Aims: Curative surgery is possible in less than a third of patients with biliary tract carcinoma (BTC). Most patients die of progressive cancer. This trial was designed to combine an optimal schedule of gemcitabine and cisplatin with the EGFR antibody panitumumab in patients with BTC. The primary objective was to determine the clinical benefit of this combination in KRAS wild-type (WT) BTC.

Methods: Patients with KRAS WT locally advanced or metastatic BTC received gemcitabine 1000mg/m², cisplatin 25mg/m² IV on days 1 and 8 of a 21 day cycle, with panitumumab 9mg/kg IV on day 1. KRAS status was determined by high resolution melt analysis PCR and confirmed with direct sequencing. The primary endpoint was objective clinical benefit at 12 weeks. The regimen was considered to be of interest if at least a 70% clinical benefit rate was achieved. Secondary endpoints included RR by RECIST v1.1; Time to treatment failure; Tolerability and safety; PFS; OS; Duration of response; CA19.9 response; QoL.

Results: 80 patients were screened, 68 were WT KRAS (85%). Of these, 48 were enrolled between 2012 and 2013, across 14 Australian centres. Baseline demographics were well balanced with mean age 62yrs (range 40-82yrs). WHO PS 0 to 1. Most common grade III/IV adverse events were neutropenia (33.3%), infection (22.9%), thrombocytopenia (20%) and anaemia (16%). In addition, acneiform rash (12.5%), hypomagnesaemia (10.4%), fatigue (10.4%) and diarrhoea (6.3%) were also reported. The objective clinical benefit rate at 12 weeks was 84.1% (95% CI 69.5 – 92.1%); 18 SD (40%), 16 PR (36%) and 1 CR (2%). At this early assessment the actuarial rate of progression free survival is 8.4 months (95% CI 5.6 – 16.6%). Among 45 assessable patients, 20 (44%) were responders according to RECIST criteria (95% CI 31 – 59%). Data relating to the Secondary Endpoints will be presented at the meeting.

Conclusions: The data presented confirms that the primary endpoint of the study was met. The combination of gemcitabine, cisplatin and panitumumab is a tolerable regimen with proven activity in our patient population. Further investigation of EGFR blockade in BTC is warranted.

Disclosure: All authors have declared no conflicts of interest.