CHARACTERIZATION OF ADVERSE REACTIONS IN PATIENTS WITH ADVANCED ENDOMETRIAL CANCER (AEc) RECEIVING LENVATINIB + PEMBROLIZUMAB (STUDY 309/KEYNOTE-775)

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Methodology In Study 309/KEYNOTE-775, patients were randomized to lenvatinib 20 mg QD PO + pembrolizumab 200 mg IV Q3W (n=411) or TPC (n=416; doxorubicin 60 mg/m2 IV Q3W or paclitaxel 80 mg/m2 IV QW, 3 weeks on/1 week off). Herein, characterization of key ARs is based on incidence and known association with lenvatinib+pembrolizumab, and interventions for ARs in aEC patients. Key ARs are grouped by preferred terms per FDA definitions for ARs in patients with endometrial carcinoma from the US prescribing information; ARs include hypertension, musculoskeletal pain, fatigue, nausea, diarrhea, decreased appetite, stomatitis, vomiting, hypothyroidism, palmar-plantar erythrodysesthesia (PPES), and decreased weight.

Conclusion* Our data suggest that the COVID-19 pandemic had a significant impact on the characteristics and patterns of care of EC patients. These findings highlight the need to implement healthcare services during the pandemic.

INCREASED SURVIVAL IN NON-ENDOMETROID ENDOMETRIAL CANCER AFTER INTRODUCTION OF SWEDISH NATIONAL GUIDELINES

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Introduction/Background* The first Swedish national guidelines for endometrial cancer (NGEC) recommended adequate staging with pelvic and paraaortic lymphadenectomy for patients with high-risk disease, including non-endometrioid endometrial cancer (EC). The recommended adjuvant oncological treatment protocol was chemotherapy to all non-endometroid EC and radiotherapy only for those with stage IIIIC. Before the NGEC, the stipulated surgery was solely hysterectomy and bilateral salpingectomy followed by adjuvant chemo-and radiotherapy to all non-endometrioid ECs. The aim of this study was to investigate the outcome in survival and recurrence of this shift in treatment strategy.

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Abstracts
Methodology All women with non-endometrioid EC, defined as serous, clearcell, carcinosarcoma and undifferentiated, were identified through the Swedish Quality Registry for Gynecologic Cancer in the western Sweden health care region (1.9 million inhabitants) between 2010-2017 where the NGEC were implemented in 2013. Recurrences were identified including location and relative survival (RS), overall survival (OS) and disease-free survival (DFS) were analysed .The cohort was divided according to treatment protocol before and after NGEC implementation and compared.

Result(s)* In total 401 patients were identified and after exclusion for neoadjuvant chemotherapy, palliative treatment and preoperative stage IV, the final study cohort consisted of 261 patients who underwent primary surgical treatment with no evidence of disease at start of follow-up. The cohort before NGEC implementation was 103 patients and 158 patients after. The total recurrence rate was 26% and 6% were localized only to vagina. The RS rate for all patients diagnosed with a recurrence was 14.1% (95%CI 7.7-26.0) compared to 92.8% (95%CI 85.7-100.5) with no recurrence. Both the RS and OS rates were significantly improved after implementation of the NGEC. The 5-year RS was 58.8% (95%CI 48.6-71.0) for treatment in the first period and 79.8% (95%CI 71.0-89.8) for the second period (p=0.005). The 5-year OS was 54.3% (95%CI 45.5-64.9) and 68.7% (95%CI 61.3-77.0) respectively (p=0.011).

Conclusion* In this populationbased study of a complete cohort of non-endometrioid ECcs we conclude that adequate lymph node staging followed by adjuvant chemotherapy to all patients and radiotherapy only to those with positive nodes is associated with superior survival compared to chemo-and radiotherapy to all regardless of lymphnode status.

**INTRODUCTION/BACKGROUND**

Pembrolizumab, an anti-PD-1 antibody, has demonstrated activity in patients with previously treated mismatch repair (MMR) deficient (dMMR; 57.1% objective response rate [ORR] as monotherapy and 63.6% ORR as combination therapy with lenvatinib) and MMR proficient (pMMR; 36.2% ORR as combination therapy with lenvatinib) endometrial cancer. ENGOT-en11/GOG-3053/KEYNOTE-B21 is a phase 3, randomized, double-blind study of pembrolizumab or placebo in combination with adjuvant chemotherapy with/without radiotherapy in patients with endometrial cancer.

Methodology Eligible patients are ≥18 years old with newly diagnosed, high-risk (stage I/II non-endometrioid or with p53 abnormality and any histology, stage III/IVA), previously untreated endometrial cancer following surgery with curative intent with no evidence of disease post-operatively. Approximately 990 patients are randomized to receive pembrolizumab 200 mg or placebo every 3 weeks (Q3W) for 6 cycles plus chemotherapy (carboplatin area under the curve [AUC] 5/6 plus paclitaxel 175 mg/m² Q3W or carboplatin AUC 2/2.7 plus paclitaxel 60 mg/m² QW) in stage 1. Patients receive pembrolizumab 400 mg or placebo Q6W for 6 cycles in stage 2. Radiotherapy (external beam radiotherapy [EBRT] and/or brachytherapy) ± radioisotopic cetuximab 50 mg/m² (days 1 and 29) may be administered after completion of chemotherapy. Randomization is stratified by MMR status (pMMR vs dMMR) and, within pMMR, by planned radiation therapy (cisplatin-EBRT vs EBRT vs no EBRT), histology (endometrioid vs non-endometrioid), and International Federation of Gynecology and Obstetrics surgical stage (I/II vs III/IVA). Dual primary endpoints are disease-free survival (DFS; per investigator assessment) and overall survival (OS). Secondary endpoints include DFS (per blinded independent central review), DFS (per investigator assessment) and OS by biomarker status (PD-L1 and tumor mutational burden), safety (per National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0), and quality of life (per European Organization for Research and Treatment of Cancer QLQ-C30).

**INTRODUCTION/BACKGROUND**

The goal is the detection of the sentinel node in initial endometrial cancer, in our center; and compare the different techniques (blue, technetium and indocyanin green).

Methodology All patients diagnosed with an early stage of endometrial cancer, who are performed sentinel node technique

The objective is to assess the detection capability of the sentinel node based on the tracer used, and the validity of this technique in low-risk tumors, in our center

Result(s)* we have recruited a total of 119 patients. Sentinel node detection results vary depending on the plotter used. The best results were those of the combination of blue with indocyanin green (91%), as already described in the literature.

The number of positive nodes in this subgroup of patients (low risk) was very low.

Conclusion* Indocyanin green is the best tracer, for sentinel node detection.

Although the number of positive nodes, in these patients, is very low, the low morbidity that presents the technique, we would not recommend the NO relocation of this technique, because we can perform a more specific analysis of these nodes.