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A Multi-institutional feasibility study of S-1/oxaliplatin (SOX) plus bevacizumab in patients with advanced/metastatic colorectal cancer: HiSCO-02 prospective phase 2 study

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Background :

mFOLFOX6 regimen, which is a standard regimen for metastatic colorectal cancer (CRC), is inconvenient owing to its requirement for continuous infusion via vascular access. We aimed to investigate the efficacy and safety of S-1/oxaliplatin (SOX) plus bevacizumab, a promising alternative treatment to replace mFOLFOX6.

Patients and methods :

We undertook a clinical phase II trial in 12 institutions in Hiroshima, Japan. We enrolled individuals aged 20–80 years who had metastatic CRC, had an Eastern Cooperative Oncology Group performance status (PS) of 0 or 1, had assessable lesions, and had received no previous chemotherapy. Eligible patients were assigned SOX plus bevacizumab (S-1: 80-120 mg/body/day, day1–14 orally administrated, oxaliplatin: 130mg/m² day1 i.v., bevacizumab: 7.5mg/kg day1 i.v. q3w). The primary endpoint was response rate (RR), and the secondary end points were progression-free survival (PFS), overall survival (OS), and safety.

Results :

From May 2011 to January 2014, 55 patients (mean age, 64 years) were enrolled. The number of metastatic organs were one: 29 cases (52.7%), two or more: 25 cases (45.4%), and 2 cases had no target lesions (3.6%). Median follow up time was 12.8 months (range, 1.4-38.6 months). RR was 45.4% (95% confidence interval (CI): 32.2-58.6%) and disease control rate was 87.3% (95%CI: 78.5-96.1%). Median PFS and OS time were 9.2 months (95%CI: 7.6-10.8) and 22.0 months (95%CI: 17.7-26.2), respectively. The median number of cycles of chemotherapy was 7 (range, 1-16). The median relative

dose intensity of oxaliplatin, S-1, and bevacizumab were 85%, 85%, and 87%, respectively. Major toxic effects (grade 3/4) were thrombocytopenia (5.7%), neutropenia (7.5%), sensory neuropathy (13.2%), and anorexia (17.0%).

Conclusion :

These data indicated that the SOX plus bevacizumab regimen is effective and well tolerated in patients with metastatic CRC.

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