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Research Paper

A phase II trial of 1st-line modified-FOLFOXIRI plus bevacizumab treatment for metastatic colorectal cancer harboring RAS mutation: JACCRO CC-11

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ABSTRACT

FOLFOXIRI plus bevacizumab is considered a standard initial therapy for metastatic colorectal cancer (mCRC). However, few prospective trials have evaluated triplet therapy plus bevacizumab in patients with RAS mutant mCRC. Patients with an age of 20 to 75 years, and unresectable, measurable tumors harboring RAS mutation were given first-line treatment with bevacizumab (5 mg/kg on day 1) plus modified-FOLFOXIRI (irinotecan 150 mg/m², oxaliplatin 85 mg/m², levofolinate 200 mg/m², and fluorouracil 2400 mg/m² as a 46-h continuous infusion on day 1, repeated every 2 weeks). The primary endpoint was the objective response rate (ORR) as evaluated by an external review board. Progression-free survival (PFS), overall survival, early tumor shrinkage (ETS), depth of response (DpR), and safety were secondary endpoints. Among 64 patients who were enrolled between October 2014 and August 2016, 62 were evaluable for efficacy (right-sided tumors in 27%). ORR and disease control rate were 75.8% (95% confidence interval [CI] 65.1-86.5) and 96.8%, respectively. ETS was 73.8%, and median DpR was 49.2%. Median PFS was 11.5 (95% CI 9.5-14.0) months as of the cut-off date of September 2017. Adverse events of grade 3 or 4 were neutropenia (54%), hypertension (32%), diarrhea (13%), anorexia (11%), peripheral neuropathy (2%), and febrile neutropenia (5%). In conclusion, this prospective trial demonstrated for the first time that FOLFOXIRI plus bevacizumab is an active first-line treatment for patients with RAS mutant mCRC. Modified-FOLFOXIRI plus bevacizumab might become an alternative regimen of triplet chemotherapy for mCRC in Japan.