A phase II study of capecitabine plus oxaliplatin (XELOX): a new first-line option in metastatic colorectal cancer.


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Abstract

BACKGROUND:
Capecitabine and oxaliplatin are both effective and well-tolerated monotherapies for the treatment of advanced colorectal cancer (CRC). Oxaliplatin has also been shown to be very effective when combined with 5-FU/LV in the first-line setting.

AIM OF THE STUDY:
Assess the efficacy and safety of capecitabine plus oxaliplatin (XELOX) in patients with previously untreated advanced CRC.

METHODS:
Fifty-three patients with measurable disease received capecitabine 1,000 mg/m2 twice daily on d 1-14 and oxaliplatin 130 mg/m2 on d 1, every 3 wk. Of these, 52 were evaluable for safety and 49 for antitumor response.

RESULTS:
There was a low rate of grade 1/2 adverse events; grade 3/4 events included leukopenia (10%), neutropenia (6%), thrombocytopenia (2%), nausea/vomiting (4%), and diarrhea (4%). The overall response rate was 39% (95% CI, 25-54%) and median time to disease progression was 7.8 mo.

CONCLUSIONS:
XELOX is an active and well-tolerated first-line treatment for advanced CRC. Randomized phase III studies are ongoing to compare XELOX with FOLFOX in view of the comparable efficacy and safety but superior convenience of XELOX therapy.