622 RANDOMIZED, OPEN-LABEL STUDY OF THE BIOLOGICAL EFFECTS OF BLP25 LIPOSOME (L-BLP25) IMMUNOTHERAPY IN RECTAL CANCER PATIENTS UNDERGOING NEOADJUVANT CHEMORADIOTHERAPY: SPRINT STUDY DESIGN

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Background: Neoadjuvant chemoradiotherapy (NCR) followed by radical resection is the standard of care for patients with stage II-III rectal cancer. L-BLP25 (Stimuvax®) is an antigen-specific cancer immunotherapeutic agent targeting the mucin 1 (MUC1) antigen. It may act by inducing the proliferation of interferon (IFN)-γ secreting MUC1-specific CD4+ T-cells and the generation of cytotoxic T lymphocytes capable of killing MUC1-expressing tumours. In the SPRINT (Stimuvax® [L-BLP25] in Rectal cancer In Neoadjuvant chemoradioTherapy) study, we will evaluate immune responses to L-BLP25 in patients with rectal cancer undergoing NCR.

Study design: SPRINT is a phase II, multi-centre, open-label study in which patients (n = 24/arm) with resectable stage II-III rectal cancer are randomized to NCR (capecitabine 825 mg/m^2 twice-daily for 5–7 d/wk; 45–52 Gy in fractions of 1.8/2 Gy for ≥5 wk) alone, NCR + L-BLP25, or NCR + L-BLP25 + cyclophosphamide (CPA). L-BLP25 is administered as 8 consecutive weekly subcutaneous doses (930 μg) beginning on the first day of NCR, followed by a final injection 7–9 d before surgery. CPA (300 mg/m^2; maximum 600 mg) is given as a single intravenous infusion 3 d before the first L-BLP25 dose. Surgery will be performed 6–8 wk after the end of NCR. The primary objective is to assess L-BLP25-induced changes in immune response profile. The intra-tumoural response will be evaluated based on analysis of tumour-infiltrating lymphocytes (especially CD8+ and CD45RO+). Peripheral antigen-specific response will be assessed by measuring IFN-γ secretion by peripheral blood mononuclear cells (ELIspot assay) in response to MUC1 and carcinoembryonic antigen (CEA) as a test for 'antigen spreading'. Secondary objectives include the assessment of additional immunological changes and correlation of intratumoural, peripheral and skin delayed-type hypersensitivity responses. Safety and pathological anti-tumour responses in resection specimens will be evaluated.

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623 EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER QLQ-C30 AND FUNCTIONAL ASSESSMENT OF CANCER THERAPY-GENERAL FOR THE MEASUREMENT OF QUALITY OF LIFE IN COLORECTAL CANCER PATIENTS WHO RECEIVED ADJUVANT CHEMOTHERAPY: A COMPARISON

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Purpose: Quality of life (QOL) was measured using the European Organization for Research and Treatment of Cancer QLQ-C30 (QLQ-C30) and Functional Assessment of Cancer Therapy-General (FACT-G) in colorectal cancer patients who received adjuvant chemotherapy with oral uracil/tegafur plus leucovorin, and two QOL measurements were compared.

Methods: QOL was assessed prospectively at baseline (pretreatment) and at 5-week intervals during treatment, using QLQ-C30 and FACT-G, and were compared with reference to the corresponding scales.

Results: The study group comprised 58 men and 41 women, with a mean age of 65 years (range, 30 to 80). The disease stage was stage II in 51 patients and stage III in 48. The 99 patients had received a total of 444 treatment cycles (median, 5 cycles; range, 0.1 to 5 cycles). The most common type of toxicity was fatigue. However, the incidence of grade 3 or 4 fatigue was very low. The most common type of hematological toxicity was anemia, which was generally mild. Six patients had grade 3 diarrhea and 6 had grade 3 anorexia. QOL was not evaluated either before or after treatment in 5 of the 99 enrolled patients; both baseline and post-treatment evaluations were available for the other 94 patients. Of 94 patients, the numbers of patients who completed the QOL questionnaires were 90 (96%) at baseline, and 87 (93%), 85 (90%), 88 (94%), 84 (89%), and 81 (86%), consecutively. The mean number of evaluations per patient was 6.2 (range, 3-7). The post-treatment assessments changed significantly from the baseline values and favored post-treatment for all scales except social well-being of the FACT-G. All scales except social well-being in patients with Grade 0-1 toxicities were better than those with Grade 2-3 toxicities. Social well-being in patients with Grade 2-3 toxicities were worse than those with Grade 0-1. When corresponding scales between the two QOL questionnaires were compared, a high correlation for physical domain or emotional domain was found. However, no correlation was noticed for the social domain.

Conclusion: The social domain of the two QOL questionnaires may evaluate different aspects of QOL each other.

Disclosure: All authors have declared no conflicts of interest.

624 PATHOLOGICAL RESPONSE OF SYNCHRONOUS LIVER METASTASES FROM COLORECTAL CANCER TREATED WITH BEVACIZUMAB PLUS MFOLFOX6 IN AN ANALYSIS OF A PHASE II STUDY OF NEOADJUVANT CHEMOTHERAPY

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Background: The prognosis of synchronous liver metastases (SLM) from colorectal cancer is poor. Therefore, we, the Miyagi Hepato-biliary pancreatic clinical oncology group (Miyagi-HBPCOG), conducted a phase II study of neoadjuvant chemotherapy for SLM to determine the appropriate initial treatment. Here, we assessed the radiologic and pathological responses.

Patients and methods: Patients were enrolled after R0-resection of the primary colorectal cancer and received 8 courses of mFOLFOX6 with bevacizumab (the first and last courses were mFOLFOX6 alone). The main inclusion criteria were SLM within 10 nodules, histologically confirmed, measurable disease. The primary endpoint was the response rate (RR).

Result: Between June 2008, and November 2008, 47 patients were enrolled from 17 centers. The median age was 62 years (range 32-72 yrs). The median number of metastases was 2 nodules, and the maximum diameter of tumors was 12.9 cm. Three patients were excluded from the evaluation of RR because they did not receive any scheduled chemotherapy. The overall RR was 70.5% (2 complete responses and 29 partial responses). Eleven patients (25%) showed stable disease and 1 patient (2.3%) had progressive disease. The liver resections rate was 90.9% (40/44) and the R0-resection rate was 86.3% (38/44). The pathological response was evaluated tumor regression grade (TRG1-5). Major response (TRG1 and 2) was 55%, partial response (TRG2) was 32.5%, and no response (TRG4 an 5) was 12.5%. This major response rate was high, so the progression-free survival and overall survival can be extended is expected. Necrosis was also graded as 1 to 4. Major necrosis of Grade 3 and 4 was 52.5%, and Grade 2 was 17.5%, and Grades 0 and 1 of no necrosis were 30.0%. Although the necrosis rate slightly correlated with the pathological response, the radiological response did not correlate with it.

Conclusion: Pathological and radiological response of liver metastases treated with bevacizumab plus mFOLFOX6 appeared favorable. Therefore, the progression-free survival and overall survival could be expected to be extended. (Trials Registry: UMIN000001568).

Disclosure: All authors have declared no conflicts of interest.

625 FEASIBILITY REPORT OF A RANDOMIZED MULTICENTER CONTROLLED PHASE III TRIAL OF ADJUVANT UFT/LV THERAPY AFTER RESECTION FOR LIVER METASTASIS FROM COLORECTAL CARCINOMA

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There is no established evidence yet to support the of postoperative adjuvant chemotherapy after resection of colorectal liver metastasis. A randomized multicenter controlled phase III trial was conducted and patients were recruited from 20 hospitals to compare the efficacy of postoperative adjuvant UFT/LV therapy (UTF: 300 mg/m^2/day and LV: 75 mg/day, Day 1-28, once every 5 weeks, 5 cycles) with that