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original report

# Addition of Docetaxel to Oral Fluoropyrimidine Improves Efficacy in Patients With Stage III Gastric Cancer: Interim Analysis of JACCRO GC-07, a Randomized Controlled Trial

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abstract

**PURPOSE** S-1 is a standard postoperative adjuvant chemotherapy for patients with stage II or III gastric cancer in Asia. Neoadjuvant or perioperative strategies dominate in Western countries, and docetaxel has recently shown significant survival benefits when combined with other standard regimens in advanced cancer and perioperative settings.

**PATIENTS AND METHODS** This randomized phase III study was designed to prove the superiority of postoperative S-1 plus docetaxel over S-1 alone for R0 resection of pathologic stage III gastric cancer. The sample size of 1,100 patients was necessary to detect a 7% increase in 3-year relapse-free survival as the primary end point (hazard ratio, 0.78; 2-sided $\alpha = .05$; $\beta = .2$).

**RESULTS** The second interim analysis was conducted when the number of events reached 216 among 915 enrolled patients (median follow-up, 12.5 months). Analysis demonstrated the superiority of S-1 plus docetaxel (66%) to S-1 (50%) for 3-year relapse-free survival (hazard ratio, 0.632; 99.99% CI, 0.400 to 0.998; stratified log-rank test, $P < .001$), and enrollment was terminated as recommended by the independent data and safety monitoring committee. Incidences of grade 3 or greater adverse events, particularly neutropenia and leukopenia, were higher in the S-1 plus docetaxel group, but all events were manageable.

**CONCLUSION** Addition of docetaxel to S-1 is effective with few safety concerns in patients with stage III gastric cancer. The present findings may also be applicable in countries in which perioperative adjuvant chemotherapy or chemoradiation is not standard.

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