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.

IGCS19-0754

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

[1]S Marnitz-Schulze, [2]A Tsunoda*, [3]P Martus, [4]MV Vieira, [5]R Affonso Jr, [6]JS Nunes, [7]V Budach, [8]A Schneider, [9]H Hertel, [10]A Mustea, [11]J Sehouli, [12]A Plaikner, [13]A Ebert, [14]C Köhler. *[1]Uniklinik Köln, Klinik und Poliklinik für Strahlentherapie, Köln, Germany; [2]Hospital Erasto Gaertner, Gynecologic Oncology, Curitiba, Brazil; [3]Tübingen University, Institute for Clinical Epidemiology and Applied Biometry, tübingen, Germany; [4]Hospital de Amor Barretos, Gynecologic Oncology, Barretos, Brazil; [5]Hospital de Amor Barretos, Radiation Oncology, Barretos, Brazil; [6]Hospital Erasto Gaertner, Medical Oncology, Curitiba, Brazil; [7]Charité – Universitätsmedizin Berlin, Radiation Oncology, Berlin, Germany; [8]Fürstenberg-Karree Berlin, Gynecologic Oncology, Berlin, Germany; [9]Hannover Medical School, Oncology, Hannover, Germany; [10]Greifswald Medical University, Gynecologic Oncology, Greifswald, Germany; [11]Charité – Universitätsmedizin Berlin, Gynecologic Oncology, Berlin, Germany; [12]Asklepios Klinik Altona, Gynecologic Oncology, Hamburg, Germany; [13]Practice for Women's Health, Gynecology and Obstetrics, Berlin, Germany; [14]Asklepios Kliniken, Gynecologic Oncology, Hamburg, Germany*

10.1136/ijgc-2019-IGCS.24

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.

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

Plenary 5

IGCS19-0143

25 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

[1]S Somashekar*, [1]C Rohit Kumar, [1]K Ashwin, [1]S Zaveri, [2]VK Ahuja, [3]A Rauthan, [1]Y Ramya. *[1]Manipal Comphrensive Cancer Centre, Surgical Oncology, Bengaluru, India; [2]Manipal Comphrensive Cancer Centre, Gynec-Oncology, Bengaluru, India; [3]Manipal Comphrensive Cancer Centre, Medical Oncology, Bengaluru, India*

10.1136/ijgc-2019-IGCS.25

Objectives Current standard of care for patients with stage IIIc epithelial ovarian cancer (EOC) is cytoreduction and intravenous (IV) chemotherapy. Intraperitoneal (IP) chemotherapy is considered superior to standard IV chemotherapy. Recent randomised study has shown benefit of cytoreductive surgery (CRS)+ hyperthermic intra-peritoneal chemotherapy (HIPEC) over IV chemotherapy.

Methods 130 patients diagnosed of stage IIIc EOC between 2013–2018 underwent extensive CRS+HIPEC. CRS+IV or CRS+IP was also done during the same period for other patients diagnosed of stage IIIC EOC. Overall details of HIPEC group is reported with comparison of only the oncological outcome of CRS & IV group & CRS+IP group.

Results Of 130 patients, 65.3% & 34.7% had primary and secondary cytoreduction plus HIPEC respectively. Mean PCI was 14.1, duration of surgery 9.41hours & hospital stay 13 days. Multivisceral resection, diaphragmatic resection & bowel resection was required in 12.7%, 50% & 41.8% respectively. Overall G3- G5 morbidity 40% & 30 day mortality 3.6%. With a median follow up of 46 months DFS

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. Intraperitoneal therapy group had lesser overall recurrence compared to IV arm.

Conclusions CRS+IP & CRS+HIPEC group had lesser overall & peritoneal 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.

IGCS19-0137

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

[1]L Moukarzel*, [2]S Leiva, [1]M Wu, [3]M Byrne, [1]N Abu-Rustum, [1]Y Sonoda, [1]G Gardner, [1]M Leitao, [1]V Broach, [1]D Chi, [1]K Long Roche, [1]O Zivanovic. *[1]Memorial Sloan Kettering Cancer Center, Gynecology Service Department of Surgery, New York, USA; [2]Hurley Medical Center, Obstetrics and Gynecology, Flint, USA; [3]Hospital of the University of Pennsylvania, Obstetrics and Gynecology, Philadelphia, USA*

10.1136/ijgc-2019-IGCS.26

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) via 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

[1]JS Park*, [2]SJ Lee, [2]SY Hur, [3]TJ Kim, [3]SR Hong, [4]JK Lee, [5]CH Cho, [6]YS Suh, [1]JW Woo, [7]YC Sung. *[1]Genexine- Inc., Clinical Development, Gyeonggi, Republic of Korea; [2]Seoul St Mary's Hospital, Department of Obstetrics and Gynecology, Seoul, Republic of Korea; [3]Konkook University Hospital, Department of Obstetrics and Gynecology, Seoul, Republic of Korea; [4]Korea University Guro Hospital, Department of Obstetrics and Gynecology, Seoul, Republic of Korea; [5]Keimyung University Dongsan Medical Center, Department of Obstetrics and Gynecology, Daegu, Republic of Korea; [6]Genexine- Inc., DNA Research Institute, Gyeonggi, Republic of Korea; [7]Genexine- Inc., Chief Technology Officer, Gyeonggi, Republic of Korea*

10.1136/ijgc-2019-IGCS.27

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.