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**P-108** A phase II study of weekly paclitaxel in patients with advanced or recurrent esophageal cancer who had previously received docetaxel-containing chemotherapy

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**Background:** Both docetaxel and paclitaxel are a class of microtubule-stabilizing anticancer agents. Partial cross-resistance between docetaxel and paclitaxel was indicated in breast and ovary cancers. In advanced gastric cancer, retrospective study showed comparable efficacy of subsequent weekly paclitaxel with or without prior docetaxel-based chemotherapy. Therefore, we evaluated the efficacy and safety of weekly paclitaxel in patients with advanced or recurrent esophageal cancer who had previously received docetaxel-containing chemotherapy.

**Methods:** This study was a multi-center, single-arm phase II study in patients with advanced or recurrent esophageal cancer. Eligible criteria included histologically confirmed esophageal squamous cell carcinoma or adenocarcinoma with measurable lesions, refractory to prior docetaxel-containing chemotherapy, aged 20 years and older, and an ECOG performance status (PS) of 0-1. Paclitaxel at 100 mg/m<sup>2</sup> was administered by intravenous infusion, and this was repeated weekly for 6 weeks followed by a 1-week rest. The primary end point was confirmed objective response rate (ORR), as assessed according to the RECIST version 1.1 criteria. The secondary end points included progression-free survival (PFS), overall survival (OS) and safety.

**Results:** Between January 2016 and November 2019, 25 patients were enrolled from 6 institutions in Japan. Two patients with ineligible (n=1) and refusal of treatment (n=1) were excluded. Therefore, 23 patients were included in this analysis. In prior treatment, all patients received fluoropyrimidine, platinum and docetaxel. The median number of treatment cycles was 2 (range 1–4). The ORR was 9% (2/23), however, the confirmed ORR was 0%. The disease control rates (DCR) was 52% (12/23). The median PFS and median OS were 81 days (95% confidence intervals (CI), 47 to 91), and 211 days (95% CI, 162 to 262), respectively. The common grade 3 or 4 treatment-related adverse events were neutropenia (34%), leukocytopenia (26%) and anemia (22%). There were no treatment-related deaths.

**Conclusions:** Although this phase II study did not meet the primary endpoint, it showed modest efficacy with an acceptable safety profile.

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**P-109** Care delivery impact of the COVID-19 pandemic on anal cancer care

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**Background:** The ongoing COVID-19 pandemic has disrupted worldwide cancer care delivery, leading to a decline in cancer screening, delayed diagnostic tests, and treatment modifications. Little has been reported on the care delivery impact of COVID-19 on patients (pts) with rare tumours, such as squamous cell carcinoma of the anus (SCCA). Our study aimed to evaluate the impact of the pandemic on care delivery of SCCA pts in two comprehensive cancer centres.

**Methods:** We performed a retrospective study of two consecutive cohorts of adult pts diagnosed with SCCA at AC Camargo Cancer Center (AC) and Princess Margaret Cancer Center (PM) from the peri-COVID-19 period (1 February 2020– 31 January 2021) to the same period in the year prior (1 February 2019– 31 January 2020), utilizing electronic medical records to collect data on pts demographics and patterns of care in the six months following their first consultation. Comparisons of patterns of care between the peri- and pre-COVID-19 (control) cohorts were conducted using

two-sided t-tests, Wilcoxon rank-sum tests,  $\chi^2$  tests, or Fisher's exact tests, as appropriate;  $p < 0.05$  were deemed significant.

**Results:** Overall, 73 pts were included: peri-COVID-19: n = 35 and pre-COVID-19: n = 38; both cohorts had similar demographic compositions in terms of age and sex [control: median age = 61.4 (IQR: 41.8 – 92.1), 55% female; peri-COVID-19: median age = 66.9 (IQR: 41–91.1), 63% female]. Pts from both institutions presented similar characteristics in both peri- and pre-COVID-19 periods. At AC, the number of pts diagnosed with SCCA during the peri-COVID-19 period was half of that prior to the pandemic. In the peri-COVID-19 period, the proportion of pts who received radiation therapy decreased in both institutions, when compared with the pre-pandemic period, however, the decrease was not found to be significant: 100% vs 83% at AC ( $p=0.32$ ) and 84% vs 76% at PM ( $p=0.52$ ). A similar proportion of pts received chemotherapy in the peri- and pre-COVID-19 periods, respectively: 80% vs 82%. Disease stage III at diagnosis was the most common (pre-COVID: 46%, peri-COVID: 46%). The proportion of pts who were operated on was similar between both cohorts (peri-COVID-19: 23%; control: 21%).

**Conclusions:** Our multicenter study shows that during the peri-COVID-19 pandemic, the number of pts who received radiotherapy therapy to treat SCCA was numerically inferior, albeit not statistically significant. In one of the cancer centers, the number of new SCCA cases dropped by 50%. Longer follow-up is needed to understand the impact of the treatment modifications on SCCA clinical outcomes.

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**P-110** Safety and efficacy of GEMOX plus donafenib and tislelizumab as first-line therapy for advanced epithelial malignant biliary tract cancer

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**Background:** Nearly 70% of the newly diagnosed patients with malignant biliary tract cancer (BTC) are in advanced stage. Gemcitabine-based systemic chemotherapy is the standard first-line treatment. Chemotherapy combined with tyrosine kinase inhibitors and immune checkpoint inhibitors as the first-line treatment has shown good efficacy but the safety profile remains to be improved. The purpose of this study was to evaluate the safety and efficacy of gemcitabine and oxaliplatin (Gemox) plus donafenib and tislelizumab.

**Methods:** In this prospective single-center exploratory study, eligible patients were aged 18–80 years (inclusive) with histologically or cytologically documented stage III/IV (AJCC Cancer Staging Manual, 8th Edition) epithelial malignant biliary tract cancer, at least one measurable disease per RECIST v1.1, ECOG performance status (PS) of 0–1, main organs function well and life expectancy of at least three months. Patients received gemcitabine 1000 mg/m<sup>2</sup> IV Q3W, oxaliplatin 100 mg/m<sup>2</sup> IV Q3W, donafenib 200 mg PO BID and tislelizumab 200 mg IV Q3W until disease progression, unacceptable toxicity or withdrawal of consent whichever occurred first. The primary endpoint was safety. The secondary endpoints included conversion rate and overall survival (OS).

**Results:** From March 2021 to August 2021, 13 patients were enrolled (5 males and 8 females; 4 stage III and 9 stage IV; all ECOG PS of 1; aged 53–72 years; 4 gallbladder cancer, 2 hilar cholangiocarcinoma and 7 intrahepatic cholangiocarcinoma). The median (IQR) levels of CA-199, AFP and CEA at baseline were 125 U/ml (4.5–1000), 3.5 ng/ml (1.8–11.4) and 6.3 ng/ml (1.6–12.8), respectively. At data cut-off (February 17, 2022), a median number of 4 cycles (range 1–14) of study treatment was received and the median treatment duration of donafenib was 87 days (range 17–277). The median follow-up time was 147 days (range 18–277). Treatment-related adverse events (TRAEs) occurred among all patients (100%), including 7 (53.8%) patients who had grade 3 TRAEs and one (7.7%) patient who had a grade 4 TRAE. No grade 5 TRAE or unexpected adverse event was reported. The most frequently reported grade 3-4 TRAEs were rash (4/13, 30.8%), platelet count decreased (2/13, 15.4%) and fatigue (2/13, 15.4%). Three stage III patients underwent subsequent surgery with a conversion rate of 23.1% (95% CI, 5.0%–53.8%). The median OS was not reached. The 6-month OS rate was 90.9% (95% CI, 50.8%–98.7%).

**Conclusions:** GEMOX plus donafenib and tislelizumab as the first-line therapy for advanced BTC showed manageable toxicity and encouraging efficacy especially in terms of a promising conversion rate in stage III patients.

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