An open-label randomized controlled trial to evaluate the efficacy of antihistamine premedication and infusion prolongation in prevention of hypersensitivity reaction to oxaliplatin.

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Background: Hypersensitivity reaction (HSR) is a common toxicity in patients receiving repeated oxaliplatin. Oxaliplatin induced HSR could be severe and results in treatment discontinuation.

Objective: To evaluate the efficacy of anti-histamine premedication and infusion prolongation in prevention of oxaliplatin induced HSR.

Methods: We conducted a prospective, single center, open-label, randomized controlled trial comparing the standard premedication and 2-hour infusion protocol to the additional antihistamine premedication, intravenous chlorpheniramine, and 3-hour infusion protocol. The randomization was done at 5 th and 7 th cycles of 3-week and 2-week oxaliplatin based regimens, respectively. The primary endpoint was the incidence of HSR.

Results: From July 2020 to March 2021, A total of 160 patients underwent randomization (80 patients in both intervention group and control group). Seventy-four (92.5%) and seventy-six (95%) patients in the intervention group and the control group, respectively, had completed all planned treatment cycles. HSRs occurred in 1 (1.4 %) and 10 (13.2%) patients in intervention and control groups, respectively, p=0.009). There were 6 (7.8%) patients with more than grade 1 HSRs in control groups, but none in intervention group. In the intervention arm, one patient experienced a cutaneous reaction (grade 1 erythema) and grade 1 palpitation. None of the patients in intervention arm developed respiratory symptoms, gastrointestinal symptoms, or anaphylaxis.

Conclusions: Additional antihistamine premedication and infusion prolongation started in 2 nd half of treatment course can reduced HSR incidence in patients receiving oxaliplatin.