with LN assessment. All pathologic specimens were centrally reviewed by an expert gynecologic pathologist.

**Results** Median age at surgery was 38 years (range: 23–67). Stage at diagnosis was IA2 (33%) and IB1 (67%). Histologic type included squamous cell carcinoma (48%) and adenocarcinoma (52%). Surgery included conization and LN assessment in 44/100 (44%) women and simple hysterectomy with LN assessment in 56/100 (56%) women. Minimally invasive surgery (MIS) was performed in 96/100 (96%) patients: laparoscopic in 83; robotic in 13. Positive LNs were noted in 5/100 women (5%). Residual disease in the hysterectomy specimen was diagnosed in 1/56 patients (1.8%). Median follow-up was 25 months (range 0–71). To date, recurrent disease has been diagnosed in 3 patients (3%).

**Conclusions** Conservative surgery is oncologically safe in women with early stage, low-risk cervical carcinoma.

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**IGCS19-0754**

**UTERUS-11 STUDY: A RANDOMIZED CLINICAL TRIAL ON SURGICAL STAGING VERSUS CT-STAGING PRIOR TO PRIMARY CHEMORADIATION IN PATIENTS WITH FIGO2009 STAGE IIIB-IVA CERVICAL CANCER**

**Methods**

- Followed by chemoradiation (CR). Primary endpoint was disease staging compared to standard clinical/radiological staging, followed by chemoradiation (CR) of ArmA, or clinical staging followed by CR (ArmB). CR consisted in pelvic external beam radiotherapy with weekly cisplatin (40mg/m²) and brachytherapy. Extented-field radiation was performed in cases of confirmed paraaortic metastases.

**Results** Among 240 patients (n=121 ArmA; n=119 ArmB), 236 (98.3%) received CR. Arms were balanced. Surgical approach was peritoneal laparoscopy in 93.4% (mean 19 pelvic/17 paraaortic lymph nodes (LN)). CR started 7–21 days after surgery. Surgery upstaged 40/121 (33%). Median follow-up: 66.5 months. ArmA was superior for DFS (HR=1.38 ArmB vs. ArmA, p=0.115) and OS (HR=1.29, p=0.24). Clinically or surgically LN+ negatively impacted DFS (pelvic: HR=2.38, p=0.007; paraaortic: HR=2.84, p=0.001; any LN+: HR=2.83, p=0.003) and OS (pelvic: HR=2.90, p=0.003; paraaortic: HR=3.03, p=0.001; any LN+: HR=3.51, p=0.001). Adeno/adenosquamous were comparable to squamous cell carcinomas (DFS: HR=1.26, p=0.44; OS: HR=1.35, p=0.32). Stages III/IV had worse prognosis than IIb (DFS: HR=1.86, p=0.003; OS: HR=2.07, p=0.001).

**Conclusions** Although statistical significance could not be reached, surgical staging in LACC lead to superior DFS and OS compared to clinical staging with acceptable morbidity and no significant CR delay. The high risk of distant metastases in both arms underlies the need for further treatment intensification.

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**IGCS19-0143**

**CRS WITH HIPEC IN ADVANCED EPITHELIAL OVARIAN CANCER WITH COMPARISON OF ONCOLOGICAL OUTCOME ONLY WITH CRS + INTRAVENOUS CHEMOTHERAPY AND CRS PLUS NORMOTHERMIC INTRA-PERITONEAL CHEMOTHERAPY**

**Objectives** Surgical staging potentially modifies radiation field in locally advanced cervical cancer (LACC), although a survival benefit has never been proved in a randomized clinical trial.

The Uterus-11 study (German GOG and Radiation Oncology Group) is a RCT designed to evaluate the impact of surgical staging compared to standard clinical/radiological staging, followed by chemoradiation (CR). Primary endpoint was disease-free survival (DFS), secondary was overall survival (OS).

**Methods** From 2009 to 2013, a total of 255 LACC patients (FIGO2009 IIB-IVA) were randomized to surgical staging and CR (ArmA), or clinical staging followed by CR (ArmB). CR consisted in pelvic external beam radiotherapy with weekly cisplatin (40mg/m²) and brachytherapy. Extended-field radiation was performed in cases of confirmed paraaortic metastases.

**Results** Among 240 patients (n=121 ArmA; n=119 ArmB), 236 (98.3%) received CR. Arms were balanced. Surgical approach was peritoneal laparoscopy in 93.4% (mean 19 pelvic/17 paraaortic lymph nodes (LN)). CR started 7–21 days after surgery. Surgery upstaged 40/121 (33%). Median follow-up: 66.5 months. ArmA was superior for DFS (HR=1.38 ArmB vs. ArmA, p=0.115) and OS (HR=1.29, p=0.24). Clinically or surgically LN+ negatively impacted DFS (pelvic: HR=2.38, p=0.007; paraaortic: HR=2.84, p=0.001; any LN+: HR=2.83, p=0.003) and OS (pelvic: HR=2.90, p=0.003; paraaortic: HR=3.03, p=0.001; any LN+: HR=3.51, p=0.001). Adeno/adenosquamous were comparable to squamous cell carcinomas (DFS: HR=1.26, p=0.44; OS: HR=1.35, p=0.32). Stages III/IV had worse prognosis than IIb (DFS: HR=1.86, p=0.003; OS: HR=2.07, p=0.001).

**Conclusions** Although statistical significance could not be reached, surgical staging in LACC lead to superior DFS and OS compared to clinical staging with acceptable morbidity and no significant CR delay. The high risk of distant metastases in both arms underlies the need for further treatment intensification.
was 33 & 16 months and OS was not achieved in primary and the recurrent setting respectively. In Comparison CRS with IV group had a DFS & OS of 28 & 42 months whereas CRS with IP group showed 38 & 55 months respectively. Intrapерitoneal therapy group had lesser overall recurrence compared to IV arm.

Conclusions CRS+IP & CRS+HIPEC group had lesser overall & perritoneal recurrences and better DFS than CRS+IV group. The role of hyperthermia for intraperitoneal chemotherapy in comparison to IP arm needs evaluation with well designed multi-institutional randomised study.

Conclusions The use of NIR proctoscopy is a safe tool to assess anastomotic rectal perfusion after rectosigmoid resection and anastomosis with a low anastomotic leak rate of 1.2%. Its potential usefulness should be evaluated within randomized trials in patients undergoing gynecologic cancer surgery.

IGCS19-0137

THE IMPACT OF USING NEAR-INFRARED ANGIOGRAPHY DURING RECTOSIGMOID RESECTION AND ANASTOMPSIS IN PATIENTS UNDERGOING GYNECOLOGIC CANCER SURGERY

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Objectives Reducing anastomotic leak rates after rectosigmoid resection and anastomosis is a priority in patients undergoing gynecologic oncology surgery. Therefore, we investigated the implications of performing near-infrared angiography (NIR) proctoscopy to assess anastomotic perfusion at the time of rectosigmoid resection and anastomosis.

Methods We identified all patients who underwent rectosigmoid resection and anastomosis for a gynecologic malignancy between January 1, 2013 until December 31, 2018. NIR proctoscopy was assessed via the PinPoint Endoscopic Imaging System (NOVADAQ, Canada).

Results A total of 410 patients were identified, among which NIR was utilized in 134 (32.7%) patients. There were no statistically significant differences in age, race, BMI, type of malignancy or surgery, histology, FIGO stage, hypertension, diabetes, or pre-operative chemotherapy between NIR and non-NIR groups. All cases of rectosigmoid resection underwent stapled anastomosis. The anastomotic leak rate was 2/134 (1.2%) in the NIR cohort compared to 13/276 (4.7%) non-NIR (p=0.10). Diverting ostomy was performed in 9/134 (6.7%) NIR patients and 53/276 (19%) non-NIR patients (p<0.001). Post-operative abscesses occurred in 4/134 (6.0%) NIR patients and 44/276 (15.9%) non-NIR patients (p=0.004). The NIR cohort had significantly fewer post-operative interventional procedures (12/134, 9.0% NIR vs. 55/276, 20.0% non-NIR, p=0.01) and significantly fewer 30-day readmissions (15/134, 11.2% NIR vs. 60/276, 21.7% non-NIR, p=0.01).

Conclusions The use of NIR proctoscopy is a safe tool to assess anastomotic rectal perfusion after rectosigmoid resection and anastomosis with a low anastomotic leak rate of 1.2%. Its potential usefulness should be evaluated within randomized trials in patients undergoing gynecologic cancer surgery.

IGCS19-0166

27 GX-188E, A THERAPEUTIC HPV VACCINE, IN COMBINATION WITH IMIQUIMOD OR IL-7-HYFC FOR TREATMENT OF HPV-16 OR HPV-18 RELATED CIN 3: RESULTS FROM PHASE 2 STUDY

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Objectives We conducted a prospective, randomized, phase 2 clinical trial of GX-188E, a therapeutic HPV vaccine in combination with Imiquimod (IMQ) or IL-7-hyFc for HPV-16 or -18 related CIN 3. The primary endpoint was to determine the histopathological regression to <CIN1 assessed at week 20 (W20), and at week 36 (W36). In addition, viral clearance, HPV E6/E7 specific T-cell response and Flt-3L concentration were also assessed.

Methods Hypothesis was that combination of GX-188E with IMQ or IL-7-hyFc could result in synergistic improvement of immune-mediated tumor clearance compared to GX-188E alone.

Results In total, 51 patients were randomized, and 1 dropout occurred due to pregnancy. Among 25 patients receiving GX-188E plus IMQ, 16 (64%) and 18 patients (72%) at W20 and W36 demonstrated histopathological regression, respectively. HPV clearance was observed in 13 (52%) and 15 patients (60%) at W20 and W36, respectively. On the other hand, in patients receiving GX-188E plus IL-7-hyFc, 4 (16%) and 11 out of 25 patients (44%) showed histopathological regression at W20 and W36, respectively.

The lower efficacy obtained in GX-188E plus IL-7-hyFc may be attributed to insufficient local delivery of IL-7-hyFc via transcytosis across mucosal layer due to its liquid formulation. Considering vaginal fluid may also disturb mucosal delivery pathway, development of appropriate formulation is necessary.

Conclusions To better understand the mechanism of systemic and local HPV-specific T cell responses induced by GX-188E, immunological analysis including intracellular cytokine staining PBMC, analysis of tumor infiltrating CD4/CD8 T cells and levels of CD69, CD103, and foxp3 are needed.