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abstract

Increased incidence of sinusoidal obstruction syndrome after hematopoietic stem cell transplantation following treatment with Inotuzumab ozogamicin: retrospective matched case-control study

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Increased incidence of sinusoidal obstruction syndrome after hematopoietic stem cell transplantation following treatment with Inotuzumab ozogamicin: retrospective matched case-control study

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Introduction: Inotuzumab ozogamicin (InO) is effectively used for treatment of pediatric patients with refractory/ relapsed B-cell acute lymphoblastic leukemia (R/R B-ALL), but it is associated with high incidence of sinusoidal obstruction syndrome (SOS). Recipients of allogeneic HSCT (allo-HSCT) with R/R B-ALL have many risk factors for SOS. The aim of this study is to evaluate whether treatment with InO elevates the incidence of SOS in heavily pretreated pediatric patients with R/R B-ALL.

Methodology: We conducted a retrospective matched case-control study. Cases were patients treated in our clinic with InO and subsequently received allo-HCST. Controls were matched according to the remission number, number of HSCT, type of conditioning (treosulfan-based, TBI-based) and type of donor (in several cases we matched control with donor with greater potential of graft versus host disease). We matched 3 controls to 1 case. The event was SOS (pediatric EBMT criteria) that occurred within 100 days after HSCT.

Results: There were 18 cases and 54 controls. Their cases and controls did not differ in respect to age, sex, remission number, types of conditioning, type of donor. In the whole cohort there were 5 events. All cases of SOS were severe, in 3 patients SOS was a concurrent reason of death, in 1 patient SOS led to liver fibrosis and in 1 patient it resolved. All events of SOS were in the case cohort. The incidence of SOS in the case cohort was significantly higher (27.8%) compared to the control group (0%), $p<0.0001$.

Conclusion: Our study showed that the use of InO increases the incidence of SOS after ongoing allo-HSCT in pediatric patients with R/R B-ALL.