gastrointestinal tumours, non-colorectal

**B150 RANDOMIZED PHASE II STUDY OF CAPECITABINE AND CISPLATIN WITH OR WITHOUT SORAFENIB IN PATIENTS WITH METASTATIC GASTRIC CANCER: STARGATE STUDY**


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**Aim:** Capecitabine and cisplatin (XP) combination chemotherapy is one of the standard 1st line regimens for the treatment of metastatic gastric cancer (MGC). Sorafenib is a multi-kinase inhibitor with activity against angiogenesis and RAF-MEK-ERK pathway. In this study, we aimed to evaluate the efficacy of sorafenib (S) in combination with XP as the 1st line chemotherapy in MGC.

**Methods:** This study was a randomized (1:1), open-label, phase II study. The patients (pts) with metastatic gastric or gastroesophageal junction adenocarcinoma with measurable lesion(s) were eligible. The primary endpoint was progression-free survival (PFS). XP + S consisted of capecitabine 800 mg/m² po bid on days 1-14, cisplatin 60 mg/m² iv on day 1, and sorafenib 400 mg po bid on days 1-21, every 3 weeks. XP consisted of capecitabine 1000 mg/m² on days 1-14, and cisplatin 80 mg/m² iv on day 1, every 3 weeks. XP was continued up to 8 cycles until disease progression or intolerance. Pts in XP arm were allowed to cross over to sorafenib alone when their diseases progressed.

**Results:** Between Jan 2011 and Feb 2013, a total of 195 pts were randomized from 12 sites in Korea, China and Taiwan. Median age was 56 years. All pts had ECOG performance status 0-1. 19% of pts had prior gastrectomy. Overall response rate was 54% in XP + S arm, and 52% in XP arm (p = 0.826). With a median follow-up of 12.6 months (range, 0.1-29.2), median PFS assessed by independent review was 5.6 months in XP + S arm, and 5.3 months in XP arm (HR 0.92, 95% CI 0.67-1.27, p = 0.609). OS was not different between the two arms (median 11.7 vs. 10.8 months; HR 0.93, 95% CI 0.65-1.31, p = 0.661). Frequencies of grade 3/4 toxicities were similar between XP + S and XP arms, except neutropenia (21% vs 37%), febrile neutropenia (2% vs 6%), and palmar-plantar erythrodysesthesia syndrome (7% vs 1%). In 51 pts who crossed over to sorafenib alone in XP arm, there was no objective response and the median PFS was 1.3 months (95% CI, 1.2-1.7).

**Conclusions:** The addition of sorafenib to XP chemotherapy was safe but not more effective than XP chemotherapy alone for the 1st line treatment of MGC. Biomarker analyses are now ongoing to identify potential patients who can get benefit with XP + S.

**Disclosure:** Y. Kang: Honorarium, consultant for Bayer, Roche Research grant from Bayer, Roche. All other authors have declared no conflicts of interest.