

Rate of recurrent neutropenia between omitted bolus fluorouracil group compared with oxaliplatin dose reduction group in colorectal cancer patients, a randomized cross-over trial

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Background: The oxaliplatin is widely used as a component of standard adjuvant or palliative chemotherapy for stage III or metastatic colorectal cancer. A common adverse event is the hematologic toxicities, especially neutropenia frequently leading to dose modification or the delay treatment. However optimal dose modification scheme for the infusional oxaliplatin based regimen remains unsettled.

Methods: In this a randomized, open label, single center, crossover trial, we randomly assigned stage III or metastatic stage colorectal cancer patients, who exposed to FOLFOX type regimen and experienced chemotherapy induced neutropenia (absolute neutrophil count < 1,500 /mm³), to receive different dose modification schemes of the mFOLFOX6, either omitting bolus fluorouracil or decreasing oxaliplatin dose. All randomized subjects were crossed over to the other dose modification scheme in subsequent cycle. The primary endpoint was rate of recurrent neutropenia and the secondary endpoints were time to next chemotherapy cycle, changed of absolute neutrophil count, other hematologic and non-hematologic toxicities.

Results: There were 32 patients enrolled during July 1, 2019 to April 30, 2020. 28 patients were allocated to both study treatment. The rate of recurrent neutropenia in the omitting bolus fluorouracil group was 10.71% compared with 17.86% in the oxaliplatin dose reduction group (P = 0.727). In addition, the rate of thrombocytopenia and time to next chemotherapy cycle were more pronounced in the oxaliplatin-dose reduction group.

Conclusions: The results from limited population show a trend of a lower rate of recurrent neutropenia and more favorable outcomes in omitting fluorouracil group than the oxaliplatin dose reduction group.
