

Objectives In endometrial cancer few randomized controlled trials were conducted to assess the role of different settings of follow-up in improving overall survival. The TOTEM study (NCT00916708) was planned to compare an intensive (INT) vs minimalist (MIN) 5-year follow-up regimen in endometrial cancer patients in terms of overall survival (OS).

Methods Patients surgically treated for endometrial cancer, were stratified by center and in low (LoR) or high (HiR) risk of recurrence and then randomized to INT or MIN hospital-based follow-up regimens. The aim of the study was to demonstrate an improvement from 75% to 80% (expected hazard ratio, HR=0.78) of the 5-year OS with the INT regimen. Secondary objectives were to compare relapse free survival (RFS) and health-related quality of life (HRQL).

Results 1884 patients were randomized in 42 centers between 2008 and 2018, and 1847 patients were available for the final analysis. After a median follow-up of 66 months, the 5-year OS was 91.3%, 90.6% in the INT and 91.9% in the MIN arms, respectively (HR=1.12, 95%CI 0.85–1.48, p=0.429). Comparing the INT vs MIN arms, the 5-year OS were 94.1% and 96.8% (HR=1.48, 0.92–2.37, p=0.104) in the LoR and 85.3% and 84.7% (HR=0.96, 0.68–1.36, p=0.814) in the HiR group. The two arms did not show differences in terms of RFS and HRQL.

Conclusions Intensive follow-up in endometrial cancer treated patients did not improve OS, even in HiR patients, nor influenced health-related quality of life. Frequent routine use of imaging and laboratory exams in these patients should be discouraged.

0005/#190

WHERE THERE IS SMOKE, THERE IS FIRE: UNDERSTANDING THE IMPLICATIONS OF POSITIVE SENTINEL LYMPH NODES IN ENDOMETRIAL CANCER

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Objectives The objective of this study is to identify clinicopathologic characteristics associated with non-sentinel lymph node (SLN) metastasis and non-vaginal recurrences in patients with SLN-positive endometrial cancer (EC).

Methods Consecutive patients with surgically staged EC and at least one positive SLN were included. SLNs were ultra-staged. Positive SLNs were reviewed and patients classified according to the size of the largest SLN metastasis.

Results 103 patients (36 isolated tumor cells (ITC), 27 micro-metastasis, 40 macrometastasis) were included. Multiple positive SLNs were observed in 38.8% of patients. Size of SLN metastasis (adjusted OR (aOR) 3.0 for macrometastasis vs ITC, 95%CI 1.1–8.1), and age (aOR 1.8 per 10-year increase, 95%CI 1.1–3.0) were independent predictors of multiple positive SLNs. Extracapsular compared to intracapsular invasion of

Abstract 0005/#190 Table 1

| Characteristic | Adjusted HR (95% CI) | P |
|----------------------------------|----------------------|--------------|
| Histology | | 0.004 |
| Non-endometrioid | 5.09 (1.66, 15.61) | |
| Endometrioid | Reference | |
| Cervical stromal invasion | | 0.002 |
| No | Reference | |
| Yes | 6.89 (2.04, 23.23) | |
| Size of SLN metastasis | | 0.04 |
| ITC/micrometastasis | Reference | |
| Macrometastasis | 3.41 (1.05, 11.09) | |

the SLN metastasis was significantly associated with multiple positive SLNs at univariate analysis (71.4% vs. 33.7%, p=0.008). Forty-seven percent (18/38) of patients who underwent completion pelvic lymphadenectomy, had additional positive lymph nodes. This was associated with increased size of SLN metastasis (0/8, 5/10, and 13/20 in ITC, micro- and macrometastasis, respectively, p=0.004). SLN macrometastasis (adjusted HR (aHR) 3.4, 95%CI 1.1–11.0), non-endometrioid histology (aHR 5.7, 95%CI 1.9–17.3), and cervical stromal invasion (aHR 9.4, 95%CI 2.9–30.4) were independent predictors of non-vaginal recurrence (table 1).

Conclusions Size and location of SLN metastasis can predict an increased risk of multiple positive SLNs, non-SLN positive nodes, and non-vaginal recurrence in SLN positive EC patients. These factors should be assessed when considering adjuvant treatment in these high-risk patients.

0006/#340

MINIMALLY INVASIVE SURGERY IN ADVANCED ENDOMETRIAL CARCINOMA IS ASSOCIATED WITH AN INCREASED RISK FOR LOCAL RECURRENCE

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Objectives To compare oncological outcomes of women with stage II -IIIc endometrial cancer (EC) who underwent minimally invasive surgery (MIS) versus laparotomy.

Methods A retrospective cohort study in an academic multi-center setting. Consecutive women with EC treated at 11 Israeli institutions between 2002 and 2017 were recorded in an assimilated database with a median follow-up of 52 months (range 12–120 months). Women with stage II -IIIc were stratified into groups by intentional route of surgery; MIS vs. laparotomy. Clinical, pathological and outcome data were compared.

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 lymphovascular 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.

0007/#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

0008/#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 [