

論 文 要 旨

Clinical Significance of Eligibility Criteria Determined by the SPIRITS Trial in Patients with Advanced Gastric Cancer

（ 進行胃癌患者における SPIRITS 試験での適格・
不適格基準の臨床的意義 ）

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Abstract

Introduction: This study aimed to assess the clinical significance of eligibility criteria determined by phase 3 clinical trials in the clinical practice of patients with advanced gastric cancer who underwent chemotherapy. **Methods:** Patients with stage IV gastric cancer who received chemotherapy between February 2002 and December 2021 were retrospectively enrolled and divided into two groups (the eligible vs. ineligible group) based on eligibility criteria determined by the SPIRITS (S-1 vs. S-1 plus cisplatin) trial. **Results:** Among the 207 patients, 103 (49.8%) and 104 (50.2%) patients were classified into eligible and ineligible groups, respectively. Eligibility criteria were significantly correlated with age, the first-line regimen of chemotherapy, the presence or absence of conversion surgery, and tumor response to the first-line chemotherapy (all $p < 0.01$). The eligible group had a significantly higher induction of post-progression chemotherapy after first- and second-line chemotherapy than did the ineligible group (all $p < 0.01$). The ineligible group had significantly poorer prognoses than the eligible group ($p < 0.0001$). Multivariate analysis showed that peritoneal dissemination, tumor response, conversion surgery, and eligibility criteria were independent prognostic factors (all $p < 0.05$). **Conclusion:** Eligibility criteria determined by the SPIRITS trial may have clinical utility for predicting tumor response, the induction of conversion surgery, and prognosis in patients with advanced gastric cancer who underwent chemotherapy.