

significantly increased survival was observed associated with higher tumor transduction levels after 5-FC treatment compared to controls.

**Conclusions:** These results using Toca 511/5-FC prodrug activator gene therapy in preclinical models of disseminated ovarian cancer support future efforts toward clinical translation.

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#### Poster #42

##### **Intraperitoneal chemotherapy is equally safe and effective in ovarian cancer patients with and without Germline BRCA1 or BRCA2 mutations**

S. Jorge, A. Kay, K. Doll, B. Norquist, K. Pennington, R. Urban, E. Swisher, H. Gray. *Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, WA 98195*

**Objectives:** Intraperitoneal chemotherapy (IPC) achieves higher local drug concentrations and has demonstrated superiority in some settings to intravenous delivery for the treatment of epithelial ovarian cancer (OC). Because OC in patients with BRCA1 or BRCA2 (BRCA) mutations is hypersensitive to platinum agents, BRCA status may modify the efficacy of IPC. It is unknown whether BRCA haploinsufficiency in normal cells of mutation carriers could result in increased toxicity from platinum based IPC. The objective of this study was to compare the toxicity profiles and survival of OC patients with and without germline BRCA mutations who received IPC.

**Methods:** We conducted a retrospective review of the medical records of patients who received at least one cycle of IPC for the treatment of OC at a single center between 2005 and 2015. We restricted the review to patients who either carried BRCA mutations or had negative multigene testing. We abstracted demographic, clinical and tumor characteristics and compared characteristics between groups using t-tests for continuous data and chi-square tests or Fisher's exact tests as appropriate for categorical data. We constructed Kaplan-Meier curves for survival analysis. We had 80% power to detect a 25% difference in toxicity and a 62.5% survival difference.

**Results:** We identified 142 patients, 31 of whom had a BRCA mutation and 111 without mutations. The average age at diagnosis was 53 for BRCA patients and 62 for non-carriers ( $p=0.003$ ). Histology and stage distributions were similar, as were the percentages of patients undergoing bowel surgery (38.7%). Most patients (74.2% in BRCA group and 91% in wildtype group) received IPC in the front-line setting, while the remainder did so for recurrences. BRCA carriers were more likely to have received chemotherapy for a prior malignancy (12.9% v 2.7%,  $p=0.04$ ). Overall, 45% of patients in the BRCA group and 51.4% in the wildtype group experienced at least one chemotherapy-related toxicity ( $p=0.54$ ). There was no difference between the two groups in rates of dose adjustments (13% v 18%,  $p=0.51$ ) or IPC discontinuation (0% v 10%,  $p=0.12$ ) due to toxicity. In the subgroup of patients who received front-line IPC ( $n=124$ ), the median overall survival was 75.4 months for the BRCA group and 77.5 months for the wildtype group ( $p=0.46$ ).

**Conclusions:** Germline BRCA mutation status does not appear to have a large impact on toxicity or survival in patients with OC treated with IPC. These findings should be replicated in larger studies.

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#### Poster #43

##### **Pelvic disease control in patients undergoing vaginal brachytherapy for stage II endometrial cancer**

S. Chow, C.M. Liu, L.M. Scala

**Objectives:** To estimate the pelvic recurrence rate in patients with stage II endometrial cancer (EC) undergoing vaginal brachytherapy without pelvic external beam radiotherapy.

**Methods:** Data from women with pathology confirmed stage II EC were extracted from our institution's brachytherapy database from January 2006 to December 2012.

**Results:** From 2006-2012, 20 women with stage II EC underwent surgery with curative intent and adjuvant vaginal brachytherapy. Patients were followed for a median time of 87.5 months (range, 17.3-120.3 months). The median age at diagnosis was 62 (range, 49-76). The majority of specimens were of endometrioid histology (75%), with serous, clear cell, carcinosarcoma, and other representing 5%, 5%, 10%, and 5%, respectively. Lymphovascular invasion was noted in 10% of cases, with 45% Grade 1, 20% Grade 2, and 35% Grade 3. Twenty percent of patients received adjuvant chemotherapy and 90% underwent pelvic nodal dissection at the time of surgery. The 5 year-estimates for in-field vaginal, pelvic, and distant control were 85% (95% CI: 69%-100%), 90% (95% CI: 75%-100%), and 70% (95% CI: 50%-90%). The five-year overall survival (OS) estimate was 85% (95% CI: 69%-100%). We noted a trend towards reduced distant disease control in patients with non-endometrioid versus endometrioid histology with 5-year rates of 79% (95% CI: 58%-100%) versus 40% (95% CI: 0%-83%); ( $p=0.11$ ). Five-year OS was significantly better in patients with distant disease control versus distant failure with 5-year rates of 100% (95% CI: 79%-100%) versus 63% (95% CI: 29%-97%); ( $p=0.02$ ). No such OS association was seen for patients who experienced pelvic failure ( $p=0.20$ ). Crude rates of Common Terminology Criteria for Adverse Events (CTCAE) grade 0 and 1 urinary toxicity were 85% and 15%. CTCAE grade 0 and 1 gastrointestinal (GI) toxicity were 65% and 35%. No patients developed grade 2 or greater urinary or GI toxicity by last follow-up. Vaginal stenosis/atrophy was seen in 15% of patients.

**Conclusions:** Vaginal brachytherapy is well-tolerated and associated with acceptable rates of pelvic disease progression in patients with stage II EC. Patients with stage II EC and non-endometrioid histology have a high-risk of distant recurrence and consideration of systemic therapy is warranted in this setting.

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#### Poster #44

##### **Topical vaginal estrogen use and risk of endometrial hyperplasia or cancer**

S. Chow<sup>a</sup>, K. Gunnison<sup>b</sup>, L.Y. Tucker<sup>c</sup>, K. Pruett<sup>a</sup>. <sup>a</sup>Kaiser Permanente Santa Clara, Santa Clara, CA. <sup>b</sup>Kaiser Permanente San Jose Medical Center, San Jose, CA. <sup>c</sup>Kaiser Permanente, Northern California, Division of Research, Oakland, CA

**Objectives:** To estimate the yearly incidence rate of endometrial hyperplasia or cancer in women categorized by their unopposed topical vaginal estrogen (VE) prescriptions.

**Methods:** Women aged 46 years and older were identified from our institution's database from 2006-2012. ICD-9 diagnosis codes and our internal cancer registry were used to identify the first date of endometrial hyperplasia/cancer diagnosis. Pharmacy records were used to identify dispensed prescriptions for VE within 3 years prior to the reference date. The reference date used for dispensed estrogen or progesterone was defined as the index date for cases and December 31 for non-cases. Women exposed to systemic estrogen (SE) or progesterone within 2 years prior of the reference date were