EP299/#684 PHARMACOKINETICS, TOXICITIES, AND TISSUE CONCENTRATIONS OF GEMCITABINE SPRAYED BY ROTATIONAL INTRAPERITONEAL PRESSURIZED AEROSOL CHEMOTHERAPY IN A PIG MODEL

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Introduction We evaluated the pharmacokinetics, tissue concentrations, and toxicities of gemcitabine during rotational intraperitoneal pressurized aerosol chemotherapy (RIPAC) in pigs.

Methods We sprayed gemcitabine of 10% and 30% of doses for intravenous chemotherapy in six pigs (cohort 1, n=3, 300 mg/m^2; cohort 2, n=3, 1,000 mg/m^2). We evaluated the time-dependent plasma concentrations of gemcitabine before RIPAC to 120 hr for the pharmacokinetics, tissue concentrations in twelve peritoneal regions, and hepatic and renal functions before RIPAC to 120 hr in the two cohorts.

Results Mean values of the peak plasma concentration (C_{max}), the time to C_{max} (T_{max}), the time taken for C_{max} to drop in half ($T_{1/2}$), and the area under the curve from time zero to the time of last quantifiable concentration (AUC_{last}) were 1,320 and 7,476 ng/ml, 1.92 and 1.83 hr, 1.52 and 1.96 hr, and 4,718 and 26,347 ng·hr/ml in cohorts 1 and 2, respectively. Mean values of tissue concentrations were 1.3 to 11.2 times higher than in cohort 2 and in cohort 1 despite the similar ratio of tissue to plasma concentration, and tissue concentrations in the two cohorts were higher in the parietal peritoneum than in the visceral peritoneum. Cohort 2 showed the change of hepatic function after RIPAC, whereas there were no changes of hepatic and renal functions in cohort 1.

Conclusion/Implications Considering the change of hepatic function in gemcitabine of 1,000 mg/m^2, gemcitabine of 300 mg/m^2 can be considered as the stating dose for RIPAC in a phase 1 trial.

EP301/#199 A STUDY OF SURGICO-PATHOLOGICAL SPECTRUM AND LYMPH NODE EVALUATION IN EPITHELIAL OVARIAN CANCERS: AN AMBISPECTIVE STUDY

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Introduction Consensus regarding lymph node evaluation in epithelial ovarian cancer is emerging. The objective of the present study was to evaluate surgico-pathological findings, lymph node (LN) involvement, and prediction of LN metastasis by preoperative imaging and intraoperative assessment in women with epithelial ovarian cancer (EOC).

Methods Women with EOCs who underwent cytoreductive surgery (CRS) between Jan 2019 to April 2022 were included. Distribution of histology, stage and LN metastasis was studied. Predictive value of radiologic and surgically enlarged LNs with final histopathology was studied.

Results A total of 101 women with EOCs underwent CRS, of which 5 (4.95%) with co-existent endometrial cancer were excluded. Fifty women (52%) underwent primary and 46 women (48%) interval CRS. HGSC was commonest (n=66, 68.75%), followed by mucinous (n=15, 15.63%), endometrioid (n=6, 6.25%), LGSC (n=4, 4.17%) and carcinosarcoma (n=2, 2.08%). Majority of women, 69 (71.88%) were stage III and IV at presentation. Complete cytoreduction was achieved in 75 (78.12%) cases. Seventy-five women (78.13%) of EOC underwent pelvic and/or para-aortic lymphadenectomy, out of which 23 (30.67%) were histologically positive. Both radiologically and surgically enlarged LNs significantly predicted LN metastasis on histopathology (p=0.02 and 0.006 respectively). The combined sensitivity, specificity, PPV, and NPV of both CECT and surgically enlarged LNs was 78.26%, 57.69%, 45%, and 85.71%, respectively

Conclusion/Implications Serous histology, high-grade tumors and suspicious LNs in CECT and during surgery are significantly associated with LN metastasis.

EP303/#621 LOW DOSE LENVATINIB PLUS TORIPALIMAB IN PATIENTS WITH HEAVILY PRETREATED GYNECOLOGICAL SOLID TUMORS: A PILOT STUDY

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Introduction Patients with heavily pretreated gynecological solid tumors have extremely limited treatment options. Lenvatinib combined therapy has efficacy in treating advanced endometrial carcinoma (including non-endometrioid), but nearly half of patients were intolerable toxicity of the recommended doses. Accordingly, we performed this pilot study to evaluate the efficacy and safety of low dose lenvatinib plus toripalimab in patients with heavily pretreated gynecological solid tumors.

Methods Lenvatinib was administered with a starting dose of 8 or 12 mg orally once daily based on patient's body weight and an intravenous infusion of toripalimab was received at a dose of 240 mg every 3 weeks. Patients received therapy for up to 24 months until disease progression or unacceptable toxicity. The primary endpoint was progression free survival (PFS).

Results Twenty-one patients (ovarian, n=14; endometrial, n=6; vulvar, n=1), who experienced disease progression after prior median 3 lines of systemic therapy, were enrolled and treated from September 2021 to April 2023. In the 21 patients, the median PFS was 5.0 months , the median duration of response (DOR) was 5.2 months, and disease control rate(DCR) was 38.1%. The most common grade 3 treatment-related adverse events(TRAEs) were hypertension (33.3%) and proteinuria (9.5%), respectively. No grade 4 TRAEs occurred.

Conclusion/Implications This study, to our knowledge, is the first to explore the effects of low-dose lenvatinib plus Toripalimab in gynecological solid tumors. The encouraging efficacy