680P A phase III study to compare the efficacy and safety of paclitaxel versus irinotecan in patients with metastatic or recurrent gastric cancer who failed in first-line therapy (KCSG ST10-01)

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Background: Although emerging treatments have been introduced to patients with metastatic or recurrent gastric cancer (MRGC) as second-line therapy, paclitaxel or irinotecan are still viable options. This phase III study compared the efficacy and safety of

paclitaxel versus irinotecan in patients with MRGC who failed to first-line chemotherapy.

Methods: Patients were randomized to receive either paclitaxel (70 mg/m^2; days 1, 8, 15, every 4 weeks) or irinotecan (150 mg/m^2 biweekly). The primary endpoint was progression-free survival (PFS).

Results: This study was stopped early due to low accrual rate. A total of 112 patients were enrolled, of which 54 were allocated to paclitaxel, and 58 to irinotecan. Median PFS of paclitaxel or irinotecan group were 3.5 and 2.1 months, respectively [hazard ratio (HR) 1.27; 95% confidence interval (CI), 0.86-1.88; $p = 0.234$]. Non-inferiority of irinotecan to paclitaxel was not proven according to the predefined upper margin of non-inferiority (1.32). Median overall survival (OS) was 8.6 months in the paclitaxel group, and 7.0 months in the irinotecan group (HR, 1.39; 95% CI, 0.91-2.11; $p = 0.126$). There was no difference in response rate ($p = 0.783$) between paclitaxel (15.8%) and irinotecan (13.6%). Among toxicities of $\geq$ grade 3, neutropenia (11.5%) was the most common toxicity, followed by peripheral neuropathy (7.7%) in the paclitaxel group, and neutropenia (34.5%) followed by nausea, vomiting and anemia (8.6%, respectively) in the irinotecan group.

Conclusions: Although paclitaxel showed numerically longer PFS and OS compared with irinotecan, this was statistically insignificant. Both irinotecan and paclitaxel are valid second-line treatment options in MRGC.

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