TPS4205 **Poster Session**

A randomized controlled trial comparing conversion surgery with palliative chemotherapy in patients with initially unresectable cStage IVB/pStage IV advanced gastric cancer who presented remarkable response to chemotherapy: JCOG2301 (Conversion study).

Itaru Yasufuku, Masanori Terashima, Naoki Takahashi, Kota Kawabata, Masayuki Yokoyama, Yukinori Kurokawa, Narikazu Boku, Takaki Yoshikawa; Department of Clinical Anatomy Development Studies, Gifu University Graduate School of Medicine, Gifu-City, Japan; Division of Gastric Surgery, Shizuoka Cancer Center, Nagaizumi, Japan; Department of Gastroenterology, Saitama Cancer Center, Saitama, Japan; Japan Clinical Oncology Group Data Center/Operations Office, National Cancer Center Hospital, Tokyo, Japan; National Cancer Center Hospital, Tokyo, Japan; Department of Gastroenterological Surgery, Osaka University, Graduate School of Medicine, Suita, Japan; Department of Oncology and General Medicine, IMSUT Hospital, Institute of Medical Science, University of Tokyo, Tokyo, Japan; Department of Gastric Surgery, National Cancer Center Hospital, Tokyo, Japan

Background: Conversion surgery is a surgical treatment for patients with initially unresectable cStage IVB gastric cancer who presented remarkable response to palliative chemotherapy aiming at n R0 resection expecting long survival including he disease. This study is a randomized controlled phase III trial aimed to evaluate the efficacy of conversion surgery comparing to palliative chemotherapy. **Methods:** Eligibility criteria include the followings : (1) Histologically proven adenocarcinoma of the stomach. (2) Diagnosed as clinical stage IVB or pathological stage IV according to the Japanese Classification of Gastric Carcinoma (15th edition), with at least one of the following unresectable distant metastases before chemotherapy. (i) Four or more liver metastases. (ii) Distant lymph node metastasis beyond para-aortic lymph node No.16a2/16b1. (iii) Peritoneal dissemination diagnosed with imaging examination or P1b/P1c peritoneal dissemination diagnosed with laparotomy or laparoscopy. (3) Undergoing first-line chemotherapy regardless of nivolumab or trastuzumab use. (4) Confirmation of no peritoneal metastasis or localization at a limited area close to the stomach by laparoscopy or laparotomy after initiation of chemotherapy, with CY0 status in peritoneal lavage cytology. (5) Response to chemotherapy of distant metastasis diagnosed before initiating first-line chemotherapy that meets the following (i) and (ii) before registration. (i) Liver metastasis: three or fewer liver metastasis. (ii) Distant lymph node metastasis excluding No.16a2/16b1: disappearance or reduction to a long axis of less than 6 mm. The primary endpoint is overall survival. After confirming eligibility, patients are registered and randomized (1:1) to either the palliative chemotherapy alone arm or the conversion surgery arm. We assumed the median survival timeis 19 months after registration for the chemotherapy alone arm additional efficacy for overall survival in the conversion surgery arm corresponding to a hazard ratio of 0.7. This study requires 126 patients to observe 102 deaths, with power of 70% and a one-sided alpha of 10%, considering the rarity of patients with stage IV gastric cancer who exhibit a significant response to palliative chemotherapy, an accrual period of 5 years, and a follow-up period of 3 years. This trial was initiated in September 2024, and the first patient was enrolled in January 2025. Clinical trial information: jRCTs031240340. Research Sponsor: Japan Agency for Medical Research and Development (AMED).