Objectives As groin node management is important for vulva cancer prognosis, this study assesses clinical outcomes of groin surgery compared to primary groin radiation for surgically unresectable vulva cancer.

Methods Patients treated with curative intent primary radiation ± chemotherapy for >4 cm, surgically unresectable vulva cancers were included in this retrospective study at 2 academic centres from 2000–2020. Groin recurrence-free survival was compared for groin surgery and primary groin radiation using the Kaplan Meier method and log rank test. Multivariable analysis was performed. Groin failures are described by treatment modality.

Results Of 476 patients treated with radiation for vulva cancer, 112 patients met inclusion criteria. The median (95% CI) follow up was 1.9 (1.4–2.5) years. Complete clinical response was 80.0% in patients with groin surgical management (n=45) compared to 58.2% for primary groin radiation (n=67) (p=0.04). The 3 year groin recurrence-free survival (RFS) was 94.4% (87.1–100) in patients undergoing groin surgery compared to 79.2% (69.1–90.9) (p=0.02) in patients treated with primary radiation. After adjusting for clinical and/or radiologically abnormal lymph nodes (p=0.67), groin surgery was significantly associated with lower groin recurrence (HR 0.2 (95%CI 0.05–0.92), p=0.04). Fifteen patients had groin treatment failures, 13 with primary radiation at a median (IQR) dose of 37.6 (45–62) Gy; 7 received concurrent chemotherapy and 2 had groin surgery prior to radiation. Three patients undergoing primary groin radiation had isolated groin treatment failures.

Conclusions In locally advanced vulva cancer, surgical groin management improves groin RFS and there were fewer groin treatment failures compared to radiation alone.

E-poster viewing: Trials in progress

TP001/#1553 GOG-3043 (NCT04831580): A RANDOMIZED NON-INFERIORITY TRIAL OF ROBOTIC VERSUS OPEN RADICAL HYSTERECTOMY FOR EARLY STAGE CERVICAL CANCER (ROCC)

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Objectives Minimally invasive radical hysterectomy (MIRH) offers many perioperative advantages compared to the open approach. The Laparoscopic Approach to Cervical Cancer (LACC) trial, however, found that MIRH was associated with an increased risk of recurrence and death from disease. Subsequent studies suggest differences in outcomes are mitigated by avoidance of intrauterine manipulators and performance of protective vaginal closure prior to colpotomy. ROCC seeks to re-examine the oncologic safety of MIRH when performed with robotic assistance utilizing comprehensive tumor containment.
Methods ROCC is a multi-center prospective, randomized, non-inferiority trial. Patients with FIGO 2018 stage IA2-IB2 cervical cancer with squamous cell, adenocarcinoma, and adenosquamous carcinoma histology are eligible. Preoperative pelvic MRI confirming tumor size <4 cm without evidence of extracervical extension or metastases is required. No transcervical manipulators are allowed and tumor containment prior to colpotomy using pre-specified surgical techniques are mandatory. The primary objective is 3-year DFS. Secondary objectives include DSS, OS, patterns of recurrence, complications, patient reported outcome measures, and lymphedema. 420 patients will be enrolled in each arm which will provide 90% power to exclude an absolute decrease in DFS by 7% (HR <= 1.375) with a log-rank test for non-inferiority with a one-sided alpha of 0.05. Interim analysis for futility planned after 370/640 patients enrolled (correlates with estimated 11/32 events). 20 sites are activated/enrolling and 4 patients have been randomized at the time of submission.

Results Trial in progress: There are no available results at time of submission.

Conclusions Trial in progress: There are no available results at time of submission.

**Objectives**

Objectives BVAC-C is a B cell- and monocyte-based immunotherapeutic vaccine transfected with recombinant HPV E6/E7, which was well tolerated in HPV positive recurrent cervical carcinoma in phase I study. We expect that combining BVAC-C with durvalumab (MEDI4736), an anti-PD-L1 therapy, will enhance the anti-tumor immune responses of an anti-PD-L1 agent.

**Methods**

This study is being evaluated in two parts. Part A explores the 3+3 dose-escalation of BVAC-C combined with durvalumab 1500 mg to identify the maximum tolerated dose (MTD) and recommended phase 2 dose. Once phase 2 dose is determined, the phase 2 expansion of up to 25 patients (part B) will evaluate the safety and clinical efficacy, as measured by 6-month PFS rate. Part A study began enrolling patients in Sep 2021 and is ongoing in 6 Korean centers. Low dose cohort (1.0x10^7 cells/dose BVAC-C +1,500 mg Durvalumab) has been completed, enrollment of high dose (5.0x10^7 cells/dose BVAC-C + 1,500 mg Durvalumab) will begin in July 2022. AEs are assessed according to CTCAE v5. Tumor response is determined according to RECIST 1.1 criteria and iRECIST. Key eligibility criteria include 1) histologically confirmed HPV 16/18-positive cervical carcinoma, 2) only 1 prior first-line platinum-based chemotherapy ± bevacizumab not amenable to local therapy, and 3) measurable disease per RECIST v1.1. An exploratory study is being conducted to identify biomarkers including PD-L1, TMB, and HLA typing using tumors and blood.

**Results**

Trial in progress: There are no available results at the time of submission.

**Conclusions**

Trial in progress: There are no available conclusions at the time of submission.