

injection for SLNM of newly diagnosed EC undergoing surgical staging. The primary endpoint of the study was to compare these two techniques in terms of para-aortic detection rate.

**Methodology** This RCT included women with apparent stage I or II histologically confirmed endometrial cancer undergoing surgery were included in the study. Two groups were distinguished according to two different techniques of indocyanine green (ICG) sentinel lymph node mapping (SLNM): cervical versus hysteroscopic injection. This randomized trial was not blinded for both the patients and the surgeons.

**Result(s)\*** Since March 2017 until April 2019, 165 patients were randomized: 85 (51.5%) in the cervical group and 80 (48.5%) in the hysteroscopic group. After randomization, 14 (8.5%) patients were excluded from the study. Finally, 151 patients were included in the analysis: 82 (54.3%) in the cervical group and 69 (45.7%) in the hysteroscopic group. Hysteroscopy injection demonstrated a 10% higher accuracy to detect SNLs in the paraaortic area compared to cervical injection, although this difference did not reach statistical significance. The hysteroscopic technique was better in detecting isolated SLN para-aortic (5.8% vs 0%). Cervical injection was correlated with higher SLN detection rates at pelvic level compared to hysteroscopic injection. Pelvic and overall detection was superior in the cervical group.

**Conclusion\*** The current study suggests the use of cervical injection rather than hysteroscopic injection due to its better identification of sentinel nodes (particularly in the pelvic area). Although, detection of SLN in the para-aortic area was slightly superior in patients undergoing a hysteroscopic injection, no significant difference with cervical injection was detected.

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#### IMPROVED PREOPERATIVE RISK STRATIFICATION IN ENDOMETRIAL CANCER: EXTERNAL VALIDATION OF THE ENDORISK NETWORK MODEL IN A POPULATION-BASED CASE SERIES

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**Introduction/Background\*** Preoperative risk stratification of newly diagnosed endometrial carcinoma (EC) patients has been hindered by only moderate prediction performance for many years. Recently ENDORISK, a Bayesian network (BN) model using easily accessible biomarkers, showed increased predictive performance when compared to current guidelines. It was the aim of this study to validate ENDORISK by applying a locked-down model to a population-based case series of endometrial carcinoma patients.

**Methodology** We assessed a retrospective cohort of women from the Tuebingen University Women's Hospital surgically treated for EC from 2003-2013. Minimal requirements for using ENDORISK were: availability of preoperative tumour

grade, at least 3 of ER, PR, p53 or L1CAM immunohistochemical biomarkers, at least 1 preoperative marker (PAP, CT-scan, CA125 or thrombocyte count), pathologic examination of lymph nodes, and 5-year disease specific survival data (DSS). ENDORISK was applied and prediction accuracy of lymph node metastasis (LNM) as well as 5-year DSS was investigated. The model's overall performance was quantified by the Brier score, discriminative performance was measured based on the area under the curve.

**Result(s)\*** A complete data set was evaluable from 247 patients. Median patient age was 64yrs (33-90), 78.1% cases were endometrioid histotype. Grade distribution included 87 (35.2%) G1, 106 (42.9%) G2, and 54 (21.9%) G3 tumours. 156 (63.2%) patients had stage IA disease, with the remaining stage IB (n=52;21.1%), stage II (n=12;4.9%), and stage III/IV (n=27;10.9%). AUC for LNM prediction was 0.851 (95% confidence interval [CI] 0.761-0.941) and 0.698 (95% CI 0.595-0.800) for 5-year DSS. The Brier scores were 0.06 for LNM and 0.09 for 5-year DSS, respectively. In 156 patients (63.2%) LNM prediction was  $\leq$  5% (false-negative rate 0.6%).

**Conclusion\*** We have successfully demonstrated ENDORISK prediction of LNM and 5-year DSS in a large single-centre population-based cohort using preoperative clinical and biomarker data. Next steps will now have to focus on ENDORISK performance in clinical practice environments, e.g. dealing with missing data. Incorporating molecular profiling will be of key importance for future extended use. This external validation study reinforces previous findings and may support further promoting of data-based decision-making tools in EC research and patient care.

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#### CHARACTERISTICS AND PATTERNS OF CARE OF ENDOMETRIAL CANCER BEFORE AND DURING COVID-19 PANDEMIC

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**Introduction/Background\*** COVID-19 outbreak has correlated with the disruption of screening activities and diagnostic assessments. The risk of delayed diagnosis has consequently increased during the pandemic. Endometrial cancer (EC) is one of the most common gynecological malignancies and it is often detected at an early stage, because it frequently produces symptoms. Here, we aim to investigate the impact of COVID-19 outbreak on patterns of presentation and treatment of EC patients.

**Methodology** This is a retrospective study involving 54 centers in Italy. We evaluated patterns of presentation and treatment of EC patients before (period 1: 03/01/2019 – 02/29/2020) and during (period 2: 01/04/2020 – 3/31/2021) the COVID-19 outbreak.

**Result(s)\*** Medical records of 5,164 EC patients have been retrieved: 2,718 and 2,446 women treated in period 1 and

period 2, respectively. Surgery was the mainstay of treatment in both periods ( $p=0.356$ ). The adoption of minimally invasive surgery was consistent in the two study periods ( $p=0.976$ ). Before COVID-19 pandemic, 1,848 (72.8%), 666 (26.3%), and 25 (0.9%) patients had minimally invasive, open and vaginal surgery, respectively. During the COVID-19 pandemic, 1,663 (72.8%), 582 (25.5%), and 41 (1.7%) patients had minimally invasive, open, and vaginal surgery, respectively. Nodal assessment was omitted in 689 (27.3%) and 484 (21.2%) patients treated in period 1 and 2, respectively ( $p<0.001$ ). While, the prevalence of patients undergoing sentinel node mapping (with or without backup lymphadenectomy) has increased during the COVID-19 pandemic (46.7% in period 1 vs. 52.8% in period 2;  $p<0.001$ ). Overall, 1,280 (50.4%) and 1,021 (44.7%) patients had not adjuvant therapy in period 1 and 2, respectively ( $p<0.001$ ). Adjuvant therapy (in particular chemotherapy) use has increased during COVID-19 pandemic ( $p<0.001$ ).

**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.

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

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**Introduction/Background\*** In Study 309/KEYNOTE-775, lenvatinib+pembrolizumab showed significant and clinically meaningful improvements in OS, PFS, and ORR versus treatment of physician's choice (TPC) in aEC patients following prior platinum-based therapy. Safety considerations are also important in EC. Herein, we characterize common adverse reactions (ARs) in patients with aEC in Study 309/KEYNOTE-775 and their respective management strategies. Additionally, the clinician's role in proactively managing ARs will be highlighted.

**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/m<sup>2</sup> IV Q3W or paclitaxel 80 mg/m<sup>2</sup> 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.

**Result(s)\*** Median times (weeks) to first onset of key ARs [any grade] were: hypertension (2.1), fatigue (2.3), musculoskeletal pain (3.2), nausea (4.7), decreased appetite (4.9), stomatitis (4.9), vomiting (7.6), diarrhea (7.9), hypothyroidism (8.9), PPES (9.6), and decreased weight (10.7). Among ARs described, those that led to withdrawal of lenvatinib included decreased appetite (2%), fatigue (2%), hypertension (2%), diarrhea (1%), musculoskeletal pain (1%), vomiting (1%), and decreased weight (1%); only decreased appetite (1%) and diarrhea (1%) led to withdrawal of pembrolizumab. Hypertension most frequently led to lenvatinib dose reduction (18%); diarrhea and hypertension most frequently led to dose interruption of lenvatinib (11% each) as last action taken with lenvatinib. Diarrhea most frequently led to pembrolizumab interruption (8%). Change in sum of target lesion diameters over time, exposure-adjusted ARs, and AR management strategies will be reported.

**Conclusion\*** In general, ARs due to lenvatinib+pembrolizumab were as expected and often occurred within 3 months of treatment initiation. As will be presented, clinicians play a critical role in prompt identification and AR-directed management of patients with aEC; such management may potentially reduce treatment interruption(s) and/or lenvatinib dose reduction.

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#### INCREASED SURVIVAL IN NON-ENDOMETRIOID 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-endometrioid EC and radiotherapy only for those with stage IIIC. 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.