gastrointestinal tumours, non-colorectal

**MULTICENTER PHASE II TRIAL OF ADJUVANT S-1 PLUS DOCETAXEL FOR 6 MONTHS IN PATIENTS WITH PATHOLOGICAL STAGE III GASTRIC CANCER (OGSG-1002)**


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**Aim:** We have previously indicated the tolerability and safety of adjuvant S-1 plus Docetaxel for 3 months after D2 gastrectomy in patients with pathological stage III gastric cancer (OGSG-0604). To achieve the further treatment outcome, we conducted a phase II study to evaluate the feasibility of S-1 plus Docetaxel for 6 months after D2 gastrectomy in counterpart patients.

**Methods:** Eligibility criteria included ECOG-PS of 0 or 1, age between 20 and 80 years and histologically proven stage III gastric cancer after R0 gastrectomy with D2 lymphadenectomy. Enrolled patients received 40mg/m² Docetaxel on day 1 intravenously and 80mg/m² oral S-1 on day 1–14 every 3 weeks (one cycle). This 3-week cycle was repeated for 8 cycles (for 6 months), followed by S-1 monotherapy until 1 year after surgery. The primary endpoint was feasibility of S-1 plus Docetaxel for 8 cycles.

**Results:** A total of 62 patients (32 stage IIIA, 30 IIIB, according to the 13th Japanese Classification of Gastric Carcinoma) were enrolled in this study from 14 institutes between Dec 2010 and Dec 2012. Forty-eight patients (77.4%, 95%CI 65.0-87.1%) completed the planned 8 cycles of S-1 plus Docetaxel and the proportion of patients completed planned cycles was comparable with that of 4 cycles (OGSG-0604). Forty-two patients completed the consequent S-1 monotherapy until 1 year after surgery and 2 patients were ongoing of consequent S-1 monotherapy. This doublet regimen was well tolerated, with 19% of Grade 4 neutropenia, 18% of Grade 3 anorexia and 10% of Grade 3 fatigue, while no febrile neutropenia, grade 4 non-hematological toxicities and treatment related death were observed.

**Conclusions:** Adjuvant S-1 plus Docetaxel for 6 months in patients with stage III gastric cancer was well tolerated after D2 gastrectomy and will be a candidate for future phase III trials studying the optimal adjuvant chemotherapy regimen for stage III gastric cancer.

**Disclosure:** All authors have declared no conflicts of interest.