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## ORIGINAL ARTICLE



## Multicenter phase II study of trastuzumab plus S-1 alone in elderly patients with HER2-positive advanced gastric cancer (JACCRO GC-06)

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### Abstract

**Background** S-1 plus cisplatin is a standard regimen for advanced gastric cancer (AGC) in Asia. The ToGA trial established a fluoropyrimidine plus cisplatin and trastuzumab as a standard treatment for human epidermal growth factor receptor 2 (HER2)-positive AGC. In the HERBIS-1 trial, trastuzumab combined with S-1 plus cisplatin showed promising antitumor activity in patients with HER2-positive AGC. However, cisplatin has several important drawbacks, including vomiting and renal toxicity. These disadvantages of cisplatin are prominent in elderly patients. Therefore, we conducted a prospective phase II study of trastuzumab plus S-1 without cisplatin in elderly patients with HER2-positive AGC.

**Methods** Patients 65 years or older who had HER2-positive AGC received S-1 orally on days 1–28 of a 42-day cycle and trastuzumab intravenously on day 1 of a 21-day cycle.

**Results** A total of 51 patients were enrolled. Two patients were ineligible. The full analysis set thus comprised 49 patients. The median age was 71 years (range 65–85). The confirmed response rate was 40.8% (95% CI 27.1–54.6%), and the null hypothesis was rejected. The median follow-up period was 10.6 months. Median overall survival was 15.8 months. Median progression-free survival was 5.1 months, and time to treatment failure was 4.0 months. Major grade 3 or 4 adverse events included neutropenia (12.0%), anemia (24.0%), diarrhea (10.0%), and anorexia (12.0%). There was one treatment-related death.

**Conclusions** Trastuzumab in combination with S-1 alone demonstrated promising antitumor activity and manageable toxic effects as well as promising survival results in elderly patients with HER2-positive AGC.

**Clinical trials registration** UMIN000007368.

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