gastrointestinal tumours, non-colorectal

PHASE II MULTI-INSTITUTIONAL PROSPECTIVE RANDOMIZED TRIAL COMPARING S-1 + PACLITAXEL WITH PACLITAXEL ALONE AS SECOND-LINE CHEMOTHERAPY IN PATIENTS WITH RECURRENT GASTRIC CANCER PRIOR TO S-1 TREATMENT (CCOG 0701)

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Aim: In Japan, S-1 has been the key drug in the first-line treatment for gastric cancer. However, there has been no evidence in support of continuation of S-1 in combination with another anticancer drug in the second-line setting. A multicenter randomized phase II trial was conducted to explore whether continuation of S-1 in addition to paclitaxel, a drug often used alone in the second-line setting, offers any benefit to the patients.

Methods: Gastric cancer patients who showed progression during the S-1-based first-line chemotherapy or has recurrence during the postoperative adjuvant treatment by S-1 were randomly assigned to the second-line treatment either by weekly administration of paclitaxel (PTX) at 80 mg/m² three times every 4 weeks or daily oral S-1 (80 mg/m²) for 2 weeks plus paclitaxel (50 mg/m²) given on days 1 and 8, every 3 weeks (S-1 + PTX). Primary end points were the progression-free survival (PFS) at 4 months and the incidence of adverse effects. Secondary end points included response rate and overall survival (OS).

Results: A total of 79 patients were eligible for efficacy analyses, 38 of whom were randomized to the S-1 + PTX group and 41 to the PTX group. PFS at 4 months was similar between the groups (45% for S-1 + PTX vs 49% for PTX, P = 0.71). The incidences of grade 3 or more haematological and non-haematological toxicities were also equivalent between the groups (21% vs 22% and 24% vs 27%, respectively). Although there were no statistically significant differences, the median OS was longer in the S-1 + PTX group (463 days vs 312 days, P = 0.46). Response rate was similar between the groups (22% for S-1 + PTX vs 29% for PTX, P = 0.75). The proportion of patients who remain progression-free for more than 300 days was higher among the S-1 + PTX group in a subset of patients who had relapse during the postoperative adjuvant chemotherapy (31% vs 7%).

Conclusions: Neither benefit nor shortcomings of S-1 administration beyond progression was proven when paclitaxel was selected as a second-line chemotherapy. S-1 + paclitaxel could be considered for patients who relapsed during postoperative adjuvant therapy by S-1.

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