Results Three hundred and four women met criteria: 200 underwent laparotomy and 104 MIS. Women in the MIS group were younger, had lower rate of diabetes and lower CA-125 level. Women who underwent laparotomy had higher grade EC and more advanced stage disease; Odds Ratio (OR) and 95% Confidence Interval (CI) 0.34 (0.21–0.56) and 0.56 (0.34–0.92), respectively. Brachytherapy rate was comparable between groups (p=0.715). In a multivariable analysis, including age, comorbidities, disease stage, tumor grade and lymphvascular space invasion, MIS was not associated with an increased risk for recurrence, progression or decreased overall survival. However, patients operated by MIS had higher risk to recur locally (vaginal cuff or pelvic) (26.9% vs. 16.5%, p=0.032, OR, 1.86, 95% CI 1.05–3.30). MIS was the only independent factor associated with local recurrence, adjusted OR, 2.09, 95% CI 1.12–3.90.

Conclusions In women with stage II-IIIc EC, MIS was associated with an increased risk for local recurrence compared to laparotomy.

O007/#202 RECURRENCE AND SURVIVAL AFTER LAPAROSCOPY VERSUS LAPAROTOMY IN EARLY-STAGE ENDOMETRIAL CANCER: LONG-TERM OUTCOMES OF A RANDOMISED TRIAL

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Objectives Laparoscopic hysterectomy is accepted globally as the standard treatment option for early-stage endometrial cancer, but there is limited long-term survival data. We compared the survival outcomes of total laparoscopic hysterectomy (TLH) and total abdominal hysterectomy (TAH) for early-stage endometrial cancer up to 5 years after each procedure.

Methods Follow-up of a multi-centre, randomised controlled trial comparing TLH and TAH, without routine lymphadenectomy, for women with stage I endometrial cancer. Enrolment was between 2007 and 2009 by 2:1 randomisation to TLH or TAH. Assessed at 5 years, the primary outcome was the disease-free survival (DFS) and the secondary outcomes were the overall survival (OS), disease-specific survival (DSS), and primary site of recurrence. Multivariable Cox regression analyses were adjusted for age, stage, and grade, with adjusted hazard ratios (aHR) and 95% confidence intervals (95%CI) reported.

Results In total, 279 women underwent procedures and 263 (94%) of these had follow-up data. For the TLH (n=185) and TAH (n=94) groups, DFS (90.3% vs 84.1%; aHR[recurrence], 0.76; 95%CI, 0.35–1.66), OS (89.2% vs 82.8%; aHR [death], 0.64; 95%CI, 0.33–1.27), and DSS (95.0% vs 89.8%; aHR[death], 0.74; 95%CI, 0.28–1.99) were comparable at 5 years. There were no port-site or wound metastases, and local recurrence rates were comparable.

Conclusions No study has reported on survival among women with early-stage endometrial cancer treated by TLH or TAH without routine lymphadenectomy. Survival outcomes (DFS, OS and DSS) were comparable between the treatment options at 5 years, supporting the widespread use of TLH as a primary treatment for early-stage, low-grade endometrial cancer.

Awards Ceremony & Plenary 4: Seminal Abstract Presentations

O008/#785 A MULTICENTER, OPEN-LABEL, RANDOMIZED, PHASE 3 STUDY TO COMPARE THE EFFICACY AND SAFETY OF LENVATINIB IN COMBINATION WITH PEMBROLIZUMAB VS TREATMENT OF PHYSICIAN'S CHOICE IN PATIENTS WITH ADVANCED ENDOMETRIAL CANCER: STUDY 309/KEYNOTE-775

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Objectives Results from a phase 1b/2 study showed lenvatinib (LEN) + pembrolizumab (pembro) has efficacy in patients (pts) with advanced endometrial carcinoma following prior treatment. Here, we describe the phase 3 study results of LEN + pembro vs treatment of physician's choice (TPC) following platinum-based therapy in pts with advanced endometrial cancer (aEC).

Methods Pts were randomized (1:1) to receive LEN 20 mg orally QD + pembro 200 mg IV Q3W or TPC (doxorubicin at 60 mg/m2 IV Q3W or paclitaxel at 80 mg/m2 IV QW [3

weeks on; 1 week off]). Eligible pts had aEC with 1 prior platinum-based chemotherapy regimen or up to 2 prior platinum-based chemotherapy regimens, if 1 was given in the neoadjuvant/adjuvant setting. Randomization was stratified by DNA mismatch repair (MMR) status (centrally determined); pts with proficient (p)MMR tumors were further stratified by ECOG PS, geographic region, and prior history of pelvic radiation. Primary endpoints were PFS by blinded independent central review per RECIST v1.1 and OS. Key secondary endpoints included objective response rate (ORR) and safety. A graphical approach for multiplicity to control for type 1 error was used to test PFS for pts with pMMR aEC, then pts irrespective of MMR tumor status (i.e., all comers), followed SGO 2021 LEN 309 Abstract

Results 827 Pts (pMMR, n=697; dMMR, n=130) were randomized to receive LEN + pembro (n=411) or TPC (n=416). Median follow-up was 12.2 mo for pts randomized to LEN + pembro and 10.7 mo for pts randomized to TPC (data cutoff October 26, 2020). PFS was significantly improved with LEN + pembro vs TPC in pMMR aEC (median 6.6 vs 3.8 mo; HR 0.60) and in all-comers (median 7.2 vs 3.8 mo; HR 0.56). OS was significantly longer with LEN + pembro vs TPC in pMMR aEC (median 17.4 vs 12.0 mo; HR 0.68) and in all-comers (median 18.3 vs 11.4 mo; HR 0.62). ORR was significantly greater with LEN + pembro vs TPC in pMMR aEC (30.3% vs 15.1%) and in all-comers (31.9% vs 14.7%). Additional results are in the table. Median treatment duration was 231 days with LEN + pembro and 104.5 days with TPC. Overall, anygrade treatment-emergent adverse events (TEAEs) occurred at similar rates across treatment arms. Grade ≥3 TEAEs occurred in 89% of pts with LEN + pembro and 73% of pts with TPC. In the LEN + pembro arm, 30.8% pts discontinued LEN, 18.7% discontinued pembro, and 14.0% discontinued both study treatments due to a TEAE; the most common TEAEs were hypertension (64%), hypothyroidism (57%), diarrhea (54%) and nausea (50%).

Abstract O008/#785 Table 1

Table

	pMMR		All-comers	
	LEN + pembro (n = 346)	TPC (N = 351)	LEN + pembro (n = 411)	TPC (N = 416)
Median PFS, months (95% CI)	6.6 (5.6, 7.4)	3.8 (3.6, 5.0)	7.2 (5.7, 7.6)	3.8 (3.6, 4.2)
PFS HR (95% CI) *P*-value	0.60 (0.50, 0.72) <0.0001		0.56 (0.47, 0.66) <0.0001	
Median OS, months (95% CI)	17.4 (14.2, 19.9)	12.0 (10.8, 13.3)	18.3 (15.2, 20.5)	11.4 (10.5, 12.9)
OS HR vs TPC (95% CI) *P*-value	0.68 (0.56, 0.84) 0.0001		0.62 (0.51, 0.75) <0.0001	
ORR, % (95% CI)	30.3 (25.5, 35.5)	15.1 (11.5, 19.3)	31.9 (27.4, 36.6)	14.7 (11.4, 18.4)
ORR Difference, % *P*-value	15.2 <0.0001		17.2 <0.0001	
Median duration of response, months (range)	9.2 (1.6*, 23.7*)	5.7 (0.0*, 24.2*)	14.4 (1.6*, 23.7*)	5.7 (0.0*, 24.2*)

*No progressive disease reported at the last disease assessment.
PFS, progression-free survival; OS, overall survival.

Conclusions LEN + pembro demonstrated statistically significant and clinically meaningful improvements in PFS, OS, and ORR vs TPC both in pts with aEC that was pMMR and in pts with aEC irrespective of MMR status. The safety profile of LEN + pembro was manageable and consistent with previously reported studies.

O009/#786 RUCAPARIB VS CHEMOTHERAPY IN PATIENTS WITH ADVANCED, RELAPSED OVARIAN CANCER AND A DELETERIOUS BRCA MUTATION: EFFICACY AND SAFETY FROM ARIEL4, A RANDOMIZED PHASE 3 STUDY

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Objectives Prospective studies comparing poly(adenosine diphosphate-ribose) polymerase (PARP) inhibitors with standard-of-care (SOC) chemotherapy (CT) in patients (pts) with relapsed ovarian cancer (OC) are currently limited. ARIEL4 (NCT02855944) is a phase 3, randomized, open-label, international, multicenter study of the efficacy and safety of rucaparib vs SOC CT as treatment for PARP-inhibitor naïve pts with relapsed high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer, who had a deleterious BRCA1/2 (BRCA) mutation and had received ≥2 prior CT regimens.

Methods Pts were randomized 2:1 to oral rucaparib 600 mg twice daily or SOC CT and stratified based on progression-free interval (≥1 to <6 months = platinum resistant; ≥6 to <12 months = partially platinum sensitive; ≥12 months = fully platinum sensitive). Pts in the CT arm with platinum-resistant or partially platinum-sensitive disease received weekly paclitaxel 60–80 mg/m^2; pts with fully platinum-sensitive disease received investigator's choice of platinum-based CT (single-agent carboplatin or cisplatin, or platinum doublet [carboplatin + paclitaxel, carboplatin + gemcitabine, or cisplatin + gemcitabine]). Pre-study-treatment plasma samples were assessed for BRCA reversion mutations. The primary endpoint was investigator-assessed progression-free survival (PFS). Secondary endpoints included objective response rate (ORR) per RECIST and safety. Each efficacy endpoint was first evaluated in the efficacy population (randomized pts with deleterious BRCA mutations excluding those with BRCA reversion mutations), stepping down to the intent-to-treat (ITT) population (all randomized pts).