

receive secondary surgeries (29.6% vs. 22.6%,  $p < 0.0001$ ) than patients who received bevacizumab.

**Conclusions:** In this nationwide cohort study, we demonstrated that among patients who received first-line chemotherapy doublets for inoperable KRAS wild-type mCRC, the combination with anti-EGFR mAb, compared with the combination with bevacizumab, led to significantly longer OS and TTF. This benefit mainly came from patients with left-sided primary tumors. In the multivariate analysis, anti-EGFR mAb treatment remained an independent predictor of longer OS and TTF for the left-sided primary tumors. To our knowledge, this is the largest ( $n = 6,482$ ) cohort study focusing on this issue.

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## P-72 Real-world treatments and outcomes for biliary tract cancer patients using administrative databases in Ontario, Canada

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**Background:** There is a paucity of literature on treatment patterns and outcomes in biliary tract cancer (BTC) patients in Canada. The aim of this study was to better understand treatment patterns and survival outcomes of BTC patients in Ontario.

**Methods:** We conducted a retrospective population-level study in Ontario using ICES datasets on patients diagnosed with de novo or recurrent, advanced BTC (including: gallbladder cancer, intrahepatic and extrahepatic cholangiocarcinoma [IHC and EHC, respectively], Ampulla of Vater [AoV]) between January 1, 2010 and December 31, 2019. Follow-up data were available until December 31, 2020. Patients were categorized as de novo if they had stage IV disease at the time of first diagnosis, and as recurrent if they had a prior diagnosis of early stage (I-III) or unknown/missing (UNK/M) disease and received a BTC treatment (proxy for progression). Patients were excluded if they died before BTC diagnosis or had a prior cancer diagnosis. To determine the longitudinal trajectory of care for BTC patients, linkages were made between 8 national/provincial data sets.

**Results:** A total of 2,666 advanced BTC patients were identified, of which 471 (17.7%) were gallbladder, 785 (29.4%) were IHC, 864 (32.4%) were EHC, 304 (11.4%) were AoV and 242 (9.1%) had an unspecified BTC diagnosis. Out of 2,666, 828 (31.1%) were diagnosed with de novo and 1,838 (68.9%) were diagnosed with recurrent disease. The median age at diagnosis was 67 (interquartile range [IQR] 59-74) that significantly ( $p < 0.001$ ) varied between de novo and recurrent patients, and a majority (50.5%) of the patients were male. A total of 2,307 (86.5%) patients received first-line (1L) treatment. The most common 1L treatments were a platinum and gemcitabine combination – cisplatin and gemcitabine (gem/cis) (50.1%) and carboplatin and gemcitabine (gem/carbo) (4.9%), followed by gemcitabine monotherapy (gemmono) (17.5%), and capecitabine- or fluorouracil-based treatments (fluoropyrimidine [FP]) (16.5%). For AoV patients, the most common 1L treatment was gemmono (47.6%). Of those treated with 1L treatments, 38.7% received subsequent treatment(s). The most common treatment in second line (2L) was FP (32.1%). Among the 2,307 treated patients, 1,132 (49.1%) of patients received a stenting procedure. The mean (standard error [SE]) and median (IQR) overall survival (OS) for all advanced BTC patients from diagnosis was 28.8 months (0.83) and 13.1 months (5.7-32.0), respectively. Mean and median OS from diagnosis was longer for patients who received a 1L treatment (32.3 months [0.93] and 16.4 months [IQR 7.8-37.0], respectively) versus untreated patients (6.2 months [0.71] and 2.8 months [1.7-5.6], respectively). Mean and median OS from initiation of treatment was 16.7 months [0.71] and 9.2 months (IQR 4.0-18.9), respectively for non-AoV patients who received gem/cis.

**Conclusions:** This is the first comprehensive, Canadian-specific, real-world evidence study of advanced BTC patients. This study showed that 1L treatment options vary between AoV and non-AoV BTC patients, and patients who receive 1L treatment have greater survival than those who do not. The short OS in advanced BTC patients highlight the need for novel and more effective first-line therapies.

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## P-73 Survival outcomes of surgical resection in perihilar cholangiocarcinoma in endemic area of O. Viverrini, Thailand

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**Background:** Perihilar cholangiocarcinoma is an intractable malignancy and still remain the most challenge for surgeon. This study aims to investigate survival outcomes and prognostic factors in perihilar cholangiocarcinoma patient receiving surgical treatment in single center in Thailand, endemic area of O. Viverrini.

**Methods:** From October 2013 to December 2018, 240 consecutive patients with perihilar cholangiocarcinoma underwent surgical exploration with or without adjuvant treatment at Sunpasitthiprasong hospital were retrospectively reviewed from medical recording system. The clinicopathological parameters and surgical outcomes were extracted. Patients were divided into two groups: unresectable and resectable group. The restricted mean survival time between two groups were analyzed. Factors associated with overall survival in resectable group were explored with multivariable Cox regression analysis.

**Results:** Of the 240 patients, 201 (83.75%) were received surgical resection. The survival outcomes of resectable group was better than unresectable group significantly. The restricted mean survival time difference were 0.5 (95%CI 0.22-0.82) months, 1.8 (95%CI 1.15-2.49) months, 4.7 (95%CI 3.58-5.87) months, and 9.1 (95%CI 7.40-10.78) months at four landmark time points of 3, 6, 12 and 24 months, respectively. The incidence of major complications and 90-day mortality in resectable group were 35.82% and 11.44%, respectively. Bismuth type IV, vascular resection, positive resection margin, lymph node metastasis, and distant metastasis were all predictive factors for long-term survival in univariable analysis. However, multivariable analysis revealed that Bismuth type IV (HR:4.43, 95%CI 1.853-10.599), positive resection margin (HR:4.24, 95%CI 1.741-10.342), and lymph node metastasis (HR:2.29, 95%CI 1.046-4.999) were all independent predictors of long-term survival. For pM0, R0 and pN0 patients, the median survival time was better than pM0, R1 or pN1/2 patients and pM0, R1 and pN1/2 patients (32.4, 10.4 and 4.9 months, respectively;  $p < 0.001$ ).

**Conclusions:** Surgical resection increased survival in perihilar cholangiocarcinoma. Bismuth type IV, positive resection margin and lymph node metastasis were independent factors for long-term survival. Patients with R0 and pN0 had a good prognosis, but those with R1/2 and/or pN1/2 had a bad prognosis. As a result, aggressive resection are essential.

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## P-74 SGNTUC-019: Phase 2 basket study of tucatinib and trastuzumab in previously treated solid tumors with HER2 alterations: Biliary tract cancer cohort (trial in progress)

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**Background:** Tucatinib (TUC), a highly selective HER2-directed tyrosine kinase inhibitor approved in multiple regions for HER2+ metastatic breast cancer, is being investigated as a novel therapy for patients with metastatic colorectal cancer, gastric cancer, and other GI tumors. In xenograft models of HER2+ and HER2-mutated tumors, dual targeting of HER2 with TUC + trastuzumab (Tras) showed superior activity to either agent alone. (Kulukian 2020) Interim results from the MOUNTAINEER study have shown promising activity for TUC + Tras in HER2+ colorectal cancer. In 23 response-evaluable patients, an objective response rate (ORR) of 52% was observed with a median progression-free survival (PFS) of 8.1 months. (Strickler 2019) The prognosis for patients with biliary tract cancers (BTCs) remains poor, and treatment options are limited. Given that approximately 12%-15% of BTC patients are HER2+, and 1%-8% have HER2 mutations, TUC + Tras warrants further evaluation in this patient population. The SGNTUC-019 basket study (NCT04579380) is evaluating TUC + Tras in patients with previously treated, locally advanced, unresectable or metastatic solid tumors, including BTC, that display HER2 overexpression/amplification or activating mutations. We describe the design of the BTC cohort.

**Trial design:** SGNTUC-019 is a multi-cohort, open-label, international phase 2 study. Patients must be  $\geq 18$  years old; have an ECOG PS of  $\leq 1$ ; have adequate hepatic, hematological, renal, and cardiac functions; and have no previous exposure to HER2-directed therapy. Exceptions for prior Tras treatment are allowed in patients with uterine serous carcinoma or HER2-mut gastroesophageal junction. Patients must have