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614.ACUTE LYMPHOBLASTIC LEUKEMIAS: THERAPIES, EXCLUDING TRANSPLANTATION AND CELLULAR IMMUNOTHERAPIES

Inotuzumab Use: A Single-Center Experience in B-Cell Acute Lymphoblastic Leukemia

Marcela Espinoza, MD¹, Jorge Rojas, PhD², Hernán López-Vidal, MD¹, Andrés José Castañeda, MD¹, José Tomás Gazmuri, MD¹

Introduction: Inotuzumab Ozogamicin (InO) is a humanized anti-CD22 monoclonal antibody conjugated to calicheamicin, a cytotoxic antibiotic agent used in B-Acute Lymphoblastic Leukemia (B-ALL). The conjugate is internalized and produces DNA cleavage and subsequent apoptosis. InO has shown better results than conventional chemotherapy. Patients and methods: We present the results of a single-center experience with a small cohort of 13 patients diagnosed with ALL who received InO outside of clinical trials. Results: Of the 13 patients, 69% (9) were male. The median age was 38 years old (range 16-64). 10 patients younger than 55 years 9 patients had relapsed diseases, 3 refractory diseases and one patient was newly diagnosed. Regardless of relapsed disease, 7 patients used InO as a first line of salvage and 2 as a second line. In refractory disease, 1 patient used InO as the second salvage and 2 as third or more. White blood cells range from 1,500 to 285,000 mm3. Peripheral blood blast from 50-80%. Before InO administration, all the patients had bilirubin lower than 2 mg/DL (range 0.15-1.26 mg/dL), an ALT (alanine aminotransferase) medium value of 34 U/dl, and an AST (aspartate aminotransferase) medium value of 33 U/dL. The most common type of leukemia was CALLA in 8 patients: B-ALL Phi positive in 2, Lymphoid blast crisis in 1, pre-B ALL 1, and t (8;22) 1 patient. 10 patients had CD-22 positivity in flow cytometry, and 3 had negative results. There was no relation between the intensity of CD 22 and the rate of response. 11 patients received InO as monotherapy, and 2 were associated with Mini-HyperCVAD-InO. 7 patients received 1 cycle and 6 patients received 2 cycles of InO; the average dose received was 2,7 mg/m2. 7 (53%) patients in complete response (CR) plus MDR (Minimal Residual disease) negative after treatment, 4 progressive diseases and 2 missing. Three patients received HCT (hematopoietic cell transplantation) post-InO, and two are waiting in complete remission. One patient relapsed while she was waiting for HCT and died. 4 patients received InO as a salvage after relapse post-HCT. All these patients had progressive diseases and died. In the patients that used InO as a bridge to HCT, the average time to transplant was 94 days. Regardless of Veno-Occlusive Disease (VOD), 1 patient developed it after InO treatment; no patients had VOD associated with HCT. Overall survival: 38 months; progression-free survival: 4.1 months. Mortality rate was 53% (7 patients). Causes were: 4 with progressive disease, 1 hemorrhagic stroke, 1 septic shock, and 1 suicide. Conclusion: We show our small local experience using this new drug in B-ALL patients. Patients who use InO as a bridge to HCT could have a good outcome. We had not found good results when InO was used in relapse post-HCT. There was no relation between the intensity of CD22 at flow cytometry and the rate of responses. The incidence of VOD was low. Rates of response are comparable to other real-world reports. This small experience could be the beginning of a multicenter Real-World study in Latin America.

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¹Hematology Division, Clínica Dávila, Santiago, Chile

² Faculty of Business and Economics, Universidad Andres Bello, Santiago, Chile