AB061. P-32. Multicenter, randomized phase II trial of S-1, leucovorin, oxaliplatin and gemcitabine (SLOG) in chemo-naïve advanced biliary tract cancer: a Taiwan Cooperative Oncology Group study

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Background: According to the 2014 Taiwan Cancer Registration, the case number of newly diagnosed biliary tract cancer (BTC) was approximately 2,000 cases per year. Previously, we conducted a single arm phase II of modified gemcitabine plus S-1 (GS) in 46 evaluable patients with advanced BTC, 10 (21.7%) patients achieved partial response (PR) and the median progression-free survival (PFS) and overall survival (OS) was 5.6 and 10.8 months, respectively. All grade 3 treatment-related adverse events (AEs) were <5%. For its excellent safety profile and moderate activity, and the feasibility of a gemcitabine-based triplet regimen, we are currently conducting a randomized phase II trial comparing S-1, leucovorin, oxaliplatin and gemcitabine (SLOG) versus gemcitabine plus cisplatin (GC) in chemo-naïve advanced BTC (NCT03406299).

Methods: Based on the assumption of a 6-month PFS rate of 45% with GC *vs*. 60% with SLOG, we estimated enrollment of 92 patients (46 patients in each arm) to achieve 80% power, with a drop-out rate of 10%. Two-sided test was performed with type I error =0.20. The primary endpoint is 6-month PFS rate and secondary endpoints include ORR, disease control rate (DCR) (ORR + stable disease ≥12 weeks), PFS, OS, safety profile and biomarker study.

Results: Ninety-two patients with chemo-naïve advanced BTC will be randomized to receive SLOG or GC regimen. The SLOG regimen consists of gemcitabine 800 mg/m^2, fixed dose-rate (10 mg/m^2/min) infusion followed by oxaliplatin 85 mg/m^2, 2-hour infusion at day 1, and S-1 35 mg/m^2/b.i.d. (maximum dose: 120 mg/day) plus leucovorin 30 mg/b.i.d., days 1–7, every 2 weeks. The GC regimen consists of gemcitabine 1,000 mg/m^2, IV drip for 30 mins followed by cisplatin 25 mg/m^2, 2 hours infusion on D1 and D8, every 3 weeks. Treatment will be continued until progressive disease, unacceptable toxicity, patients' refusal or death. The study has been opened in March 2018, and expected to complete accrual within 24 months.

Conclusions: Since the ABC-02 trial result published in 2010, GC became the standard regimen of advanced BTC but the prognosis remains dismal. This randomized phase II trial is ongoing and we wish the result can further improve the outcome of advanced BTC.

Keywords: Advanced biliary tract cancer (advanced BTC); chemotherapy; clinical trial

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