

## Phase II trial of oxaliplatin plus oral capecitabine as first-line chemotherapy for patients with advanced gastric cancer

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### ABSTRACT

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**Aims and background.** The efficacy of chemotherapy for advanced gastric cancer is now widely accepted. However, the survival advantage is small, and no internationally accepted standard regimen has emerged. The present study investigated the efficacy and safety of oxaliplatin plus oral capecitabine (XELOX regimen) as first-line chemotherapy in previously untreated patients with advanced gastric cancer.

**Methods and study design.** Patients received intravenous oxaliplatin (130 mg/m<sup>2</sup> over 2 h on day 1) plus oral capecitabine (1,000 mg/m<sup>2</sup> twice daily on days 1-14). Treatments were repeated every 3 weeks.

**Results.** Seventy-four patients were enrolled in the study, median age was 61 years (range, 32-74); median follow-up was 13.2 months (range, 2-24.5). In total, 364 cycles of chemotherapy were delivered. Overall response rate was 62.2% (95% CI, 51.2-73.2), with 3 complete and 43 partial responses; median time to progression and overall survival were 5.9 (95% CI, 4.8-7.0) and 10.8 months (95% CI, 7.9-13.7), respectively. The most common hematological adverse event was anemia (67.6% of patients). Grade 3-4 neutropenia was observed in 5 patients. The most common nonhematological toxicities were neuropathy (64.9%), nausea/vomiting (48.6%), diarrhea (28.4%), and hand-foot syndrome (39.2%). Grade 3-4 toxicities were rare. There were no treatment-related deaths.

**Conclusions.** The XELOX regimen was active and well-tolerated as first-line chemotherapy in patients with advanced gastric cancer.

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**Key words:** advanced gastric cancer, capecitabine, oxaliplatin.

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