Preoperative oxaliplatin, capecitabine, and external beam radiotherapy in patients with newly diagnosed, primary operable, cT₃NxM0, low rectal cancer: a phase II study.


Collaborators (47)


Source

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Abstract

PURPOSE:

In patients with locally advanced rectal cancer (LARC), preoperative chemoradiation is known to improve local control, and down-staging of the tumor serves as a surrogate for survival. Intensification of the systemic therapy may lead to higher downstaging rates and, thus, enhance survival. This phase II study investigated the efficacy and safety of preoperative capecitabine and oxaliplatin in combination with radiotherapy.

PATIENTS AND METHODS:

Patients with LARC of the mid and lower rectum, T₃NxM0 staged by MRI received radiotherapy (total dose 45 Gy) in combination with oral capecitabine (825 mg/m² twice a day on radiotherapy days; weeks 1-4) and oxaliplatin 50 mg/m² intravenously (days 1, 8, 15, and 22). Efficacy was evaluated as rate of tumor down-categorization at the T level.

RESULTS:
A total of 59 patients were enrolled (19 women, 40 men; median age of 61 years) and all were evaluable for efficacy and toxicity. Down-categorization at the T level was observed in 53% with pathological complete response in 6 patients (10%). Actual total radiotherapy, oxaliplatin and capecitabine doses received were 97%, 90%, and 93% of the protocol-specified preplanned doses, respectively. Grade 3/4 toxicity was observed in 15 patients (25%). The most frequent was diarrhea (12%).

CONCLUSIONS:

Preoperative chemoradiation with capecitabine and oxaliplatin is feasible in patients with MRI-proven cT₃ LARC. The only clinically relevant toxicity was diarrhea. Overall, efficacy of the multimodality treatment was good, but not markedly exceeding that of 5-FU- or capecitabine-based chemoradiation approaches.

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