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abstract

Treatment of Pediatric Patients with Relapsed and Refractory B-Cell Acute Lymphoblastic Leukemia with Inotuzumab Ozogamicin: A Single-Center Experience

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abstract

Treatment of Pediatric Patients with Relapsed and Refractory B-Cell Acute Lymphoblastic Leukemia with Inotuzumab Ozogamicin: A Single-Center Experience

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Introduction: Overall survival of pediatric patients with refractory/relapsed B-cell acute lymphoblastic leukemia (R/R B-ALL) is still not optimal, despite such treatment options as blinatumomab and CAR T-cell therapy. Inotuzumab ozogamicin (InO) is a CD22-directed antibody conjugated to calicheamicin, that is used for treatment patients with R/R B-ALL

Methodology: Twenty-seven patients <18 years with R/R B-ALL were treated with InO in our clinic from 01.01.2019 to 30.08.2024. Twenty-six patients received 1 cycle of InO (0.8 mg/m2 -1 day, 0.5 mg/m2 – 8, 15 days), and 1 patient received only 1 dose because of liver toxicity.

Results: Among all patients 21 (77.8%) had blast cells >5% and 26 (96.3%) had detectable leukemic cells by flow cytometry. One patient (3.7%) received in first remission due to severe infection, two patients (7.4%) – to achieve first remission, 15 patients (55.6%) – in first relapse, 7 patients (25.9%) – in second relapse, 2 patients (7.4%) in third relapse. Most of the patients were heavily pretreated, including blinatumomab n=13, 48.1%), CAR T (n=8, 29.6%) and allo-HSCT (n=3, 11.1%). Among 26 patients with detectable leukemic cells 13 (50%) patients achieved MRD-negative (<0.01%) remission without extramedullary lesions. Nineteen (70.4%) patients received further therapy: blinatumomab – 10 patients, chemotherapy – 7 patients, CAR T- cell therapy 2 patients.

Eighteen patients received allo-HSCT, in 5 of them (27.8%) sinusoidal obstruction syndrome occurred. The probability of overall survival (OS) in 2 years was 39.4% (95%CI: 19.1-59.8%). Two-year OS was significantly lower in patients who did not achieve MRD- negative remission without extramedullary lesions (28.6%, 95%CI:4.9-52%) compared to patients who achieved (50.1%, 95%CI: 17.4-82.9%), p=0.046. Patients that had been previously treated with blinatumomab also had inferior two-year OS (30.8%, 96%CI: 5.7-55.9%) compared to others (48.7%, 95%CI: 19.1-78.3%), p=0.046.

Conclusion: InO is effective in heavily pretreated pediatric patients with R/R B-ALL.