friday, November 7, 14:20 - 16:05 | Hall A&B | in-person & on-demand

OP001 / #166

Topic: *AS05. Social Responsibility: Global Health, Economic Challenges & Inequity*

ONE SIZE DOES NOT FIT ALL: MODELING CONTEXT-SPECIFIC PATHWAYS TO ELIMINATE CERVICAL CANCER GLOBALLY

PLENARY: HIGH-IMPACT ORAL ABSTRACT PRESENTATIONS

Mauricio Cuello[1], Fernan Gomez-Valenzuela[2], Ignacio Wichmann[3], Alexander Olawaiye[4]
[1]School of Medicine, Pontificia Universidad Católica de Chile, Gynecology/cecan, Santiago, Chile, [2]Universidad Mayor, Precision Oncology Center, Santiago, Chile, [3]School of Medicine, Stanford University, Division Of Oncology, Stanford, United States of America, [4]School of Medicine, University of Pittsburgh, Division Of Gynecologic Oncology, Department Of Obstetrics, Gynecology And Reproductive Sciences, Pittsburgh, United States of America

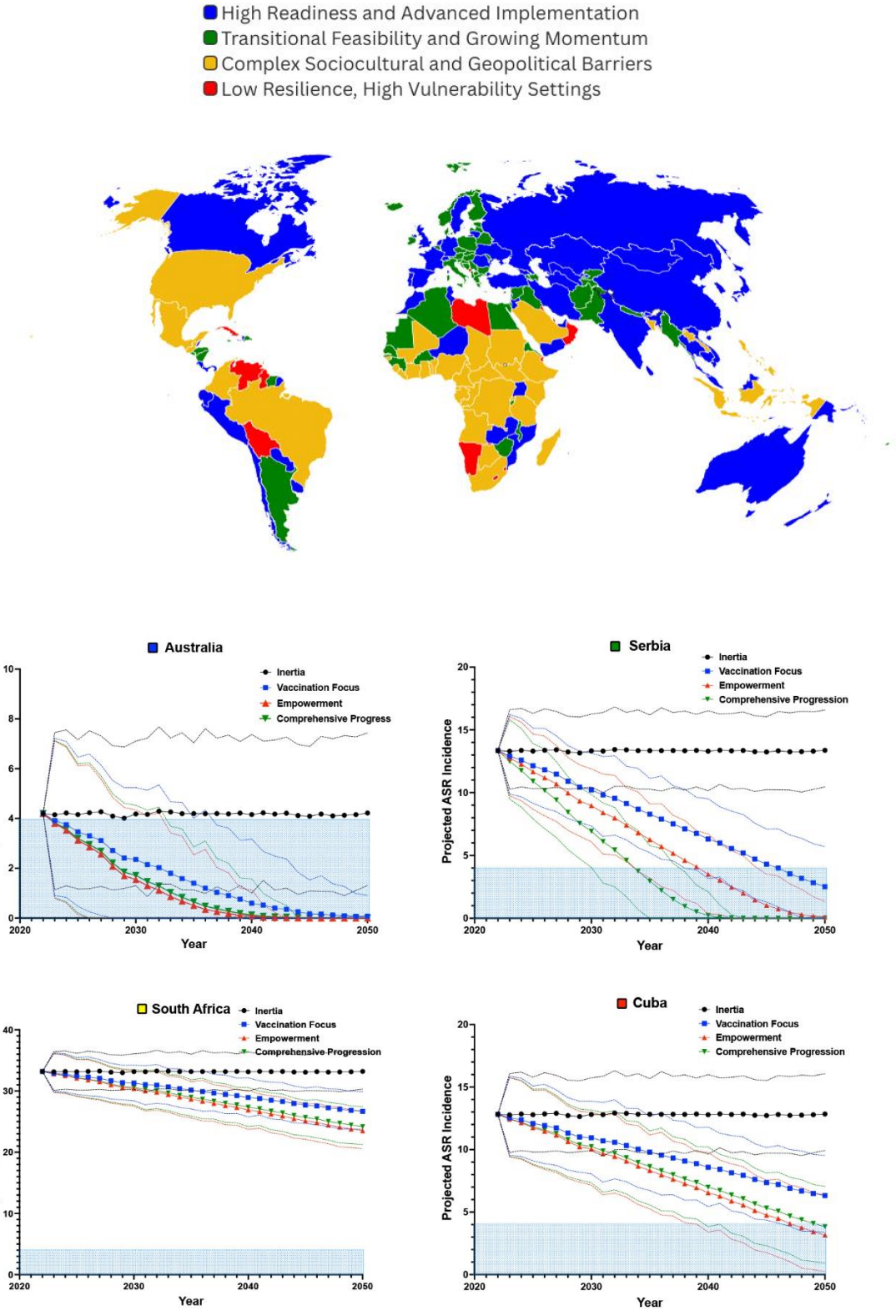
Introduction: The WHO's 90-70-90 targets offer a compelling roadmap for cervical cancer elimination. Yet many countries lack the structural, cultural, or political conditions to achieve them. Traditional indicators such as HDI or income fail to capture implementation barriers. This study aimed to project cervical cancer incidence and mortality trends through 2050 using a structural-context framework. Structural modeling was conducted across 175 countries; 30 were selected for country-specific projections.

Methods: We compiled 275 indicators excluding outcome variables. PCA and clustering identified four structural clusters based on 11 composite scores. Four strategic indices—including a Vaccination Scale-Up Index—were developed. Variable selection via LASSO, Elastic Net, and Random Forest informed two regression models predicting ASR incidence and mortality. Projections (2023–2050) were generated under four policy scenarios using Monte Carlo simulation (500 iterations/year).

Results: Vaccination alone reduced incidence by up to 65% in some countries but had minimal impact on mortality unless paired with education and health system improvements. South Africa showed a >50% mortality reduction only under empowerment and full-progress scenarios. In contrast, Japan and the U.S. remained vulnerable to vaccine hesitancy and policy fragmentation. Saudi Arabia, despite low incidence, demonstrated unrealized mortality gains. Cross-country differences in the slope of projected decline highlighted how structural factors—not income—shape elimination feasibility.

Conclusion/Implications: Cervical cancer elimination is feasible—but only through context-specific, structurally tailored strategies. Global goals must be adapted to national realities to achieve equitable and lasting impact.

Global Feasibility Landscape for Cervical Cancer Elimination: Four Distinct Implementation Clusters



OP002 / #663

Topic: *AS02. Clinical Disciplines / AS02d. Radiation Oncology*

COST-UTILITY ANALYSIS OF A MOLECULAR-INTEGRATED-PROFILE FOR WOMEN WITH (HIGH)INTERMEDIATE RISK ENDOMETRIAL CANCER - PORTEC-4A AN INTERNATIONAL, MULTICENTRE, RANDOMISED, PHASE 3 TRIAL

PLENARY: ENDOMETRIAL CANCER ORAL ABSTRACT PRESENTATIONS

Anne Sophie Van Den Heerik[1], Nanda Horeweg[1], Marie Haverkort[2], Nienke Kuijsters[3], Stefan Kommoss[4], Friederike Koppe[5], Marlies Nowee[6], Henrike Westerveld[7,8], Marianne De Jong[9], Filip Frühauf[10], Jeltsje Cnossen[11], Jan Willem Mens[8], Jannet Beukema[12], Cyrus Chargari[13], Charles Gillham[14], Ina Jurgenliemk-Schulz[15], Katrien Vandecasteele[16], Moritz Hamann[17], Mandy Kiderlen[18], Stefan Polterauer[19], Annette Staebler[20], Hans Nijman[21], Elefteria Asteinidou[1], Bastiaan Wortman[1,11], Stephanie De Boer[1], Karen Verhoeven-Adema[22], Remi Nout[1,8], Hein Putter[23], Vincent Smit[24], Carien Creutzberg[1], Wilbert Van Den Hout[25]
[1]Leiden University Medical Center, Radiation Oncology, Leiden, Netherlands, [2]Radiotherapiegroep, Arnhem, Netherlands, [3]Maastro, Maastricht, Netherlands, [4]Diak Klinikum, Gynecology & Obstetrics, Schwaebisch Hall, Germany, [5]Institute Verbeeten, Radiation Oncology, Tilburg, Netherlands, [6]The Netherlands Cancer Institute, Radiation Oncology, Amsterdam, Netherlands, [7]Amsterdam University Medical Centers, Radiation Oncology, Amsterdam, Netherlands, [8]Erasmus MC – Cancer Institute, University Medical Center Rotterdam, Radiation Oncology, Rotterdam, Netherlands, [9]Radiotherapeutisch Instituut Friesland, Leeuwarden, Netherlands, [10]Gynecology and Neonatology First Faculty of Medicine, Charles University and General University Hospital in Prague, Department Of Obstetrics, Prague, Czech Republic, [11]Catharina Hospital Eindhoven, Radiation Oncology, Eindhoven, Netherlands, [12]University Medical Center Groningen,, Radiation Oncology, Groningen, Netherlands, [13]Institut Gustave Roussy, Radiation Oncology, Paris, France, [14]St. Luke's Hospital, Radiation Oncology, Dublin, Ireland, [15]University Medical Center Utrecht, Radiation Oncology, Utrecht, Netherlands, [16]Ghent University, Radiation Oncology, Ghent, Belgium, [17]Rotkreuzklinikum München, Gynecology, Munich, Germany, [18]Haaglanden Medisch Centrum, Radiation Oncology, Leidschendam, Netherlands, [19]Medical University of Vienna, Obstetrics And Gynecology, Vienna, Austria, [20]University of Tübingen, Institute Of Pathology And Neuropathology, Tuebingen, Germany, [21]University Medical Center Groningen, Gynecology, Groningen, Netherlands, [22]Netherlands Comprehensive Cancer Organisation, Utrecht, Utrecht, Netherlands, [23]Leiden University Medical Center, Statistics, Leiden, Netherlands, [24]Leiden University Medical Center, Pathology, Leiden, Netherlands, [25]Leiden University Medical Center, Medical Decision Making, Leiden, Netherlands

Introduction: The randomised PORTEC-4a trial was the first to investigate tailoring of adjuvant treatment for (high)intermediate risk endometrial cancer (EC) using a molecular-integrated-profile. This profile combines the molecular classification with substantial lymph-vascular-space-invasion, L1CAM-overexpression, and CTNNB1-exon-3-mutations into favourable, intermediate and unfavourable profiles. Results presented at ESTRO-2025, demonstrated similar high local control, while nearly half of the patients were spared the burden of adjuvant treatment. Although the molecular-integrated-risk-profile incurs higher diagnostic costs, these may be offset by reducing overtreatment.

Methods: All patients from the intention-to-treat analysis of the PORTEC-4a trial were included in the cost-utility-analysis. EC-related costs were estimated from a healthcare-perspective over a three-year follow-up period. Costs were related to quality-adjusted-life-years (QALY) using the EORTC Quality-of-Life-Utility-Measure Core-10-dimension (QLU-C10D). T-tests compared mean QALYs and costs, with multiple imputation for missing data.

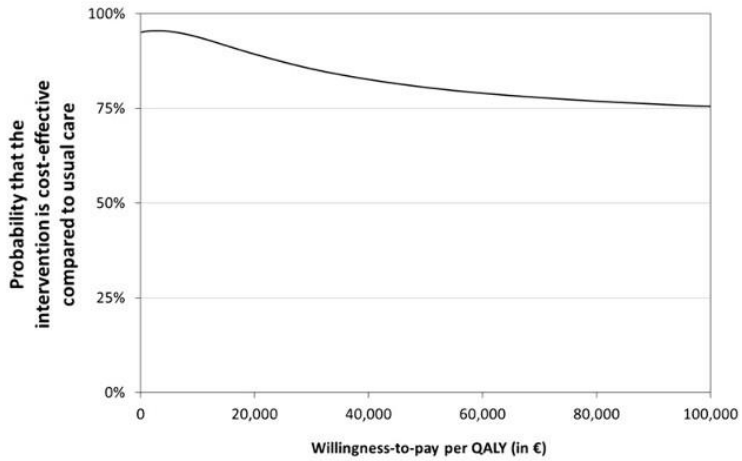
Results: 592 patients were enrolled between 2016-2021, of whom 564 were eligible and evaluable. 367 were randomised to the molecular-profile-arm and 197 to the VBT-arm. QALYs were comparable between the two arms (p=0.26). Mean total healthcare costs were slightly lower for the molecular-profile-arm (€11808) than the VBT-arm (€12893, p=0.1), while mean total healthcare costs until recurrence were significantly lower in the molecular-profile-arm (€9.934 vs. €11.779, p<0.001). There was no significant difference in costs for recurrence treatment (€1.873 vs. €1.114, p=0.09), table 1. For a willingness-to-pay threshold of €20.000 per QALY, the molecular-profile-arm was proven to be cost-effective.

Table 1: Mean three-year healthcare use and costs per patient, by randomisation group.

	Molecular-profile-arm n =367		VBT-arm n =197		Difference in costs	
	%	€	%	€	€	P
Diagnostic procedures						
Pathology review	100%	75	100%	75	-	
Screening for LS by IHC for MMR	100%	600	100%	600	-	
In case of MLH1-hypermethylation	25.1%	163	28.1%	143	20	0.40
Consultation and diagnostics clinical genetics in case of suspicion for LS	6.3%	148	4.6%	109	39	0.39
Molecular-integrated profile by IHC and DNA-sequencing	100%	1180	0,0%	0	1180	<0.001
Costs of diagnostic procedures	2166		927		1239	<0.001
Adjuvant therapy						
Observation	46.0%	2427	1.0%	83	2344	<0.001
Vaginal brachytherapy	40.0%	2110	99.0%	8200	-6090	<0.001
Pelvic external beam radiotherapy	14.0%	739	0.0%	0	739	<0.001
Costs of Adjuvant therapy	5276		8283		-3007	<0.001
Follow-up and toxicity						
Radiation Oncologist visits[§]	5.9	1194	5.9	1190	4	0.96
Gynaecologist visits[§]	5.8	1216	5.8	1217	1	0.91
Diagnostics for suspected recurrence/progression	9.3%	83	8.7%	77	6	0.79
Surgery for toxicity	0.0%	0	1.5%	85	-85	0.13
Costs of follow-up and toxicity	2493		2569		-74	0.88
Total healthcare costs until recurrence	9935		11779		-1842	<0.001
Treatment of recurrence or progression						
Surgery	2.5%	296	3.1%	162	134	0.34
Radiation therapy	5.2%	674	3.6%	443	231	0.35
Chemotherapy[*]	4.1%	505	2.6%	284	221	0.24
Other trial medication[#]	1.4%	271	0.5%	62	209	0.14
Hormonal therapy	3.0%	14	4.6%	35	-21	0.25
Hospital admission	1.9%	113	2.0%	128	-15	0.85
Costs of recurrence and progression	1873		1114		759	0.09
Total healthcare costs	11808		12893		-1085	0.10

Abbreviations: LS, lynch syndrome; IHC, immunohistochemistry; MMR, mismatch repair proteins; MLH1, mutL homolog 1; VBT, vaginal brachytherapy.
[§]Follow up visits at both the gynaecology and radiotherapy department took place twice a year.
[*]For chemotherapy doses depend on patient-specific factors, an average was calculated for a 70-year-old female patient (height of 170cm, weight of 80kg, creatinine excretion ratio of 75 µmol/L).
[#]Instead of costs for treatments provided in the context of (phase I/II) clinical trials, such as immunotherapy, an additional 6 cycles of carboplatin/paclitaxel, which was the standard second line therapy at the time of the trial were used a substitution for the costs

Figure 1: Cost-effective acceptability curve



Probability that the molecular-integrated profile is cost-effective compared to standard vaginal brachytherapy depending on the willingness-to-pay for patient outcomes.

Conclusion/Implications: Individualised molecular-integrated adjuvant treatment was more cost-effective for (high)intermediate EC patients, than standard VBT. The results support the integration of the molecular-integrated-risk-profile into routine clinical practice.

OP003 / #511

Topic: *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

LONG-TERM FOLLOW-UP OF SELINEXOR MAINTENANCE TREATMENT IN PATIENTS WITH TP53 WILD TYPE ADVANCED/RECURRENT ENDOMETRIAL CANCER: INTERMEDIATE ENDPOINTS BY MISMATCH REPAIR STATUS IN THE ENGOT-EN5/GOG-3055/SIENDO STUDY

PLENARY: ENDOMETRIAL CANCER ORAL ABSTRACT PRESENTATIONS

Alejandro Pérez-Fidalgo[1], Ignace Vergote[2], Erika Hamilton[3], Giorgio Valabrega[4], Toon Van Gorp[2], Jalid Sehouli[5], Jan Kümmel[6], Amit Oza[7], Debra Richardson[8], Eva Guerra-Alia[9], Alice Bergamini[10], Stephanie Henry[11], David Miller[12], Jerónimo Martinez-Garcia[13], Daniel Spitz[14], Kai Li[15], Pratheek Kalyanapu[15], Vicky Makker[16]
[1]GEICO and Hospital Clínico Universitario de Valencia, Valencia, Spain, [2]University Hospitals Leuven, Leuven Cancer Institute, Leuven, and Belgium and Luxembourg Gynaecological Oncology Group (BGOG), Leuven, Belgium, [3]Sarah Cannon Research Institute, Nashville, United States of America, [4]MITO and Department of Oncology, University of Torino, Mauriziano Hospital, Turin, Italy, [5]NOGGO and Department of Gynecology with Center for Oncological Surgery, European Competence Center for Ovarian Cancer, Charité Comprehensive Cancer Center, Charité–Universitätsmedizin Berlin, Berlin, Germany, [6]University Hospital Ostrava, Department Of Gynaecology And Obstetrics, Ostrava, Czech Republic, [7]Princess Margaret Cancer Centre, Toronto, Canada, [8]Stephenson Cancer Center, University of Oklahoma Health Sciences Center, Oklahoma City, United States of America, [9]GEICO and Hospital Universitario Ramón y Cajal, Madrid, Spain, [10]San Raffaele Milano and Università Vita-Salute San Raffaele, Department Of Obstetrics And Gynecology, Milano, Italy, [11]BGOG and Université Catholique de Louvain CHU UCL Namur Site Ste Elisabeth, Service d'onco-hématologie (SORMIN), Namur, Belgium, [12]Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Department Of Obstetrics And Gynecology, Dallas, United States of America, [13]GEICO and Hospital Clínico Universitario Virgen de la Arrixaca, Murcia, Spain, [14]Florida Cancer Specialists & Research Institute, West Palm Beach, United States of America, [15]Karyopharm Therapeutics, Newton, United States of America, [16]Memorial Sloan Kettering Cancer Center, Weill Cornell Medical College, New York, United States of America

Introduction: *TP53* is a recognized prognostic biomarker for endometrial cancer (EC). *TP53*wt is found in ~50% of advanced/recurrent EC tumors, with *TP53*wt/pMMR being a unique subgroup with significant unmet need to improve treatment outcomes. Selinexor has shown a strong PFS signal in *TP53*wt EC regardless of MMR status, with marked PFS benefit in *TP53*wt/pMMR.

Methods: ENGOT-EN5/GOG-3055/SIENDO (NCT03555422), a randomized, double-blind, Ph3 trial, evaluated selinexor vs placebo (2:1) as maintenance treatment for advanced/recurrent EC with response on first-line chemotherapy. Time to first subsequent therapy (TFST), PFS2, and time to second subsequent therapy (TSST) were assessed in *TP53*wt pMMR and dMMR subgroups. *P*-values are 1-sided and nominal.

Results: As of April 2024, 50% of patients in the *TP53*wt subgroup discontinued selinexor and initiated subsequent therapy vs 83% in placebo. Median TFST was 31.7 months in selinexor vs 10.6 months in placebo (HR 0.41, p=0.0002). Median PFS2 and TSST were both not reached (NR) in selinexor vs 35.2 and 22.1 months, respectively, in placebo (HR 0.62, p=0.0581; HR 0.47, p= 0.0041). Intermediate endpoint improvements were seen in both MMR subgroups, particularly in *TP53*wt/pMMR (Table). TEAEs, including Grade ≥3, were generally manageable and reversible with no new safety signals identified.

Conclusion/Implications: TFST, PFS2, and TSST improvements provide supportive evidence of treatment durability and cumulative effectiveness of subsequent treatment, further characterizing selinexor's potential clinical benefit and potential to prolong systemic therapy benefit in *TP53*wt EC. No new safety signals were identified. ENGOT-EN20/GOG-3083/XPORT-EC-042, currently enrolling, will further investigate selinexor maintenance therapy in advanced/recurrent *TP53*wt EC (NCT05611931).

Table

	*TP53*wt/pMMR			*TP53*wt/dMMR		
	SEL (n=47)	PBO (n=23)	Hazard ratio (95%CI)	SEL (n=20)	PBO (n=9)	Hazard ratio (95%CI)
TFST	NR (24.6, NR)	8.5 months (4.3, NR)	0.31 (0.16, 0.61) p=0.0002	25.7 months (6.6, NR)	4.8 months (3.8, NR)	0.47 (0.17, 1.28) p=0.0659
PFS2	43.9 months (41.1, NR)	30.1 months (17.3, NR)	0.56 (0.27, 1.18) p=0.0611	NR (NR, NR)	NR (7.2, NR)	0.43 (0.10, 1.84) p=0.1229
TSST	NR (43.9, NR)	17.2 months (12.9, NR)	0.39 (0.19, 0.81) p=0.0043	NR (NR, NR)	NR (8.0, NR)	0.43 (0.10, 1.84) p=0.1229

Data represent median (95% CI); p-values are one-sided nominal
TFST, PFS2 and TSST calculation begins at randomization of maintenance therapy

OP004 / #563

Topic: *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

LEVER: PHASE II TRIAL OF LEVONORGESTREL INTRAUTERINE DEVICE ALONE OR IN COMBINATION WITH THE MTORC1 INHIBITOR EVEROLIMUS FOR THE TREATMENT OF ATYPICAL ENDOMETRIAL HYPERPLASIA AND EARLY-STAGE ENDOMETRIAL CANCER

PLENARY: ENDOMETRIAL CANCER ORAL ABSTRACT PRESENTATIONS

Ravali Reddy[1], Michaela Onstad Grinsfelder[1], Elizabeth Euscher[2], Mark Munsell[3], Kari Ring[4], Marina Frimer[5], Laura Holman[6], Larissa Meyer[1], Jolyn Taylor[1], Lauren Cobb[1], Melinda Yates[7], Richard Guevarra[1], Mariana Gallardo[1], David Warshal[8], Aine Clements[9], Aaron Shafer[1], Nicole Fleming[10], Kathleen Schmeler[1], Lois Ramondetta[1], Amir Jazaeri[1], Jose Alejandro Rauh-Hain[1], Robin Lacour[11], Pamela Soliman[1], Shannon Westin[1]
[1]The University of Texas MD Anderson Cancer Center, Department Of Gynecologic Oncology And Reproductive Medicine, Houston, United States of America, [2]The University of Texas MD Anderson Cancer Center, Department Of Anatomic Pathology, Houston, United States of America, [3]The University of Texas MD Anderson Cancer Center, Department Of Biostatistics, Houston, United States of America, [4]University of Virginia Health System, Department Of Medical Oncology, Charlottesville, United States of America, [5]Zucker School of Medicine at Hofstra/Northwell, Department Of Gynecologic Oncology, Hempstead, United States of America, [6]University of Oklahoma, Department Of Gynecologic Oncology, Oklahoma City, United States of America, [7]University of North Carolina School of Medicine, Department Of Pathology And Laboratory Medicine, Chapel Hill, United States of America, [8]Cooper University Health Care, Department Of Gynecologic Oncology, Voorhees Township, United States of America, [9]OhioHealth, Department Of Gynecologic Oncology, Columbus, United States of America, [10]Fred Hutch Cancer Center, Seattle, United States of America, [11]Banner MD Anderson Cancer Center at North Colorado Medical Center (NCMC), Department Of Gynecologic Oncology, Greeley, United States of America

Introduction: Progesterone resistance in early endometrial neoplasia may arise from PI3K/AKT/mTOR pathway activation. Addition of a PI3K/AKT/mTOR inhibitor, such as everolimus, to progesterone therapy via the levonorgestrel intrauterine device (LIUD) could overcome resistance in atypical endometrial hyperplasia (AEH) or stage 1A grade 1 endometrioid endometrial carcinoma (G1EEC).

Methods: This multi-institution, two-stage, randomized phase II trial treated patients with AEH/G1EEC and potential progesterone resistance. In Stage 1, all patients received LIUD alone (52 mg levonorgestrel). Endometrial biopsy was obtained every three months. Participants were assessed for persistent/progressive disease, defined as

persistent AEH/G1EEC after 3 months or progression to higher-grade disease). In Stage 2, patients with resistance were randomized to LIUD alone or LIUD with everolimus (10 mg daily, 28-day cycle). Primary endpoint was pathologic response rate at 3/6 months for LIUD alone and 6 months for LIUD/everolimus.

Results: Stage 1: 94 patients (61 AEH, 33 G1EEC, median age 36) were treated. Of 91 evaluable patients, 3-month response rate was 59.3% (90% CI: 48.2-69.6; 54 complete response (CR), 35 stable disease (SD), and 2 progressive disease (PD)). Stage 2: 42 patients (22 AEH, 20 G1EEC) were treated. Of 39 evaluable patients, 21 received LIUD alone and 18 received LIUD/everolimus. The 6-month response rate for LIUD alone was 47.6% (90% CI: 27.0-69.1) versus 35.3% (90% CI: 16.3-60.5) for combination therapy (p=0.5205). No Grade 4/5 adverse events (AEs) occurred. Grade 3 AEs for LIUD/everolimus included transaminitis and hyperglycemia.

Conclusion/Implications: Combination treatment with LIUD/everolimus is safe/feasible but did not increase pathologic response compared to LIUD alone in progesterone-resistant AEH/G1EEC.

OP005 / #575

Topic: *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

PHASE II RANDOMIZED CONTROLLED TRIAL OF EVEROLIMUS AND LETROZOLE WITH OR WITHOUT RIBOCICLIB IN ADVANCED/RECURRENT ENDOMETRIAL CANCER

PLENARY: ENDOMETRIAL CANCER ORAL ABSTRACT PRESENTATIONS

Jeffrey How[1], Shannon Westin[2], Melissa Pham[2], Barrett Lawson[3], Minxing Chen[4], Bryan Fellman[4], Ying Yuan[5], Amir Jazaeri[2], Michaela Onstad Grinsfelder[2], Kathleen Schmeler[1], Mikayla Bowen[2], Karen Lu[2], Melinda Yates[2], Russell Broaddus[3], Pamela Soliman[2]
[1]The University of Texas MD Anderson Cancer Center, Gynecologic Oncology And Reproductive Medicine, Houston, United States of America, [2]The University of Texas MD Anderson Cancer Center, Department Of Gynecologic Oncology And Reproductive Medicine, Houston, United States of America, [3]The University of Texas MD Anderson Cancer Center, Pathology, Houston, United States of America, [4]The University of Texas MD Anderson Cancer Center, Biostatistics, Houston, United States of America, [5]The University of Texas MD Anderson Cancer Center, Department Of Biostatistics, Houston, United States of America

Introduction: We report the results of a multicenter, randomized phase II trial evaluating the efficacy of everolimus and letrozole with or without ribociclib in advanced/recurrent endometrioid endometrial cancer (NCT03008408).

Methods: Following a safety lead-in for RP2D determination in the experimental arm (Arm_{exp}), patients were randomized 1:1 to receive everolimus 2.5 mg po daily, letrozole 2.5 mg po daily, and ribociclib 200 mg po daily (Arm_{exp}) or everolimus 10 mg po daily and letrozole 2.5 mg po daily ($Arm_{control}$) in 28-day cycles. Prespecified-protocol enrollment ≥14 patients with *CTNNB1* mutations was required. The primary endpoint was PFS. Secondary endpoints were toxicity, OS, and ORR.

Results: Seventy patients were randomized (n=35 each). No difference in mPFS (16.7 vs 11.9 months), mOS (28.9 vs 31.5 months), and ORR (44.1% vs 25.7%) observed. Toxicity-related treatment discontinuation was similar (8.6% vs 11.4%). The addition of ribociclib resulted in higher ORR among those with $CTNNB1_{mut}$ tumors (56.3% vs 16.7%, p=0.05) and those with prior endocrine therapy (61.5% vs 0%, p<0.001). Within Arm_{exp}, $CTNNB1_{mut}$ tumors were associated with improved mPFS (20.6 vs 5.5 months, p=0.04) and mOS (not reached vs 22.7 months, p=0.02) compared to $CTNNB1_{WT}$ tumors. A similar trend was observed within $Arm_{control}$ for mPFS (38.8 vs 8.2 months, p=0.03) and mOS (39.7 vs 13.3 months, p=0.23).

Conclusion/Implications: The addition of ribociclib to everolimus/letrozole may improve efficacy among those with *CTNNB1*$_{mut}$ tumors or prior endocrine therapy. Despite the aggressiveness of *CTNNB1*$_{mut}$ tumors and their association with worse prognosis, everolimus-based therapy among those with *CTNNB1*$_{mut}$ tumors was associated with improved survival outcomes.

OP006 / #718

Topic: *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

A PHASE II EVALUATION OF THE EFFICACY AND SAFETY OF SACITUZUMAB GOVITECAN IN PATIENTS WITH RECURRENT UTERINE CANCER

PLENARY: ENDOMETRIAL CANCER ORAL ABSTRACT PRESENTATIONS

Alessandro D. Santin[1], Dana M. Roque[2], Eric Siegel[3], Victoria Ettorre[1], Michelle Greenman[1], Blair Mcnamara[1], Katya Papatla[1], Aparna Kailasam[1], Masoud Azodi[1], Natalia Buza[4], Mitchell Clark[1], Pei Hui[4], Gary Altwerger[1], Peter Dottino[1], Elena Ratner[1], Stefania Bellone[1]
[1]Yale University School of Medicine, Department Of Obstetrics, Gynecology And Reproductive Sciences, New Haven, United States of America, [2]University of Maryland School of Medicine, Division Of Gynecologic Oncology, Greenebaum Comprehensive Cancer Center, Baltimore, United States of America, [3]University of Arkansas for Medical Sciences, Department Of Biostatistics, Little Rock, United States of America, [4]Yale University School of Medicine, Department Of Pathology, New Haven, United States of America

Introduction: Endometrial cancer (EC) patients who progress after chemotherapy/immunotherapy have limited treatment options. We evaluated sacituzumab govitecan (SG), a Trop-2-directed antibody-drug conjugate, in patients with persistent/recurrent EC, including carcinosarcoma.

Methods: This was a phase 2, two-stage open-label investigator-initiated trial in patients with progression after ≥1 prior therapy. Stage 1 enriched for tumors with elevated Trop-2 expression (≥50%, SP295 antibody); stage 2 included all-comers. Patients received SG 10 mg/kg on days 1,8 every 3 weeks. The primary endpoint was objective response rate (ORR). Secondary endpoints included clinical benefit rate (CBR=complete response [CR]+partial response [PR]+stable disease ≥6mo), duration of response (DOR), progression-free survival (PFS), overall survival (OS), and safety. Trop-2 H-score (0-300) was calculated using immunohistochemistry (EPR20043 antibody).

Results: Fifty patients were enrolled/evaluable, including 21 (50 screened) and 29 (34 screened) in stages 1/2, respectively. Eighty-four percent (n=42) harbored serous carcinoma, carcinosarcoma, or grade 3 endometrioid tumors (**Table 1**). Median follow-up was 10.3 months (range:2.4-59.5). Patients received a median of 2 prior therapies (range:1-4) and 50% had failed pembrolizumab/dostarlimab. ORR was 26% (95%CI,11-38), including CRs (4%) and PRs (22%). CBR was 50% (24/48). Median DOR was 3.3 months (95%CI,1.9-5.5); median PFS/OS were 5.5 (95%CI, 3.7-7.3) and 17.6 (95%CI,11.1-22.5) months, respectively (**Figure 1**). Grade 3-4 toxicity occurred in 80%

with no deaths attributable to SG. Mean Trop-2 H-scores (43 biomarker evaluable) did not predict response.

Table 1: Patient and disease characteristics

	n	%
Age (years)		
<65	32	64
≥65	18	36
Race		
Non-Hispanic White	33	66
Non-Hispanic Black	7	14
Non-Hispanic Asian	2	4
Non-Hispanic Other	3	6
Hispanic	5	10
Disease Status		
Recurrent	36	72
Refractory	14	28
ECOG Performance Status		
0	27	54
1	23	46
FIGO (2008) stage		
IA	6	12
IB	4	8
II	2	4
IIIA	5	10
IIIB	1	2
IIIC1	4	8
IIIC2	7	14
IVA	4	8
IVB	17	34

	n	%
Histology		
Endometrioid	11	22
-grade 1	2	4
-grade 2	2	4
-grade 3	7	14
Mixed serous	3	6
Serous	21	42
Carcinosarcoma	11	22
Other	4	8
Mismatch repair status (n=46)		
proficient	44	96
	mean	**SD**
Membrane Trop-2 H-Score (n=43)		
all	212.4	75.2
non-responders	199.7	79.5
responders	245.3	52.1
	p=0.07	
Cytomembrane Trop-2 H-Score (n=43)		
all	221.8	75.8
non-responders	209.3	80.9
responders	253.9	50.1
	p=0.08	
Tumor Necrosis (%) (n=43)		
all	9.2	13.6
non-responders	4.3	9.1
responders	11.2	14.6
	p=0.009	

ECOG, Eastern Cooperative Oncology Group; *FIGO*, Federation Internationale d'Obstetrique et Gynecologie; Trop-2, trophoblast cell surface antigen 2; *SD*, standard deviation

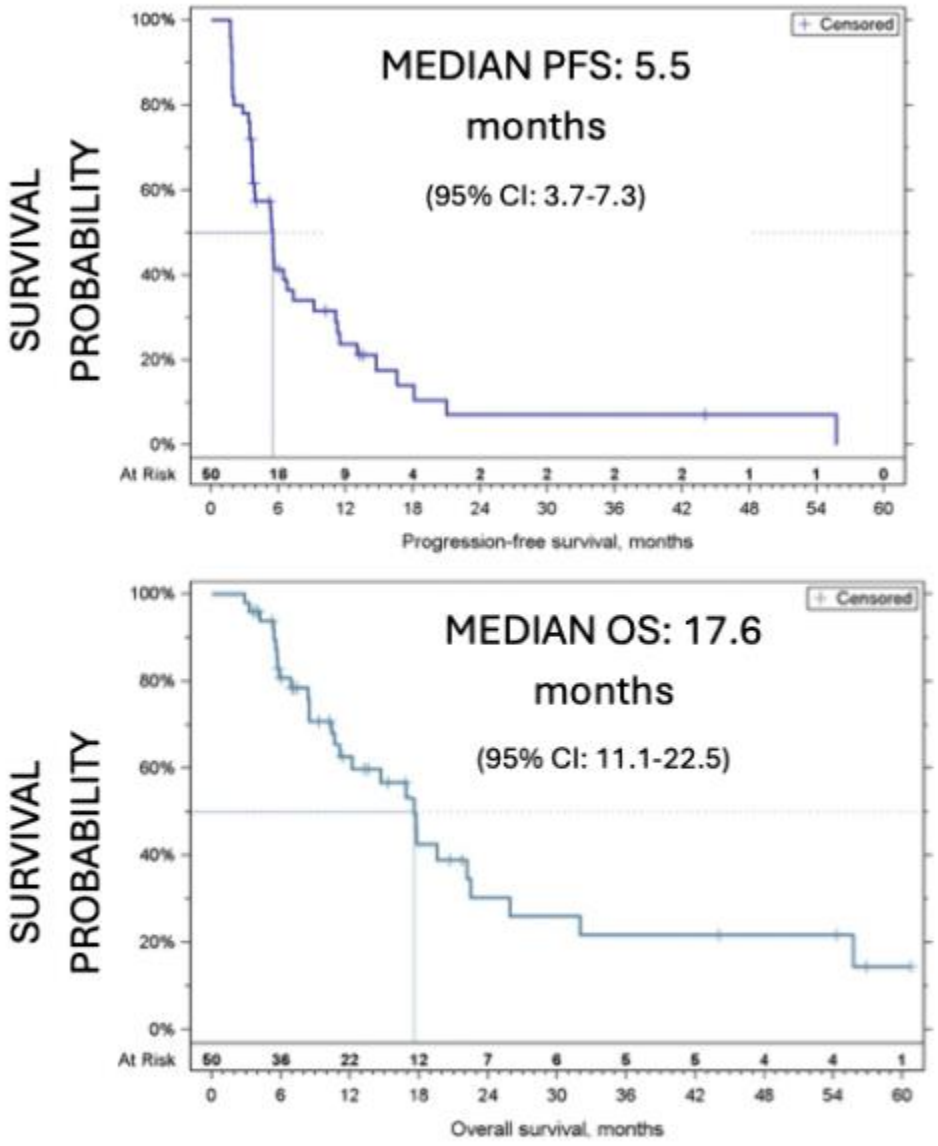


Figure 1: Progression-free (top, PFS) and overall survival (bottom, OS).

Conclusion/Implications: SG demonstrated encouraging efficacy with manageable toxicity in a pretreated population of biologically aggressive recurrent EC. Adverse events were consistent with prior reports of SG.

OP007 / #481

Topic: *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

LENVATINIB PLUS PEMBROLIZUMAB VERSUS TREATMENT OF PHYSICIAN'S CHOICE IN PARTICIPANTS WITH ADVANCED ENDOMETRIAL CANCER: 5-YEAR OUTCOMES FROM STUDY 309/KEYNOTE-775

ENDOMETRIAL CANCER MASTER SESSION: NEW APPROACHES IN THE ADJUVANT AND METASTATIC SETTING

Vicky Makker[1], Nicoletta Colombo[2], Antonio Casado Herráez[3], Alessandro D. Santin[4], Emeline Colomba[5], David Miller[6], Keiichi Fujiwara[7], Sandro Pignata[8], Kan Yonemori[9], Yong Man Kim[10], Sally Baron-Hay[11], Isabelle Ray-Coquard[12], Ronnie Shapira-Frommer[13], Rebecca Kristeleit[14], Zhou Yu[15], Jodi Mckenzie[16], Stephan Kruger[15], Robin Meng[15], Chinyere E. Okpara[17], Domenica Lorusso[18]
[1]Department of Medicine, Memorial Sloan Kettering Cancer Center, Weill Cornell Medical College, New York, United States of America, [2]Gynecologic Oncology Program, European Institute of Oncology, IRCSS and Department of Medicine and Surgery, University of Milano Bicocca, Milan, Italy, [3]Medical Oncology Department, Hospital Clinico Universitario San Carlos, Madrid, Spain, [4]Department of Obstetrics, Gynecology and Reproductive Sciences, Yale University School of Medicine, New Haven, United States of America, [5]Department of Medical Oncology, Gustave Roussy Cancer Campus, Villejuif, France, [6]Division of Gynecologic Oncology, University of Texas Southwestern Medical Center, Dallas, United States of America, [7]Department of Gynecologic Oncology, Saitama Medical University International Medical Center, Saitama, Japan, [8]Department of Urology and Gynecology, Istituto Nazionale Tumori IRCCS Fondazione G. Pascale and MITO, Rome, Italy, [9]Department of Medical Oncology, National Cancer Center Hospital, Chuo-ku, Japan, [10]Department of Obstetrics and Gynecology, Asan Medical Center, University of Ulsan, Seoul, Korea, Republic of, [11]Medical Oncology Department, Royal North Shore Hospital, St Leonards, Australia, [12]Medical Oncology Department, Centre Léon Bérard, University Claude Bernard, GINECO Group, Lyon, France, [13]The Ella Institute for Immuno-Oncology, Sheba Medical Center, Ramat Gan, Israel, [14]Department of Oncology, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom, [15]Merck & Co., Inc., Rahway, United States of America, [16]Eisai Inc., Nutley, United States of America, [17]Eisai Ltd., Hatfield, United Kingdom, [18]Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan; Gynaecological Oncology Medical Unit, Humanitas San Pio X Hospital, Milan; Department of Women and Child Health, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy

Introduction: In phase 3 Study 309/KEYNOTE-775 (NCT03517449), lenvatinib+pembrolizumab (L+P) vs treatment of physician's choice (TPC) significantly

improved PFS, OS, and ORR in pMMR advanced endometrial cancer (EC) and all-comers. We report 5-year follow-up results.

Methods: Participants had advanced, recurrent, or metastatic EC with PD after 1 prior platinum-based chemotherapy regimen, measurable disease per RECISTv1.1, no prior receipt of anti–PD-(L)1 agents, and tumor tissue sample for determining MMR status. Two lines of platinum-based chemotherapy were permitted if 1 was (neo)adjuvant therapy. Participants were randomized 1:1 to L 20mg orally QD plus P 200mg IV Q3W or TPC (doxorubicin or paclitaxel). P was given for ≤35 cycles. Primary endpoints were OS and PFS per RECISTv1.1 by BICR. Secondary endpoints included ORR per RECISTv1.1 by BICR and safety.

Results: 827 participants were randomized. At data cutoff (26-February-2025), overall median follow-up was 68.8 (range, 60.8–80.0) months; 139 participants were alive (L+P, 86; TPC, 53), and all had ended their treatment. Results are in **Tables 1–2**. Additional data will be presented (tumor dynamics by BOR, participants who continued P beyond RECISTv1.1 progression, response/dose modification change over time, participant characteristics in those with durable response, and poststudy therapies).

Conclusion/Implications: Five-year follow-up results are consistent with primary analysis, despite increased use of subsequent systemic anticancer treatment and crossover to L+P in TPC arm. Results continued to show durable benefit with L+P vs TPC in participants with previously treated advanced EC, with no new safety signals.

	pMMR		dMMR		All-Comers	
	L+P (n = 346)	TPC (n = 351)	L+P (n = 65)	TPC (n = 65)	L+P (n = 411)	TPC (n = 416)
OS						
Median (95% CI),[a] mo	18.0 (14.9–20.5)	12.2 (11.0–14.1)	31.9 (15.6–47.7)	8.6 (5.5–13.4)	18.7 (15.6–21.3)	11.9 (10.6–13.3)
HR (95% CI)[b]	0.70 (0.60–0.83)		0.44 (0.29–0.67)		0.66 (0.57–0.77)	
HR (95% CI)[b] at primary OS analysis[1]	0.70 (0.58–0.83)		0.43 (0.28–0.68)		0.65 (0.55–0.77)	
5-y rate (95% CI),[a] %	16.7 (12.8–21.1)	7.3 (4.6–10.8)	36.5 (24.6–48.5)	9.8 (3.1–21.1)	19.9 (16.0–24.2)	7.7 (5.1–11.0)
PFS						
Median (95% CI),[a] mo	6.7 (5.6–7.4)	3.8 (3.6–5.0)	14.8 (5.6–31.9)	3.7 (3.1–4.4)	7.3 (5.7–7.6)	3.8 (3.6–4.2)
HR (95% CI)[b]	0.60 (0.51–0.72)		0.39 (0.25–0.60)		0.56 (0.48–0.66)	
HR (95% CI)[b] at primary PFS analysis[2]	0.60 (0.50–0.72)		0.36 (0.23–0.57)		0.56 (0.47–0.66)	
5-y rate (95% CI),[a] %	6.3 (3.7–9.8)	2.1 (0.6–5.4)	26.4 (15.6–38.6)	10.8 (3.9–21.7)	9.8 (6.8–13.4)	3.2 (1.3–6.5)
PFS2 (next-line therapy)						
Median (95% CI),[a] mo	14.7 (12.5–17.3)	10.0 (8.8–11.3)	25.0 (14.9–46.0)	8.0 (5.5–10.6)	15.3 (13.5–18.2)	9.8 (8.6–10.9)
HR (95% CI)[b]	0.69 (0.58–0.82)		0.40 (0.26–0.60)		0.64 (0.55–0.74)	
6-mo rate (95% CI),[a] %	82.0 (77.5–85.7)	74.9 (69.9–79.2)	80.0 (68.1–87.9)	60.2 (47.0–71.1)	81.7 (77.6–85.1)	72.6 (68.0–76.7)
BOR (95% CI),[c] %						
ORR	32.4 (27.5–37.6)	14.8 (11.3–19.0)	41.5 (29.4–54.4)	12.3 (5.5–22.8)	33.8 (29.3–38.6)	14.4 (11.2–18.2)
CR	6.4 (4.0–9.5)	2.6 (1.2–4.8)	21.5 (12.3–33.5)	3.1 (0.4–10.7)	8.8 (6.2–11.9)	2.6 (1.3–4.7)
PR	26.0 (21.5–31.0)	12.3 (9.0–16.1)	20.0 (11.1–31.8)	9.2 (3.5–19.0)	25.1 (20.9–29.5)	11.8 (8.8–15.3)
SD	46.5 (41.2–51.9)	39.6 (34.4–44.9)	36.9 (25.3–49.8)	43.1 (30.8–56.0)	45.0 (40.1–50.0)	40.1 (35.4–45.0)
PD	15.6 (11.9–19.9)	30.8 (26.0–35.9)	10.8 (4.4–20.9)	23.1 (13.5–35.2)	14.8 (11.5–18.7)	29.6 (25.2–34.2)
Not evaluable[d]	0.6 (0.1–2.1)	2.3 (1.0–4.4)	4.6 (1.0–12.9)	1.5 (0.0–8.3)	1.2 (0.4–2.8)	2.2 (1.0–4.1)
No assessment[e]	4.9 (2.9–7.8)	12.5 (9.3–16.5)	6.2 (1.7–15.0)	20.0 (11.1–31.8)	5.1 (3.2–7.7)	13.7 (10.5–17.4)
DOR, median (95% CI),[a] mo	9.3 (7.4–14.4)	5.7 (4.7–11.4)	NR (29.1–NR)	4.1 (2.6–NR)	13.4 (9.2–16.5)	5.7 (4.5–9.5)
Subsequent systemic anticancer treatment,[f] n (%)	171 (49.4)	185 (52.7)	13 (20.0)	28 (43.1)	184 (44.8)	213 (51.2)
L+P	10 (2.9)	41 (11.7)	0	1 (1.5)	10 (2.4)	42 (10.1)
Any PD-(L)1 checkpoint inhibitor	18 (5.2)	54 (15.4)	2 (3.1)	15 (23.1)	20 (4.9)	69 (16.6)
Subsequent systemic anticancer treatment at primary OS analysis,[1] n (%)	154 (44.5)	180 (51.3)	11 (16.9)	27 (41.5)	165 (40.1)	207 (49.8)
L+P	6 (1.7)	35 (10.0)	0	1 (1.5)	6 (1.5)	36 (8.7)
Any PD-(L)1 checkpoint inhibitor	11 (3.2)	45 (12.8)	–	–	12 (2.9)	62 (14.9)

NR, not reached.

1. Makker V, et al. *J Clin Oncol.* 2023;41:2904–2910. 2. Makker V, et al. *N Engl J Med.* 2022;386:437–448.

[a]Kaplan-Meier method for censored data

[b]Based on stratified (all-comers) or unstratified (pMMR, dMMR) Cox regression model with the Efron method of tie handling.

[c]Based on binomial exact CI method.

[d]Postbaseline assessment available but not evaluable.

[e]No postbaseline assessment available for response evaluation.

[f]Any line of subsequent treatment; each participant is counted a single time for each applicable specific anticancer treatment.

	L+P (n = 406)	TPC (n = 388)
Duration on therapy, median (range), d	231.5 (1.0–2212.0)	104.5 (1.0–1177.0)
Both L+P	192.0 (1.0–967.0)	–
L	215.5 (1.0–2212.0)	–
P	211.5 (1.0–967.0)	–
L dose reduction, n (%)	293 (72.2)	–
0	113 (27.8)	–
1	95 (23.4)	–
2	99 (24.4)	–
3	63 (15.5)	–
4	36 (8.9)	–
Time to first L dose reduction, median (range), mo	2.0 (0.1–32.5)	–
AEs leading to L or TPC dose reduction, n (%)	279 (68.7)	49 (12.6)
AEs leading to interruption of any treatment, n (%)	294 (72.4)	109 (28.1)
L	253 (62.3)	–
P	212 (52.2)	–
Both L+P	129 (31.8)	–
AEs leading to discontinuation of any treatment, n (%)	163 (40.1)	31 (8.0)
L	149 (36.7)	–
P	90 (22.2)	–
Both L+P	65 (16.0)	–
Treatment-related AEs, n (%)	395 (97.3)	364 (93.8)
Grade 3–5	321 (79.1)	233 (60.1)
Led to any treatment discontinuation	131 (32.3)	23 (5.9)
Serious	144 (35.5)	55 (14.2)
Led to death	6 (1.5)	9 (2.3)

OP008 / #384

Topic: *AS06. Tumor Types / AS06d. Ovarian Cancer*

EFFICACY AND SAFETY OF LOW-DOSE LENVATINIB AND TORIPALIMAB IN PATIENTS WITH PLATINUM-RESISTANT RECURRENT OVARIAN CANCER: A MULTICENTER, OPEN-LABEL, SINGLE-ARM, PHASE II CLINICAL TRIAL

PLENARY: OVARIAN CANCER ORAL ABSTRACT PRESENTATIONS

Hao Su[1], Xiao Shang[1], Hongruo Liu[2], Mingle Tian[3], Yang Yu[4], Yanhua Xu[5], Kui Jiang[2], Fengzhi Feng[1]
[1]Peking Union Medical College Hospital, Department Of Obstetrics And Gynecology, Beijing, China, [2]The Second Affiliated Hospital of Dalian Medical University, Department Of Medical Oncology, Dalian, China, [3]Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China, [4]Xing'an League People's Hospital, Department Of Obstetrics And Gynecology, Xing'an League, China, [5]Jinan Maternity and Child Health Care Hospital, Department Of Obstetrics And Gynecology, Jinan, China

Introduction: Platinum-resistant ovarian cancer (PROC) remains therapeutic challenges. While immune checkpoint inhibitor plus lenvatinib demonstrates potential efficacy, the standard 20 mg lenvatinib dosage causes significant adverse events leading to treatment disruption. We present results of a multicenter, single-arm phase II trial evaluating low-dose lenvatinib plus toripalimab for recurrent PROC.

Methods: Eligible patients with recurrent PROC received low-dose lenvatinib (8 or 12 mg daily, based on body weight) and toripalimab (240 mg, every three weeks). Primary endpoint was progression-free survival (PFS) by investigator assessment. Second endpoints included objective response rate (ORR) per RECIST v1.1, duration of response (DOR), disease control rate (DCR), overall survival (OS), and safety.

Results: A total of 33 patients were enrolled. All experienced disease progression during or within 6 months after the last platinum-based chemotherapy (91% platinum-resistant, 9% platinum-refractory), with a median of 3 prior therapy lines (range 1-12). Median PFS and OS were 5.0 months (95% CI 3.8-6.2) and 13.3 months (95% CI 12.4-14.2), respectively. Patients with CA125 decrease after the first cycle had longer PFS (median 7.9 vs 3.7 months, P=0.0003). The ORR was 27% (95% CI 13%-46%) and DCR was 54% (95% CI 36%-72%). Median DOR was 5.1 months (range 2.6-≥16.4). Treatment-related adverse events occurred in 97% of patients (39% grade 3; no grade 4-5). Four (12%) patients required lenvatinib dose reduction, with treatment interruption and discontinuation rates of 42% and 12%, respectively.

Conclusion/Implications: Low-dose lenvatinib plus toripalimab demonstrated encouraging efficacy and favorable tolerability in patients with heavily pretreated, recurrent PROC.

OP009 / #726

Topic: *AS06. Tumor Types / AS06d. Ovarian Cancer*

OVARIAN CANCER TREATMENT IN LOW AND MIDDLE INCOME COUNTRIES:HOW THE EVERY WOMAN STUDY REFLECTS THE LANDSCAPE

PLENARY: OVARIAN CANCER ORAL ABSTRACT PRESENTATIONS

Tracey Adams[1,2], Garth Funston[3], Robin Cohen[4], Frances Reid[5], Martin Origa[6], Rafe Adel[7], Runcie Chidebe[8], Eva-Maria Stromsholm[9], Irene Lau[10], Sara Nasser[11], Asima Mukhopadhyay[12], Basel Refky[13], Ngoc Phan[14], Florencia Noll[15], Isabelle Soerjomataram[16], Eileen Morgan[16], Karen Kapur[5], Anthony Gitari[17], Raikhan Bolatbekova[18], Dilyara Kaidarova[19], Precious Makondi[20], Aisha Mustapha[21], Shahana Pervin[22], Jitendra Pariyar[23], Carlos Andrade[24], Juliana Rodriguez[25], Nargiza Zahirova[26], Mary Eiken[27], Clara Mackay[28], Sook-Yee Yoon[29], Rebecca Ramirez-Morales[30]
[1]Groote Schuur Hospital, University of Cape Town, Gynecologic Oncology Unit, Department Of Obstetrics And Gynaecology, Cape Town, South Africa, [2]Groote Schuur Hospital, University of Cape Town, Gynecologic Oncology, Cape Town, South Africa, [3]Queen Mary University of London, Wolfson Institute Of Population Health, London, United Kingdom, [4]Sandy Rollman Ovarian Cancer Foundation, Wynnewood, United States of America, [5]World Ovarian Cancer Coalition, Thirsk, United Kingdom, [6]Uganda Cancer Institute, Kampala, Uganda, [7]Cancer Bangladesh, Dhaka, Bangladesh, [8]Project PINK BLUE, Abuja, Nigeria, [9]Gynecologic Cancer Patients in Finland, Espoo, Finland, [10]Ovarian Cancer Malaysia, Kuala Lampur, Malaysia, [11]Charite University Hospital Campus Virchow Klinikum,, Berlin, Germany, [12]Kolkata Gynecological Oncology Trials and Translational Research Group, Kolkata, India, [13]Mansoura University Oncology Center, Mansoura, Egypt, [14]Danang Oncology Hospital, Danang, Viet Nam, [15]Sanatorio allende, cordoba, Argentina, [16]International Agency for Research on Cancer, Department Of Cancer Surveillance, Lyon, France, [17]moi university, Reproductive Health, eldoret, Kenya, [18]Almaty Oncological Center, Almaty, Kazakhstan, [19]Kazakh Institute of Oncology and Radiation, Almaty, Kazakhstan, [20]Kamuzu Central Hospital, Lilongwe, Malawi, [21]Ahmadu Bello University Teaching Hospital, Zaria, Nigeria, [22]National Institute of Cancer Research and Hospital, Gynaecological Oncology, Dhaka, Bangladesh, [23]Civil Service Hospital, Gynaecologic Oncology, Kathmandu, Nepal, [24]Barretos Cancer Hospital, Oncogenetics, Barretos, Brazil, [25]Instituto Nacional de Cancerología/Universidad Nacional de Colombia/Fundación Santa Fe de Bogotá, Bogotá, Bogotá, Colombia, [26]Republican Specialized Scientific and Practical Center of Oncology and Radiology, Department Of Gynaecological Oncology, Tashkent, Uzbekistan, [27]International Gynecologic Cancer Society, Head Office, Austin, United States of America, [28]World Ovarian Cancer Coalition, Toronto, Canada, [29]Cancer Research Malaysia, Kuala Lumpur, Malaysia, [30]Instituto Nacional de Cancerologia, Mexico City, Mexico

Introduction: There is limited data on ovarian cancer (OC) treatment and its availability in low- and middle-income countries (LMICs). To address this gap, the Every Woman Study™, a multi-centred, multi-country observational study, examined treatment given to women with OC.

Methods: Data from women in 22 LMICs, diagnosed with OC in the 5 years preceding their participation was retrieved from medical records. We divided the countries according to human development index (HDI) and reviewed the proportion who had access to surgery, chemotherapy and targeted treatments.

Results: Of the 2446 women in the study, 85,8% received surgery as part of their treatment, with wide variation by country (49% in Peru to 100% in Guatemala). Rates of optimal cytoreductive surgery also varied (27.3% in Uganda to 96% in Peru). Borderline ovarian tumours were excluded and of the 2272 women, 1798 (79%) received chemotherapy. Access to chemotherapy varied, as only 21.9% of women with OC in Malawi had access to chemotherapy (FIG 1). Access to targeted agents were relatively low for those with epithelial OC due to the high cost, affordability and lack of genetic testing (FIG 2 :Parp-inhibitors). Only 4% of women with OC (79 of 1960) received PARP-inhibitors. Use was highest in Argentina (21.7%). Not one patient in Africa received the treatment.

Conclusion/Implications: The EWS-LMIC edition has clearly highlighted the inequities in treatment access. Surgery remains the most accessible option as it relies on human resources. Older anti-cancer systemic treatment can be limited by accessibility, and patient preference. Newer treatments are limited by cost and infrastructure.

OP010 / #404

Topic: *AS03. Patient-Centered Care / AS03b. Palliative, Symptomatic & Supportive Care*

ORAL ANTICOAGULANTS IN PATIENTS ON 1ST LINE CHEMOTHERAPY FOR OVARIAN CANCER TO REDUCE VTE RATES – A QUALITY IMPROVEMENT PROJECT

PLENARY: OVARIAN CANCER ORAL ABSTRACT PRESENTATIONS

Dana Josephy[1], Jacob Korach[1], Victoria Tkach[1], Daniel Shai[1], Sonya Bar-Adon[1], Hadas Heger[2], Keren Levanon[1], Ronnie Shapira-Frommer[3], Aharon Lubetsky[4], Anna Blecher[1], Orgad Rosenblatt[1], Itai Yagel[1], Akram Saad[3], Smadar Bauer[3], Ludmila Irmin[1], Danielle Mor-Hadar[1], Tima Davidson[5], Limor Helpman[1]
[1]Sheba Medical Center, Gynecologic Oncology, Tel Hashomer, Israel, [2]Sheba Medical Center, Arc Innovation Center, Tel Hashomer, Israel, [3]Oncology Department, Sheba Medical Center, Tel Hashomer, Tel Aviv District, Israel, [4]Sheba Medical Center, Hematology, Tel Hashomer, Israel, [5]Sheba Medical Center, Nuclear Medicine And Imaging, Tel Hashomer, Israel

Introduction: Ovarian cancer (OC) is commonly diagnosed at advanced stages and often treated with neoadjuvant chemotherapy to reduce tumor burden. Metastatic cancer patients receiving systemic chemotherapy face increased risks for VTE. Benefit has been shown for prophylactic anticoagulants in risk-stratified oncologic populations. While limited publications describe high VTE rates among OC patients, predictors of risk in this population are not well studied. Information on the benefit of oral anticoagulants, specifically in first-line and neoadjuvant settings, is urgently needed. This quality improvement (QI) study aimed to increase prescription rates of oral anticoagulants for risk-selected patients receiving first-line chemotherapy for OC and prospectively assess VTE risk reduction.

Methods: Patients receiving first-line chemotherapy for OC at Sheba Medical Center between 2020-2024 were included. A QI program implemented in July 2023 included staff education, EMR-incorporated Khorana scoring, automated apixaban prescriptions and targeted chemo-suite nursing questionnaires. Data was extracted from the EMR using proprietary MDClone® software with Natural Language Processing to identify VTE events in imaging reports. Descriptive statistics were used to compare patients treated before and after program implementation. Predictors of VTE were evaluated with logistic regression.

Results: VTE rates were high among OC patients on first-line treatment (18%). Patient characteristics were comparable before and after program implementation (Table 1). Performance status, Khorana score and treatment period emerged as significant predictors of VTE risk. Program implementation remained a significant protective factor on multivariable analysis (aOR=0.27, CI 0.10-0.72) (Table 2).

Table 1: patient characteristics across treatment periods

	Before QI implementation	After QI implementation	P value
N	229	87	
Age -mean (SD)	55 (12)	63 (15)	0.206
BMI -median (IQR)	24 (23-28)	25 (22-29)	0.111
ECOG – n(%)			0.113
0	75 (54%)	41 (54.7%)	
1	49 (35.3%)	20 (26.7%)	
2	9 (6.5%)	12 (16%)	
3	6 (4.3%)	2 (2.7%)	
Albumin -mean (SD)	3.28 (0.63)	3.46 (0.64)	0.083
CA125 -median (IQR)	1044.1 (423.8-2544.5)	606.1 (322.8-2407.8)	0.574
Neoadjuvant treatment – n(%)	101 (44.1%)	30 (34.5%)	0.077
Khorana score – n(%)			0.049
1	170 (74.2%)	57 (65.5%)	
2	43 (18.8%)	15 (17.2%)	
3	13 (5.7%)	11 (12.6%)	
4	3 (1.3%)	4 (4.6%)	
Khorana ≥2 – n(%)	59 (25.8%)	30 (34.5%)	0.082
VTE (any) – n(%)	**48 (21%)**	**10 (11.5%)**	**0.034**

*T-test for normally distributed variables, Mann-Whitney for non-normally distributed variables
**Chi-sq for categorical variables

Table 2: Logistic Regression – factors associated with risk of VTE

	OR (CI)	P value	aOR (CI)	P value
Neoadjuvant chemo (ref: none)	0.91 (0.51-1.63)	0.883	1.36 (0.61-3.00)	0.451
ECOG (2-3 vs. 0-1)	2.63 (1.09-6.37)	0.028	3.09 (1.03-9.25)	0.045
Khorana score ≥2 (ref: 1)	1.91 (1.05-3.47)	0.036	1.6 (0.71-3.58)	0.257
After QI implementation (ref: before)	0.49 (0.24-1.02)	0.053	0.27 (0.10-0.72)	0.008

Conclusion/Implications: The implementation of an oral anticoagulation QI program successfully decreased VTE events during first-line chemotherapy for OC.

OP011 / #530

Topic: *AS06. Tumor Types / AS06d. Ovarian Cancer*

FOCUS-ICG:FLUORESCENCE-GUIDED OVARIAN CANCER CYTOREDUCTION USING INDOCYANINE GREEN

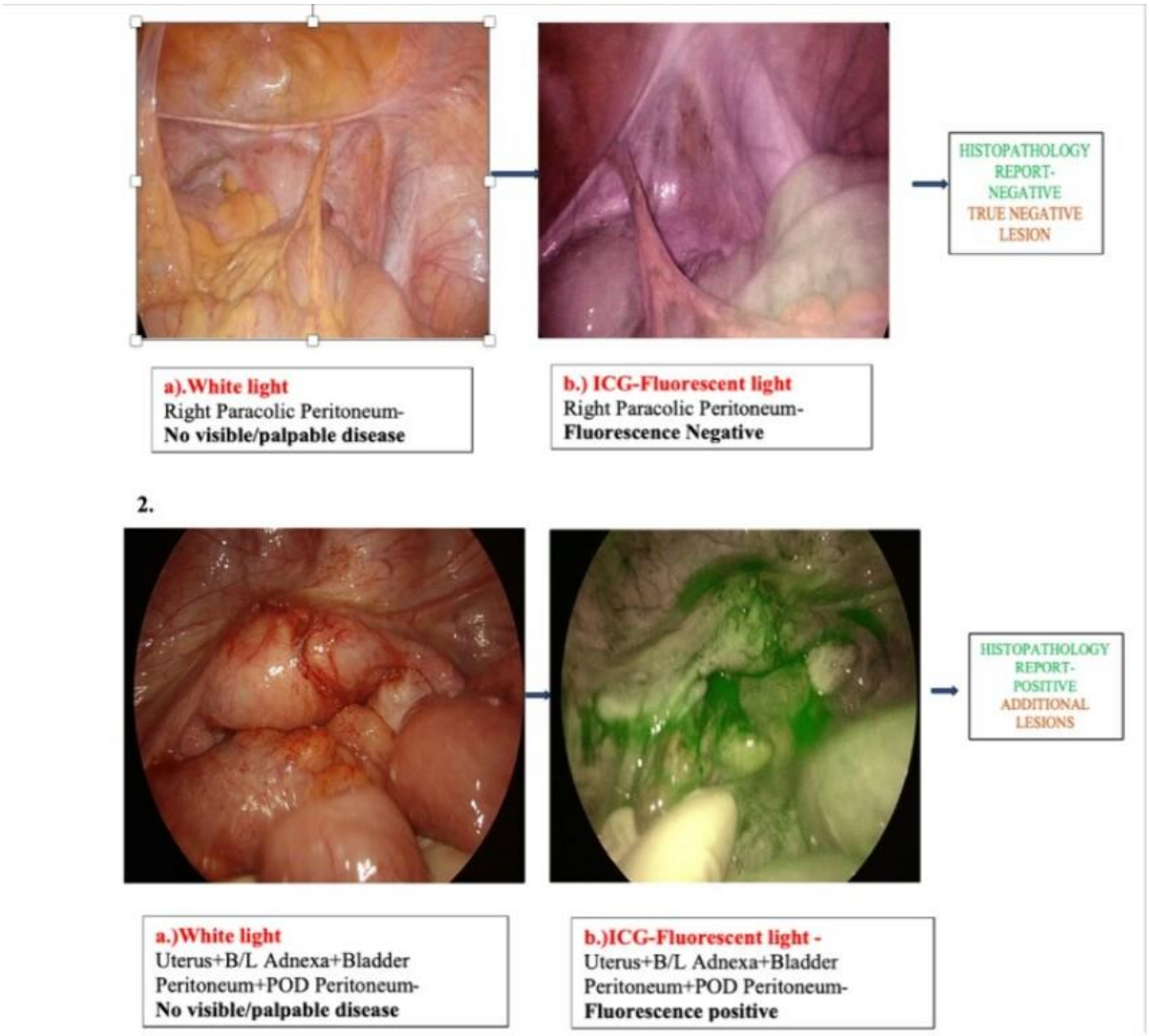
PLENARY: OVARIAN CANCER ORAL ABSTRACT PRESENTATIONS

Richa Garg[1], Neena Malhotra[1], Jyoti Meena[1], Rajesh Kumari[1], Sandeep Mathur[2], Nilanchali Singh[1], Anju Singh[1], Saurabh Vig[3], Amitabha Mandal[4], Aarthi Jayraj[1], Arnika Kashyap[1], Seema Singhal[1]
[1]ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Obstetrics And Gynaecology, New Delhi, India, [2]ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Department Of Pathology, New Delhi, India, [3]ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Department Of Onco-anaesthesia, New Delhi, India, [4]ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Department Of Surgical Oncology, New Delhi, India

Introduction: Complete cytoreduction is key in epithelial ovarian cancer(EOC),but standard inspection may miss peritoneal metastases.Indocyanine green (ICG) is easily accessible and affordable and enables real-time tumor detection.This study evaluates the diagnostic accuracy of ICG for detecting peritoneal metastases in advanced EOC.

Methods: Single-center prospective cohort study(August 2024–February 2025)included advanced ovarian cancer patients with radiological peritoneal disease undergoing cytoreduction.Following institutional ethics approval and informed consent,patients received 0.25mg/kg intravenous ICG at anaesthesia induction.Fluorescent and/or palpable lesions were resected,non-fluorescent,non-palpable peritoneal regions were systematically biopsied.The primary endpoint was the diagnostic accuracy of ICG for detecting peritoneal metastases.Secondary endpoints included detection of post-chemotherapy scar tissue,impact on surgical planning,correlation of fluorescence with pre-chemotherapy CA-125,CECT correlation with ICG and histopathology, and perioperative complications.

Results: A total of 287 peritoneal samples from 33 patients were analyzed.High-grade-serous histology was seen in 94% of patients.Among 72 histologically positive samples,55 were ICG-fluorescent,yielding 76.4% sensitivity,93% specificity,92.1% NPV and an overall diagnostic accuracy of 88.9%.The sensitivity for post-chemotherapy scar detection was 54.5%.ICG detected 13.8% additional lesions,influencing surgical strategy.Weak fluorescence was noted in 9.3% of patients with low baseline CA-125.In 39.3% of cases with CECT-suspected peritoneal disease,both histopathology and ICG-fluorescence were negative,underscoring the limited specificity of CECT.No adverse events were related to ICG.



HISTOPATHOLOGICAL-CORRELATION

	HPR+	HPR-	TOTAL
ICG+	55-(TP)	15-(FP)	70
ICG-	17-(FN)	200-(TN)	217
TOTAL	72	215	**287**

Conclusion/Implications: Indocyanine green-fluorescence-guided surgery offered high diagnostic accuracy which may help in ruling out peritoneal disease and reducing overtreatment.Although sensitivity was limited,its added value in detecting otherwise missed lesions supports its role as a practical adjunct in ovarian cancer cytoreduction.

OP016 / #662

Topic: *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

PROGNOSTIC ROLE OF LYMPHOVASCULAR SPACE INVASION IN STAGE I ENDOMETRIAL CANCER: DOES QUANTITY MATTER?

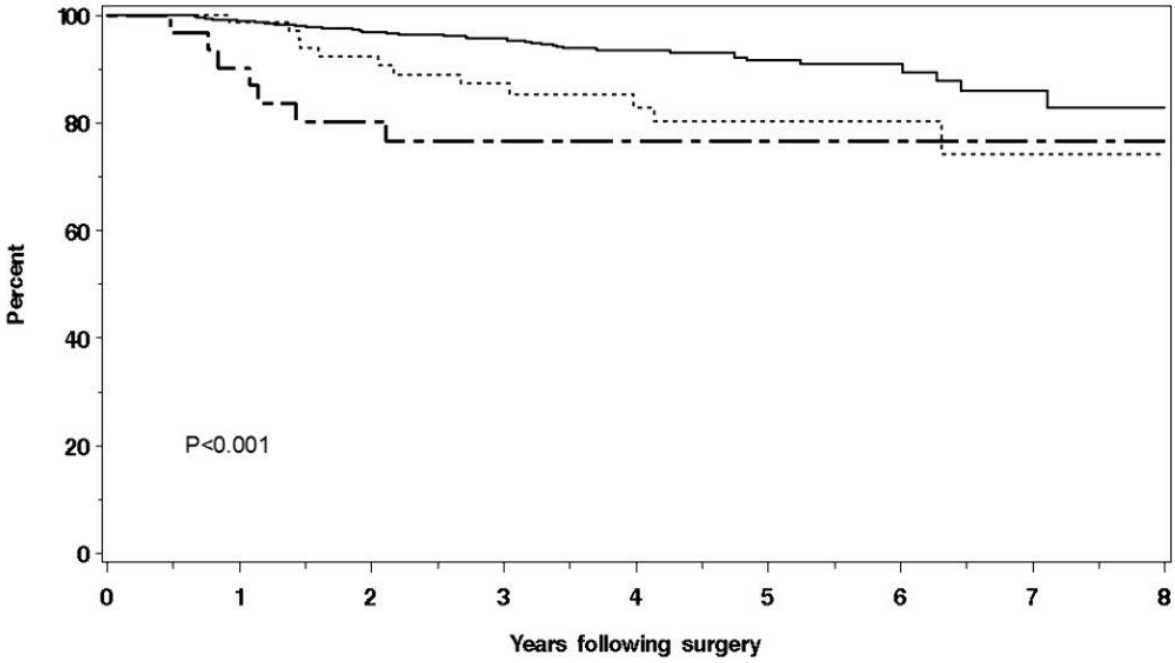
PATHOLOGY WORKSHOP PART II: ENDOMETRIAL CANCER PATHOLOGY – FROM THE FUNDAMENTALS TO THE FUTURE

Emilia Palmieri[1,2], Vincenzo Tarantino[1,2], Anna Giudici[2,3], Luigi De Vitis[2], Michaela Mc Gree[4], Amanda Tapia[4], Evelyn Reynolds[2], Maryam Shahi[5], Andrea Mariani[2], Gretchen Glaser[2], Mark Hopkins[5]
[1]Fondazione Policlinico Universitario A Gemelli IRCCS, Ginecologia Oncologica, Rome, Italy, [2]Mayo Clinic, Gynecologic Oncology, Rochester, United States of America, [3]University of Insubria, Womens' and Children's Del Ponte Hospital, Gynecology And Obstetrics, Varese, Italy, [4]Mayo Clinic, Department Of Quantitative Health Sciences, Division Of Clinical Trials And Biostatistics, Rochester, United States of America, [5]Mayo Clinic, Department Of Pathology, Rochester, United States of America

Introduction: Lymphovascular space invasion (LVSI) is an established adverse prognostic factor in endometrial cancer (EC). For stage assignment, risk stratification and treatment decisions, current guidelines group focal LVSI (1–4 vessels) with no LVSI, yet recent evidence suggests that even focal LVSI may also increase recurrence risk compared to no LVSI.

Methods: We retrospectively analyzed patients with FIGO 2009 stage I EC surgically staged at Mayo Clinic (2015 – 2021) that underwent hysterectomy, bilateral salpingo-oophorectomy, and sentinel lymph node biopsy. LVSI-positive cases were reviewed by a gynecologic oncology pathologist to quantify the greatest number of vessels involved (0 to ≥5) on a single slide. Patients were classified into three groups: no LVSI, focal LVSI (1–4 vessels), and substantial LVSI (≥5 vessels). Kaplan-Meier method was used to estimate recurrence-free survival (RFS) and compared between groups.

Results: Among 988 patients, 886 (89.7%) had no LVSI, 71 (7.2%) had focal LVSI, and 31 (3.1%) had substantial LVSI. Both focal and substantial LVSI were associated with worse RFS compared to no LVSI (both $p<0.01$), with no statistical difference between focal and substantial LVSI ($p=0.42$) (Figure). Univariate analysis confirmed that any extent of LVSI was associated with an increased risk of recurrence compared to no LVSI (Table).



N at risk	0 yrs	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs
—— No LVSI	886	763	685	526	302	172	63	26	8
····· Focal LVSI	71	66	56	48	34	22	15	5	1
- — Substantial LVSI	31	28	22	20	16	8	3	3	3

Characteristic	HR (95% CI)	P
LVSI status		<0.001
No LVSI	Reference	
Focal	2.42 (1.28, 4.55)	
Substantial	3.57 (1.62, 7.89)	
LVSI vessels		0.003
0	Reference	
1	4.37 (1.58, 12.11)	
2	2.08 (0.75, 5.77)	
3	2.18 (0.68, 7.02)	
4	1.30 (0.18, 9.44)	
5+	3.57 (1.61, 7.87)	

Conclusion/Implications: In this retrospective analysis, we confirmed that even focal LVSI increases the risk of recurrence. Our findings highlight the need for further investigation to determine whether prognosis is influenced by the mere presence of LVSI or by a specific threshold of vessel involvement.

OP017 / #1129

Topic: *AS04. Prevention & Downstaging / AS04c. Screening & Early Detection*

COMMUNITY-BASED SCREENING OF CERVICAL HIGH-RISK HUMAN PAPILLOMAVIRUS IN WESTERN UGANDA: A DOOR-TO-DOOR APPROACH WITH CHALLENGING OUTCOMES IN FOLLOW-UP

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Carolyn Nakisige[1], Pan Fengming[2], Shamim Namagembe[3], Dan Atukonyera[3], Catherine Amuge[4], Jackson Orem[4], Janine De Zeuw[2], Heather Cubie[5], Marlieke De Fouw[6], Jogchum Beltman[6]
[1]Uganda Cancer Institute, Gynaecology, Kampala, Uganda, [2]Department of Health Sciences, Global Health Unit, University Medical Centre Groningen, The Netherlands., Groningen, Netherlands, [3]Uganda Rural Training and Development Program, Kagadi, Uganda, Kagadi, Uganda, [4]Uganda Cancer Institute, Kampala, Uganda, [5]Global Health Academy and Usher Institute, University of Edinburgh, Edinburgh, United Kingdom, Edinburgh, United Kingdom, [6]Department of Gynecology, Leiden University Medical Centre, Leiden University, Leiden, The Netherlands, Leiden, Netherlands

Introduction: WHO recommends hrHPV-based screening as part of the strategy for elimination of cervical cancer. Based on the screen-and-treat policy recommended in Uganda, we evaluated uptake of self-sampling for hrHPV detection in a community-based screening program in rural Uganda.

Methods: As part of the PRESCRIP-TEC project in Western Uganda; from July 2022-October 2023, eligible women aged 30-49 years were invited by community health workers (CHWs) to collect a vaginal FloqSwab®. CHWs immersed the swab in mSwab® medium and transported it to the laboratory for testing using GeneXpert® HPV. hrHPV positive women were invited to nearby facilities for visual assessment for treatment (VAT) followed by thermal ablation or referral, according to national guidelines.

Results: A total of 7142 women were invited, 7125 (99.7%) self-collected a vaginal swab and 1716 (24.1%) tested hrHPV positive. 'Other hrHPV" genotype (n=1107, 64.5%) was commonest, followed by HPV 16 (n=184, 10.7%) and HPV 18/45 (n= 172, 10.0 %). Mixed infections were found in 253 women (14.7%). Among hrHPV-positive women, 1,278 self-reported (74.5%) HIV testing with 32 (2.5%) HIV positive results. Of all hrHPV positive women 1208 (70.4%) attended facilities and 1061 (61.8%) underwent VAT, 159 (15.0%) turned VIA positive. Management consisted of thermal ablation in 1043 women (98.3%) and 18 referrals (1.6%), of which 8 (0.8%) had confirmed cancer and were treated accordingly.

Conclusion/Implications: Community-based hrHPV cervical screening resulted in high uptake of screening and demonstrated high hrHPV prevalence. However, there was

significant loss to follow-up for treatment of hrHPV positive women. We recommend future studies to evaluate interventions to further reduce loss to follow-up.

OP018 / #814

Topic: *AS06. Tumor Types / AS06b. Cervical Cancer*

RADICAL TRACHELECTOMY FOR EARLY STAGE CERVICAL CANCER IN THE NETHERLANDS: A NATIONWIDE COHORT STUDY ON LONG-TERM ONCOLOGIC, FERTILITY, AND OBSTETRIC OUTCOMES.

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Yaël Stroeken[1], Madeleine Van Den Berg[2], Moniek Ter Kuile[1], Christianne Lok[2], Nienke Van Trommel[2], Teska Schuurman[2], Ronald Zweemer[3], Refika Yigit[4], Constantijne Mom[5], Ruud Bekkers[6], Petra Zusterzeel[7], Jogchum Beltman[1]
[1]Leiden University Medical Center, Gynecology, Leiden, Netherlands, [2]Antoni van Leeuwenhoek, Center Of Gynecologic Oncology, Amsterdam, Netherlands, [3]University Medical Center Utrecht, Gynecology, Utrecht, Netherlands, [4]University Medical Center Groningen, Gynecology, Groningen, Netherlands, [5]Amsterdam University Medical Center, Gynecology, Amsterdam, Netherlands, [6]Catharina Cancer Institute, Gynecologic Oncology, Eindhoven, Netherlands, [7]Radboudumc Nijmegen, Nijmegen, Netherlands

Introduction: With improved survival rates for early stage cervical cancer, emphasis has shifted towards preserving QoL, particularly regarding fertility. Abdominal radical trachelectomy (ART) and vaginal radical trachelectomy (VRT) are frequently performed fertility-sparing surgery (FSS) options, with VRT predominantly indicated for tumors ≤2 cm, and ART for tumors 2≤4 cm. Current limited evidence on long-term reproductive outcomes post-FSS is based on single-center studies with small sample sizes. This study presents the first nationwide analysis of long-term reproductive outcomes in women with cervical cancer treated with radical trachelectomy.

Methods: Data of patients diagnosed with clinical early stage cervical cancer, treated in Dutch gyneco-oncology centers with VRT or ART between 2000-2020, were collected. Participants completed a one-time online questionnaire addressing pregnancy attempts, fertility, and obstetric outcomes.

Results: A total of 298 patients were eligible for this study, of whom 129 (43%) participated, 75 (58.1%) in the VRT and 54 (41.9%) in the ART group (see flowchart). Median age was 39 years (IQR 35.5-44), with a median follow-up of 9 years (IQR 5-13). Ninety-four patients (72.9%) attempted to conceive, with 45 (47.9%) requiring assisted reproductive techniques. The overall pregnancy rate was 63.8%, with a live birth rate of 52.3%. Preterm birth was common (65.5%), notably with preterm birth <32 weeks occurring after ART (45%) and less following VRT (16.7%). Additional reproductive outcomes are summarized in table 1.

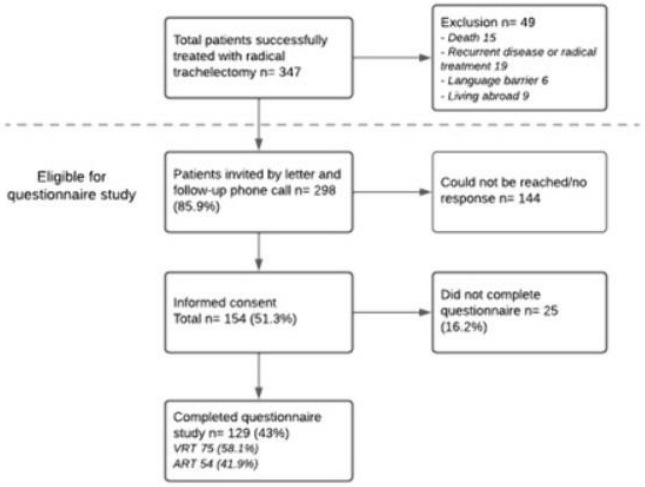


Figure 1: Flowchart inclusion of participants for questionnaire study

Table 1: Reproductive outcomes (patient-reported questionnaire)

Baseline characteristics	Total	VRT	ART
N (%)	129	75 (58.1%)	54 (41.9%)
Age at questionnaire, median (IQR)	39 (35.5-44.0)	39 (36.0-46.0)	38.5 (34.8-43.0)
Time since diagnosis in years, median (IQR)	9 (5-13)	10 (6.0-14.0)	8 (4.8-12.0)
Patient history before cancer treatment			
Pretreatment abdominal surgery	14 (10.8%)	4 (5.3%)	10 (18.5%)
Pelvic Inflammatory disease	3 (2.3%)	1 (1.3%)	2 (3.7%)
Endometriosis	7 (5.4%)	3 (4.0%)	4 (7.4%)
Pre-operative fertility procedures	2 (1.6%)	1 (1.3%)	1 (1.9%)
Parity at diagnosis			
Nulliparous	99 (76.7%)	59 (78.7%)	40 (74.1%)
Parous	30 (23.3%)	16 (21.3%)	14 (25.9%)
After cancer treatment			
Desire for children after treatment	111 (86.0%)	63 (84.0%)	48 (88.9%)
Consulted a gynecologist for fertility	71 (55.0%)	42 (56.0%)	29 (53.7%)
Tried to conceive (%)	94 (72.9%)	53 (70.7%)	41 (75.9%)
Assisted Reproductive Techniques	45 (47.9%)	26 (49.0%)	19 (46.3%)
IUI	28	18	10
IVF	30	15	15
Surrogacy	1	0	1
Time until conception+			
Did not achieve pregnancy	15 (33.3%)	5 (19.2%)	10 (52.6%)
< 1 year	15 (33.3%)	12 (46.2%)	3 (15.8%)
> 1 year	15 (33.3%)	9 (34.6%)	6 (31.6%)
Pregnancy rate (%) *	60 (63.8%)	38 (71.7%)	22 (53.7%)
Total pregnancies after treatment	110	71	39
TOP (%)	8 (7.3%)	5 (7.0%)	3 (7.7%)
Miscarriages (%)	46 (41.8%)	30 (42.2%)	16 (41.0%)
<12 weeks	36 (78.3%)	24 (80%)	12 (75%)
12-16 weeks	4 (8.7%)	3 (10%)	1 (6.25%)
16-24 weeks	6 (13.0%)	3 (10%)	3 (18.75%)
Live birth rate (%)	56 (52.3%)	36 (52.2%)	20 (51.3%)
Gestational age at delivery			
24-28 weeks	9 (16.4%)	2 (5.6%)	7 (35%)
28-32 weeks	6 (10.9%)	4 (11.1%)	2 (10%)
32-37 weeks	21 (38.2%)	17 (47.2%)	4 (20%)
>37 weeks	19 (34.5%)	12 (33.3%)	7 (35%)
Twin pregnancies	1	1	0
Pregnant at time of questionnaire	2 (1.9%)	2	0
Future pregnancy wish n (%)			
Yes	37 (31.9%)	18 (27.7%)	19 (37.3%)
No	66 (56.9%)	40 (61.5%)	26 (51%)
Uncertain	13 (11.2%)	7 (10.8%)	6 (11.8%)

^ 16 patients underwent multiple assisted reproductive techniques
+ Time until conception (from first consultation at the fertility clinic)
*pregnancy rate (N women who tried to conceive/ women who became pregnant)
ART: Abdominal Radical Trachelectomy, IQR: Inter Quartile Range, IUI: Intra-Uterine Insemination, IVF: In Vitro Fertilization, TOP: Termination Of Pregnancy, VRT: Vaginal Radical Trachelectomy.

Conclusion/Implications: This national study offers critical insights into pregnancy attempts and repr oductive outcomes following radical trachelectomy. The findings will enhance guidance throughout the fertility and pregnancy journey for affected women.

OP019 / #452

Topic: *AS04. Prevention & Downstaging / AS04b. Prevention & Vaccination*

ROLE OF HPV VACCINATION AFTER CARCINOMA IN SITU OF CERVIX UTERI (CIN) IN REAL-WORLD PATIENTS

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Alberto Farolfi[1], Elisabetta Petracci[1], Chiara Casadei[1], Eleonora Paoletti[1], Caterina Gianni[1], Michela Palleschi[1], Simone Sabbioni[1], Daniela Montanari[1], Giulia Miserocchi[1], Nicola Gentili[1], Marita Mariotti[1], Sara Testoni[1], Giandomenico Di Menna[1], Francesca Rusconi[2], Alice Andalò[1], Filippo Merloni[1], Andrea Carlini[1], Marianna Sirico[1], Roberta Maltoni[1], Olga Serra[1], Lorenzo Cecconetto[1], Samanta Sarti[1], Antonino Muscolino[1]
[1]IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST) "Dino Amadori", Medical Oncology, Breast & Gyn Unit, Meldola, Italy, [2]TriNetX, Cambridge, United States of America

Introduction: The role of HPV vaccination after a diagnosis of CIN on the risk of a subsequent cervical cancer (CC) is still matter of debate.

Methods: The analysis was conducted with the TriNetX Global Collaborative Network. In our study, we defined two cohorts of previously unvaccinated CIN patients (ICD10CM:N87; N87.0; N87.1; Z86.001; D06) who underwent regular screening (ICD10CM:Z12.4): one who subsequently encountered HPV vaccination within 6 months from CIN diagnosis (4,590 patients) and a control group not vaccinated thereafter (159,030 patients). Patients underwent to hysterectomy after CIN were excluded. Propensity score matching (PSM) was used to balance the cohorts by age, race, body mass index, human immunodeficiency virus (HIV) disease, trachelectomy and nicotine dependence. The data analysis was limited to 20 years after the index event. Hazard ratio (HR) was used to compare the risk of subsequent CC in the matched cohorts.

Results: In our analysis, we defined two cohorts of 4,588 pairs of CIN patients, with a mean age of 32.7 years (+/-8.7). The racial breakdown of the patients was as follows: 51% white, 19.9% Black or African American, 11.3% Asian. 3.2% were smokers, and 0.7% had HIV disease. There were 58 CC cases in the HPV vaccinated cohort and 99 CC cases in the unvaccinated cohort, respectively (HR = 0.70, 95% CI 0.50-0.97, p = 0.031). A subgroup analysis based on the grading of CIN was performed.

Conclusion/Implications: In our real-world study, HPV vaccination after CIN diagnosis seems to reduce the risk of CC.

OP020 / #549

Topic: *AS04. Prevention & Downstaging / AS04a. Pre-Invasive Disease*

THE IGCS PREINVASIVE PROGRAM: CREATING A WORLDWIDE WORKFORCE IN CERVICAL CANCER PREVENTION IN LOW AND MIDDLE-INCOME COUNTRIES.

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Mila P. Salcedo[1], Ida Ismail-Pratt[2], Emma Allanson[3], Alan Waxman[4], Maximillian Klar[5], Andrea Neves[6], Suzana Pessini[7], Katina Robison[8], Lauren Lanzotti[9], Susan Ralph[9], Thomas Randall[10], Kathleen Schmeler[1]
[1]The University of Texas MD Anderson Cancer Center, Gynecologic Oncology And Reproductive Medicine, Houston, United States of America, [2]Athena Women's Specialist, Singapore, Singapore, [3]The University of Western Australia, Perth, Australia, [4]University of New Mexico, Albuquerque, United States of America, [5]University of Freiburg, Freiburg, Germany, [6]Hospital Geral Jose Macamo, Maputo, Mozambique, [7]Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil, [8]Tufts University School of Medicine, Boston, United States of America, [9]International Gynecologic Cancer Society, Atlanta, United States of America, [10]Columbia University Medical Center, New York City, United States of America

Introduction: Cervical cancer is preventable, yet global incidence and mortality rates remain high, especially in low- and middle-income countries (LMICs). Limited local capacity to diagnose and treat pre-invasive/invasive cancer contributes to this burden. The goal of the IGCS Preinvasive Program is to teach healthcare providers necessary skills to diagnose and treat preinvasive cervical disease.

Methods: This training program focuses on cervical cancer prevention, including screening, early detection, and treatment of preinvasive lesions for IGCS fellows and clinicians using a 'Train the Trainers' approach. The program includes four phases: Phases 1 and 2 are self-paced on-line lectures. Phase 3 requires in-person participation at IGCS certified courses followed by hands-on training with local mentors. Phase 4 is to establish Project ECHO (Extension for Community Healthcare Outcomes), a tele-mentoring platform for continuing education.

Results: As of April 2025, the program has engaged 721 participants from 105 countries. Of those, 281 participants from 66 countries have completed Phases 1 and 2. The countries with the highest participation are India (59), Belize (47), United States (41) and Nigeria (34). To date, over 10 workshops were held, training 136 participants. Thirty approved mentors from 15 countries are training providers at their own sites. Since September 2023, we have held 16 ECHO sessions with 18 countries represented, 11 in Africa.

Conclusion/Implications: The IGCS Preinvasive Program has successfully engaged multiple countries through its 'Train the Trainers' approach. Local champions trained by the program are now mentoring peers, strengthening capacity in cervical cancer prevention and advancing progress toward cervical cancer elimination.

OP021 / #645

Topic: *AS06. Tumor Types / AS06b. Cervical Cancer*

RECURRENCE AND SURVIVAL AFTER FERTILITY-SPARING VS RADICAL SURGERY IN CERVICAL CANCER ACCORDING TO FIGO 2018: A POPULATION-BASED COHORT STUDY IN WOMEN ≤45 YEARS

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

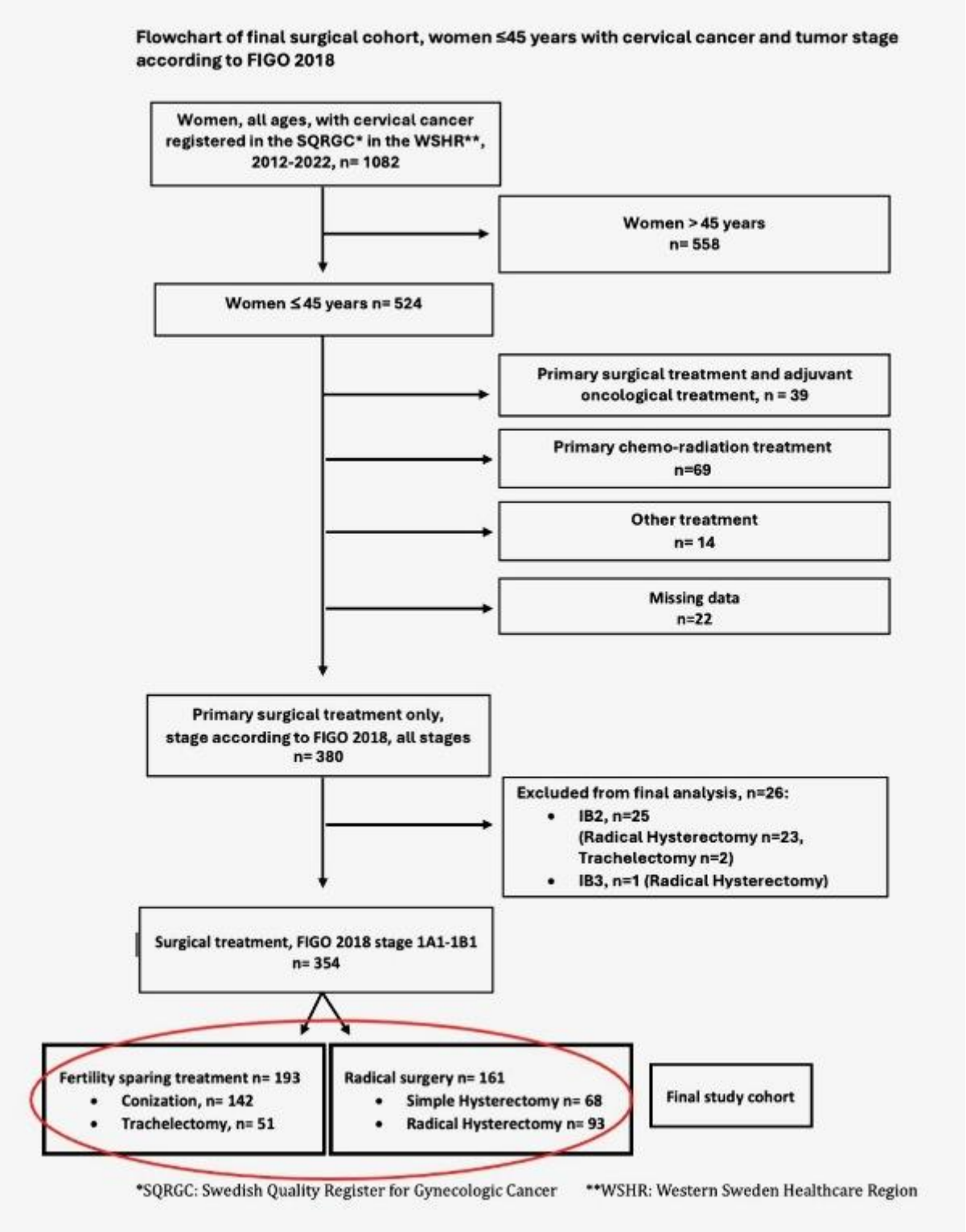
Cecilia Malmsten[1], Katja Stenström-Bohlin[1], Christian Staf[2], Anna Lindfors[1], Maria Lycke[1], Emilia Alfonzo[1], Åsa Åkesson[1], Pernilla Dahm-Kähler[1]
[1]Department of Obstetrics and Gynecology, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden, [2]Regional cancer center, Gothenburg, Sweden

Introduction: Comprehensive population-based studies comparing fertility-sparing surgery (FSS) to radical surgery (RS) according to the latest FIGO 2018 classification are lacking. Study objectives were to explore treatments and survival in a complete population-based cohort of women ≤45 years with cervical cancer, focusing on comparing FSS and RS according to FIGO 2018 classification.

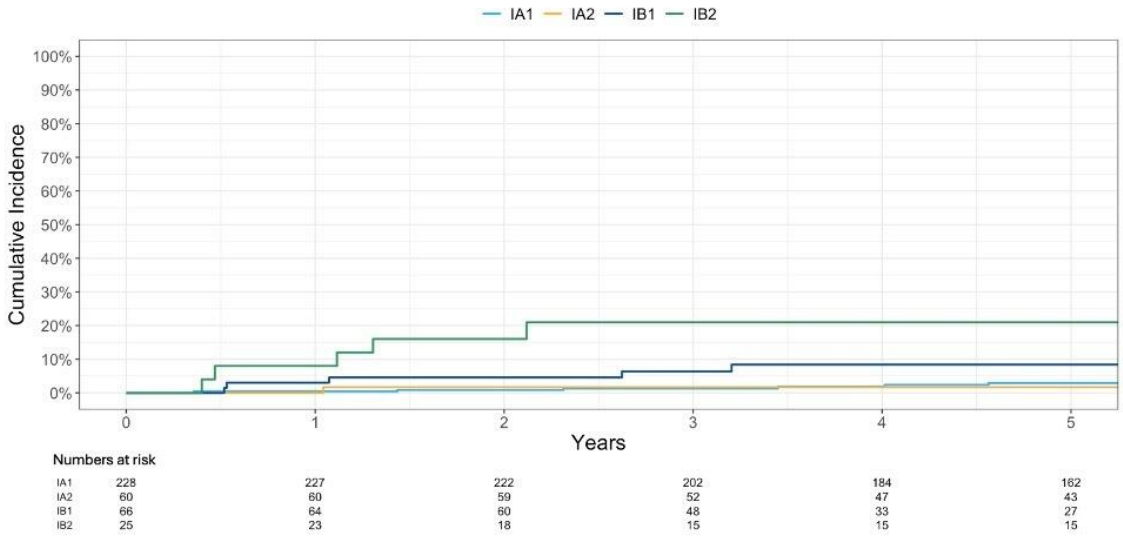
Methods: Women ≤45 years with cervical cancer 2012-2022 were identified using data from Swedish registries and supplemented by reviewing medical records. Surgically treated tumors were converted into FIGO 2018 stages. Overall (OS) and disease-free survival (DFS) were calculated according to the Kaplan-Meier method. Regression models were used to analyze risk factors (surgical method, stage, LVSI, histology, preoperative conization, residual disease) for recurrence and cumulative incidence of recurrence was calculated.

Results: Out of 524 included women, 380 had only surgical treatments and tumor stages converted into FIGO 2018. Median follow-up time was 79.5 months, and 19 recurrences were found. The 5-year cumulative recurrence incidence was 4% in stage ≤IB1 and 20% in stage IB2. The final surgical cohort (stage ≤IB1) comprised of 354 women: 193 FSS and 161 RS. Analyses showed no difference in 5-year OS between FSS 99% (95%CI98-100) and RS 98% (95%CI96-100) or 5-year DFS; FSS 97% (95%CI94-100) and RS 95% (95%CI91-99). No significant factor for recurrence was identified.

Conclusion/Implications: FSS in cervical cancer FIGO 2018 stage ≤IB1 has an excellent prognosis and no difference in oncological outcomes compared to RS. The 5-year recurrence rate in stage IB2 was 20% and tailored treatments should be considered.


Flowchart of final surgical cohort, women ≤45 years with cervical cancer and tumor stage according to FIGO 2018
Women, all ages, with cervical cancer registered in the SQRGC* in the WSHR**, 2012-2022, n= 1082
Women >45 years n= 558
Women ≤45 years n= 524
Primary surgical treatment and adjuvant oncological treatment, n = 39
Primary chemo-radiation treatment n=69
Other treatment n= 14
Missing data n=22
Primary surgical treatment only, stage according to FIGO 2018, all stages n= 380
Excluded from final analysis, n=26:
IB2, n=25 (Radical Hysterectomy n=23, Trachelectomy n=2)
IB3, n=1 (Radical Hysterectomy)
Surgical treatment, FIGO 2018 stage 1A1-1B1 n= 354
Fertility sparing treatment n= 193
Conization, n= 142
Trachelectomy, n= 51
Radical surgery n= 161
Simple Hysterectomy n= 68
Radical Hysterectomy n= 93
Final study cohort
*SQRGC: Swedish Quality Register for Gynecologic Cancer
**WSHR: Western Sweden Healthcare Region

Time to recurrence after only surgical treatments of cervical cancer IA1-IB2 (FIGO 2018) in women ≤45years between 2012-2022 (*n* = 380)



OP022 / #688

Topic: *AS06. Tumor Types / AS06b. Cervical Cancer*

ACCURACY AND PROGNOSTIC RELEVANCE OF HPV-MRNA DETECTION IN LYMPH NODES OF 216 CERVICAL CANCER PATIENTS USING THE APTIMA TEST – RESULTS OF A PROSPECTIVE MONOCENTRIC STUDY

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Christhardt Köhler[1], Lara Altmann[2], Xin Le[3], Anja Petzel[4], Gerd Boehmer[5], Simone Marnitz[6], Giovanni Favero[7], Peter Martus[8], Thomas Welcker[9], Kathi Schreiber[10], Ruediger Klapdor[11], Achim Schneider[12], Hendrik Jütte[13]
[1]Albertinen KH Hamburg, Gynecologic Oncology, Hamburg, Germany, [2]Hospital Buchholz, Buchholz, Germany, Department Of Obstetrics And Gynecology,, Buchholz, Germany, [3]Hospital, Capital Medical University, Beijing Maternal and Child Health Care Hospital, Beijing, China, Gynecology, Bejing, China, [4]Eviamed MVZ DRK-Klinik Westend, Ob/gyn, Berlin, Germany, [5]IZD Hannover, Gyn Oncol, Hannover, Germany, [6]Clinic Vosspalais, Radiation Oncology, Berlin, Germany, [7]Asklepios Hospital Lich, Germany, Department Of Obstetrics And Gynecology,, Lich, Germany, [8]Eberhard Karls University Tübingen, Institute For Clinical Epidemiology And Biometry, Tübingen, Germany, [9]MVZ, Gynecology, Goettingen, Germany, [10]DRK-Klinik Westend, Ob/gyn, Berlin, Germany, [11]Albertinen Krankenhaus, Department Of Obstetrics And Gynecology,, Hamburg, Germany, [12]Eviamed, Gynecologic Oncology, Berlin, Germany, [13]Eviamed MVZ DRK-Klinik Westend, Pathology, Berlin, Germany

Introduction: In cervical cancer patients of all stages lymph node metastases have a negative prognostic impact. Ultrastaging can significantly increase detection rate of pelvic lymph nodes metastases but is limited to sentinel nodes due to high pathologic workload. This trial aims to assess the accuracy rate of commercially available E6/E7-mRNA test (APTIMA-Test) and it's predictive value.

Methods: Samples were collected from cervix, transsected (sentinel) lymph nodes and cul-de-sac fluid of all consecutive cervical cancer patients who underwent surgery at Asklepios Clinic Hamburg between 08/2016 and 12/2018. Demographic, histological, HPV-mRNA results and follow-up data were prospectively recorded and analyzed retrospectively.

Results: 216 patients were included with FIGO (2009) stages IA1 in 18(8%), IA2 in 12(6%), IB1 in 116(54%), IB2 in 15(7%), IIA in 5(2%), IIB in 31(14%), IIIB in 5(2%), IVA in 3(1%), recurrent tumors in 7(3%) and others in 4(1%) of patients, respectively. Lymphadenectomy was performed in 41% by sentinel technique and in 59% by systematic lymphadenectomy. Of 4.749 harvested lymph nodes 524 were analyzed using APTIMA. HPV-mRNA status versus histology resulted in negative/negative in 444,

positive/positive in 59, positive/negative in 19(1.9%) and negative/positive in 2 lymph nodes. Cul-de-sac fluid was cytologically positive in 2 versus 22 samples with APTIMA. Correlation of HPV-mRNA positivity with OS and DFS will be presented.

Conclusion/Implications: APTIMA detects tumor cells in 1.9% of histologically negative lymph nodes, which has the potential to shift lymph node analysis from microscopic to molecular level. The predictive relevance of this finding will be discussed.

OP023 / #426

Topic: *AS06. Tumor Types / AS06b. Cervical Cancer*

PEMBROLIZUMAB PLUS CHEMOTHERAPY WITH OR WITHOUT BEVACIZUMAB IN PARTICIPANTS WITH PERSISTENT, RECURRENT, OR METASTATIC CERVICAL CANCER: 5-YEAR FOLLOW-UP RESULTS FROM KEYNOTE-826

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Kosei Hasegawa[1], Nicoletta Colombo[2], Krishnansu S. Tewari[3], Coraline Dubot[4], M. Valeria Cáceres[5], Domenica Lorusso[6], Ronnie Shapira-Frommer[7], Pamela Salman[8], Eduardo Yañez[9], Mahmut Gumus[10], Mivael Olivera Hurtado De Mendoza[11], Vanessa Samouëlian[12], Vincent Castonguay[13], Alexander Arkhipov[14], Cumhur Tekin[15], Kan Li[15], Sarper Toker[15], Bradley Monk[16]
[1]Saitama Medical University International Medical Center, Hidaka, Saitama, Japan, [2]European Institute of Oncology, IRCCS, Milan, Italy; and University of Milano-Bicocca, Milan, Italy, [3]University of California, Irvine, Orange, United States of America, [4]Institut Curie Saint Cloud, Paris, France; and GINECO, Paris, France, [5]Instituto de Oncología Ángel H. Roffo, Buenos Aires, Argentina, [6]Humanitas University, Pieve Emanuele, Milan, Italy; Humanitas San Pio X Hospital, Milan, Italy; Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy, [7]The Ella Institute for Immuno-Oncology, Sheba Medical Center, Ramat Gan, Israel, [8]Oncovida Cancer Center, Providencia, Santiago, Chile, [9]Universidad de la Frontera, Temuco, Chile, [10]Istanbul Medeniyet University Hospital, Istanbul, Turkey, [11]Instituto Nacional de Enfermedades Neoplásicas, Lima, Peru, [12]Centre Hospitalier de l'Université de Montréal (CHUM), Centre de Recherche de l'Université de Montréal (CRCHUM), Université de Montréal, Montreal, Quebec, Canada, [13]Centre Hospitalier Universitaire de Québec, Université Laval, Quebec City, Quebec, Canada, [14]Medical Rehabilitation Center Under the Ministry of Health of Russian Federation, Moscow, Russian Federation, [15]Merck & Co., Inc., Rahway, United States of America, [16]Florida Cancer Specialists and Research Institute, West Palm Beach, United States of America

Introduction: In the phase 3 KEYNOTE-826 study (NCT03635567), pembrolizumab (vs placebo) plus chemotherapy with or without bevacizumab significantly improved PFS and OS at interim analysis 1 with continued benefit at final analysis in participants with persistent, recurrent, or metastatic cervical cancer. We report ad hoc analysis findings after ~5 years of follow-up.

Methods: Participants with persistent, recurrent, or metastatic squamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix that was not treated with systemic chemotherapy and not amenable to curative treatment (surgery or radiation) were randomized to pembrolizumab 200mg or placebo Q3W for ≤35 cycles. All participants received chemotherapy (paclitaxel plus carboplatin or cisplatin);

bevacizumab use was per investigator's discretion. Primary endpoints were PFS per RECISTv1.1 by investigator and OS.

Results: 617 participants were randomized. At data cutoff (June 4, 2024), after median follow-up of 59.1 (range, 52.1–66.5) months, pembrolizumab maintained an OS and PFS benefit versus placebo in all populations (**Table**). Grade ≥3 treatment-related AEs occurred in 69.4% of participants in the pembrolizumab group and 65.4% in the placebo group, and immune-mediated AEs/infusion reactions in 43.6% and 29.8%, respectively. The most common treatment-related AEs included alopecia (55.7% vs 55.7%), anemia (48.9% vs 42.7%), and nausea (33.9% vs 38.8%).

Table

	PD-L1 CPS ≥1		ITT		PD-L1 CPS ≥10	
	Pembro n = 273	Placebo n = 275	Pembro n = 308	Placebo n = 309	Pembro n = 158	Placebo n = 159
PFS						
Median (95% CI), mo	10.5 (9.7–12.3)	8.2 (6.3–8.5)	10.4 (9.1–12.2)	8.2 (6.4–8.4)	10.4 (8.9–15.1)	8.1 (6.2–8.8)
HR (95% CI)	0.58 (0.48–0.71)		0.61 (0.51–0.74)		0.52 (0.40–0.68)	
5-y rate (95% CI), %	27.3 (21.8–33.0)	9.9 (6.5–14.2)	26.2 (21.1–31.6)	9.0 (5.9–12.9)	31.1 (23.5–38.9)	NR (NR–NR)
OS						
Median (95% CI), mo	28.6 (22.1–38.0)	16.5 (14.5–19.9)	26.4 (21.3–32.5)	16.8 (14.6–19.4)	29.7 (20.6–47.7)	17.4 (14.0–24.7)
HR (95% CI)	0.62 (0.50–0.76)		0.64 (0.53–0.78)		0.57 (0.43–0.75)	
5-y rate (95% CI), %	33.9 (27.8–40.2)	19.7 (14.5–25.5)	33.0 (27.2–38.8)	18.1 (13.3–23.5)	40.3 (32.4–47.9)	16.6 (9.7–25.1)

NR, not reached; pembro, pembrolizumab.

Conclusion/Implications: Pembrolizumab plus chemotherapy with or without bevacizumab maintained an OS and PFS benefit versus placebo plus chemotherapy at 5 years in participants with persistent, recurrent, or metastatic cervical cancer. These findings confirm previous interim data, providing further support for this regimen as a standard of care first-line treatment option for this population.

OP024 / #476

Topic: *AS06. Tumor Types / AS06b. Cervical Cancer*

PEMBROLIZUMAB PLUS CONCURRENT CHEMORADIOTHERAPY FOR HIGH-RISK LOCALLY ADVANCED CERVICAL CANCER: POST HOC SUBGROUP ANALYSES FROM THE PHASE 3 ENGOT-CX11/GOG-3047/KEYNOTE-A18 STUDY

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Tomoka Usami[1], Vladyslav Sukhin[2], Julia Vizkeleti[3], Hong Zhu[4], Pier Ramos-Elias[5], José Revilla-López[6], Alejandro Acevedo[7], Ritu Salani[8], Felipe José Silva Melo Cruz[9], Valeriya Saevets[10], Ayman Salhab[11], Bahriye Aktas[12], Flora Zagouri[13], Jung-Yun Lee[14], Vanessa Samouëlian[15], Peng Liu[16], Karin Yamada[16], Sarper Toker[16], Domenica Lorusso[17]
[1]Department of Obstetrics and Gynaecology, Ehime University School of Medicine, Toon, Japan, [2]CEEGOG and Gynecological Oncology Department, Grigoriev Institute for Medical Radiology and Oncology NAMS Ukraine, Kharkiv, Ukraine, [3]CEEGOG and National Institute of Oncology, Centre of Radiotherapy, Budapest, Hungary, [4]Department of Oncology, Xiangya Hospital, Central South University and National Clinical Research Center for Geriatric Disorders, Xiangya Hospital, Central South University, Changsha, Hunan, China, [5]Integra Cancer Institute, Edificio Integra Medical Center, Guatemala City, Guatemala, [6]Cancer Prevention and Control Service, ALIADA Contra el Cáncer, Lima, Peru, [7]Oncocentro, Valparaiso, Chile, [8]GOG Foundation and Department of Obstetrics and Gynecology, University of California Los Angeles, Los Angeles, United States of America, [9]Instituto Brasileiro de Controle do Câncer and Centro Universitário São Camilo, São Paulo, SP, Brazil, [10]Chelyabinsk Regional Clinical Center Oncology and Nuclear Medicine, Chelyabinsk, Russian Federation, [11]ISGO and Department of Oncology, Hadassah Medical Center and Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel, [12]University Hospital Leipzig, Department of Gynecology and NOGGO, Leipzig, Germany, [13]HeCOG and Department of Clinical Therapeutics, Alexandra Hospital, Medical School, Athens, Greece, [14]Yonsei Cancer Center and Severance Hospital, Yonsei University College of Medicine, Seoul, Korea, Republic of, [15]Department of Gynecologic Oncology, Centre Hospitalier de l'Université de Montréal (CHUM), Centre de Recherche du CHUM (CRCHUM), Université de Montréal, Montréal, Canada, [16]Merck & Co., Inc., Rahway, United States of America, [17]MITO and Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan; Gynaecological Oncology Medical Unit, Humanitas San Pio X Hospital, Milan; Department of Women and Child Health, Fondazione Policlinico Universitario Agostino Gemelli, Rome, Italy

Introduction: In the phase 3 ENGOT-cx11/GOG-3047/KEYNOTE-A18 study (NCT04221945), pembrolizumab+concurrent chemoradiotherapy (CCRT) followed by pembrolizumab led to significant improvements in PFS at interim analysis 1 and OS at

interim analysis 2 vs placebo+CCRT followed by placebo in participants with high-risk locally advanced cervical cancer (LACC). Here, we present post hoc subgroup analyses of PFS and OS at final analysis in participants with FIGO 2014 stage III–IVA disease, based on lymph node (LN) involvement, and in participants with FIGO 2014 stage IB2–IIB disease with target lesions >5 cm.

Methods: Participants aged ≥18 years with newly diagnosed, high-risk LACC (FIGO 2014 stage IB2–IIB with node-positive disease or stage III–IVA regardless of nodal status) were randomized 1:1 to receive 5 cycles of pembrolizumab 200 mg or placebo Q3W+CCRT, followed by 15 cycles of pembrolizumab 400 mg or placebo Q6W. CCRT was 5 cycles (optional 6th dose) of cisplatin 40 mg/m^2 Q1W+external beam radiotherapy then brachytherapy. Primary endpoints were PFS (RECIST v1.1 by investigator or histopathologic confirmation) and OS. Post hoc subgroup analyses were based on an unstratified Cox regression model with the Efron method of tie handling with treatment as a covariate. Data cutoff was January 7, 2025

Results: Results: PFS and OS results are shown in **Table 1** and **2**, respectively.

Conclusion/Implications: In this post hoc analysis, pembrolizumab+CCRT improved PFS and OS vs placebo+CCRT in participants with FIGO 2014 stage III–IVA LACC, regardless of pelvic/para-aortic LN involvement. PFS benefit was also seen with pembrolizumab+CCRT in participants with stage IB2–IIB disease with target lesions >5 cm.

	Pembrolizumab + CCRT	Placebo + CCRT	HR (95% CI)
ITT population	177/529 (33.5)	225/531 (42.4)	0.72 (0.59–0.87)
Stage IB2–IIB	82/233 (35.2)	92/226 (40.7)	0.84 (0.63–1.14)
Target lesions >5 cm[a]	56/145 (38.6)	58/125 (46.4)	0.76 (0.52–1.09)
Stage III–IVA	95/296 (32.1)	133/305 (43.6)	0.63 (0.48–0.82)
Pelvic or para-aortic LN	75/213 (35.2)	100/212 (47.2)	0.63 (0.46–0.85)
Pelvic only	52/162 (32.1)	70/156 (44.9)	0.60 (0.42–0.86)
Para-aortic ± pelvic	23/51 (45.1)	30/56 (53.6)	0.74 (0.43–1.27)
No pelvic or para-aortic LN	20/83 (24.1)	33/93 (35.5)	0.58 (0.33–1.02)

Data are n/N (%) unless otherwise specified.
[a]Sum of diameters of target lesions >5 cm at screening.

	Pembrolizumab + CCRT	Placebo + CCRT	HR (95% CI)
ITT population	107/529 (20.2)	140/531 (26.4)	0.73 (0.57–0.94)
Stage IB2–IIB	46/233 (19.7)	49/226 (21.7)	0.92 (0.62–1.38)
Target lesions >5 cm[a]	36/145 (24.8)	33/125 (26.4)	0.94 (0.58–1.50)
Stage III–IVA	61/296 (20.6)	91/305 (29.8)	0.64 (0.46–0.88)
Pelvic or para-aortic LN	49/213 (23.0)	73/212 (34.4)	0.60 (0.42–0.87)
Pelvic only	32/162 (19.8)	49/156 (31.4)	0.56 (0.36–0.88)
Para-aortic ± pelvic	17/51 (33.3)	24/56 (42.9)	0.74 (0.40–1.39)
No pelvic or para-aortic LN	12/83 (14.5)	18/93 (19.4)	0.71 (0.34–1.48)

Data are n/N (%) unless otherwise specified.
[a]Sum of diameters of target lesions >5 cm at screening.

OP025 / #631

Topic: *AS06. Tumor Types / AS06b. Cervical Cancer*

PREDICTIVE BLOOD-BASED BIOMARKERS IN CERVICAL CANCER PATIENTS TREATED WITH PACLITAXEL-BASED CHEMOTHERAPY WITH OR WITHOUT BEVACIZUMAB: RESULTS FROM GOG-0240

PLENARY: CERVICAL CANCER ORAL ABSTRACT PRESENTATIONS

Angeles Alvarez Secord[1], Michael Sill[2], Heather Lankes[3], Michael Birrer[4], Bradley Monk[5], Yingmiao Liu[6], Mark Starr[6], Chris Brady[6], Mario Leitao Jr.[7], Lois Ramondetta[8], Kiran Clair[9], Meredith Newton[10], Saketh Guntupalli[11], Debra Richardson[12], Paul Disilvestro[13], Guillerme Cantuaria[14], Charles Leath Iii[15], Caroline Billingsley[16], Megan Mcdonald[17], Jayanthi Lea[18], Frederick Ueland[19], Laura Chambers[20], Krishnansu S. Tewari[21], Andrew Nixon[6]
[1]Duke, Durham, United States of America, [2]Roswell Park, Biostatistics And Bioinformatics, Roswell, United States of America, [3]NRG Statistical and Data Center, Statistics, Buffalo, United States of America, [4]UAMS Health, Little Rock, United States of America, [5]Gynecologic Oncology Group (GOG)-Foundation and Florida Cancer Specialists and Research Institute,, West Palm Beach, United States of America, [6]Duke Cancer Institute, Medicine, Durham, United States of America, [7]Memorial Sloan Kettering Cancer Center, Department Of Surgery, New York, United States of America, [8]MD Anderson Cancer Center, Houston, United States of America, [9]University of California, Irvine, Orange County, United States of America, [10]University of North Carolina, Chapel Hill, Chapel Hill, United States of America, [11]University of Colorado, Denver, United States of America, [12]Stephenson Cancer Center, University of Oklahoma Health Sciences Center, Oklahoma City, United States of America, [13]Women and Infants Hospital, Providence, United States of America, [14]Georgia Center for Oncology Research and Education, Atlanta, United States of America, [15]University of Alabama, Birmingham, United States of America, [16]University of Cincinnati, Cincinnati, United States of America, [17]University of Iowa Hospitals and Clinics, Iowa City, United States of America, [18]UT Southwestern, Dallas, United States of America, [19]University of Kentucky, Lexington, United States of America, [20]The Ohio State University, Columbus, United States of America, [21]University of California, Irvine, Orange, United States of America

Introduction: GOG-0240, an open-label phase III trial, randomized patients with advanced/recurrent cervical cancer (CC) to paclitaxel-based chemotherapy alone compared to chemotherapy with concurrent and maintenance bevacizumab. The data demonstrated significantly improved progression-free survival (PFS) and overall survival (OS) benefit with bevacizumab. Blood samples were collected for biomarker analyses.

Methods: Plasma samples were analyzed via multiplex ELISA technology for IL6 and 22 other pre-specified biomarkers using the locked-down Angiome panel. Prognostic

markers were evaluated using Cox models. The predictive value of each biomarker was assessed using a marker by treatment interaction term and Cox proportional hazards models.

Results: Baseline samples were available from 305 patients. Patients with high IL6 levels had a 1.6- and 1.7-fold increased risk of progression (p=0.0049, p=0.0022) and 1.7- and 1.8-fold increased risk of death (p=0.0022, p=0.0008) on the bevacizumab and placebo arms, respectively. IL6 levels (dichotomized at pre-specified cutpoints) were not predictive for bevacizumab efficacy. Exploratory analyses of other Angiome panel markers suggested that high ICAM1 levels were associated with worse PFS (p=0.0003) and OS (p=0.002) in the placebo arm, and suggestive of interaction with bevacizumab efficacy (p=0.06) for PFS. Additionally, high PDGF-BB (p=0.09) and TIMP1 (p=0.08) levels may be predictive of bevacizumab efficacy on OS, suggesting that patients with higher levels of these proteins may do better in the bevacizumab arm.

Conclusion/Implications: IL6 is prognostic for survival in advanced CC patients treated with chemotherapy alone or with bevacizumab. IL6 levels don't appear to be predictive of bevacizumab benefit. Further evaluation of ICAM1, PDGFBB, and TIMP1 may be warranted.