Background: Oral fluoropyrimidine plus platinum regimen as a first-line and weekly paclitaxel monotherapy as a second-line were one of Japanese standard care for advanced gastric cancer. The irinotecan monotherapy has become a common practice as a third-line chemotherapy, though there are few reports regarding the efficacy. The aim of this study was to evaluate the efficacy and safety of irinotecan as a third-line chemotherapy in patients refractory or intolerant to first-line oral fluoropyrimidine plus platinum and second-line taxane.

Methods: We retrospectively analyzed 52 patients received irinotecan as a third-line chemotherapy at the National Cancer Center Hospital, between February 2008 and December 2013.

Results: The characteristics of the 52 patients were as follows: median age, 65 years (range, 41 to 78); male/female, 41/11; PS 0/1/2, 2/40/10; number of metastatic sites 1/≥2, 14/38; and peritoneal metastasis yes/no, 30/22. The median number of irinotecan administration was three (range, 1 to 25), and 25 patients (48%) had initial dose reduction. Among the 32 patients who had measurable lesions by RECISTv1.1 criteria, one patient achieved confirmed partial response and six patients had stable disease. The overall response rate was 3% and the disease control rate was 21%. The median progression-free survival was 2.3 months (95% confidence interval [CI], 1.8 to 2.8) and median overall survival was 4.0 months (95% CI, 2.5 to 5.5). The adverse events of grade 3/4 included neutropenia in 14 patients (27%), febrile neutropenia in six patients (12%), anorexia in six patients (12%), and diarrhea in three patients (6%), respectively.

Conclusion: Irinotecan would be reasonably well tolerated as a third-line therapy regimen for patients with advanced gastric cancer, however the efficacy might be limited.