therapy for many adults with acute lymphoblastic leukemia (ALL). The role of HCT is especially critical in settings where pediatric-inspired protocols may be excessively toxic or difficult to implement, and novel agents for B-cell ALL are not readily available. In recent years, the use of haploidentical donors and reduced-intensity conditioning (RIC) regimens expanded treatment options for selected patients. However, there are currently no comprehensive data describing HCT outcomes for ALL in Latin America (LA). **Aim:** In this study, we aimed to assess survival and response outcomes in a large, multicenter cohort, with an additional focus on less-studied subgroups of the disease. **Material e methods:** This is a retrospective registry-based study that included HCT data from 18 centers in LA. We included patients aged ≥ 15 years with ALL or ambiguous lineage leukemia who underwent a first HCT between January 2007 and December 2024. Primary endpoints were overall survival (OS), disease-free survival (DFS), cumulative incidence of relapse (CIR), and non-relapse mortality (NRM). Multivariate Cox regression analyses (MVA) were performed. Country was incorporated as a frailty term in the models. **Results:** A total of 748 patients were included (median age 29; 84% B-cell ALL). Transplants occurred in Brazil (49.9%), Mexico (22.7%), Argentina (15.4%), and Chile (12%). Ph+ ALL was present in 28.5%, CNS disease in 16.9%. HCT was performed in CR1 (57.2%), CR2+ (37.4%), or refractory disease (5.4%); pre-HCT MRD was positive in 22.8%. Donors were haploidentical (40.6%), MSD (39.3%), MUD (11.6%), MMUD (5.5%), or cord blood (2.7%); 78.1% used peripheral blood. Myeloablative conditioning (MAC) was predominant (84.3%), with TBI in 69.6%. At 47.7 months' median follow-up, 4-year OS and DFS were 46.8% and 42.5% (45.4% excluding refractory). CIR and NRM were 29.9% and 28.5%. Donor type did not affect OS, but MUD lowered relapse risk (HR 0.551, $p = 0.027$). OS predictors included age (HR 1.014, $p = 0.005$), CR2+ (HR 1.398, $p = 0.01$), TBI (HR 0.749, $p = 0.02$), donor age (HR 1.01, $p = 0.035$), and HCT from 2019 (HR 0.759, $p = 0.038$). TBI improved DFS ($p = 0.0003$) and reduced relapse ($p = 0.003$) without raising NRM, persisting in MAC ($p = 0.044$) but not RIC ($p = 0.25$). Donor age predicted DFS ($p = 0.036$) and NRM ($p = 0.03$). HCT from 2019 protected against relapse (HR 0.546, $p = 0.0005$). MRD positivity worsened all outcomes ($p < 0.05$). In Ph+ ALL ($n = 196$), donor age impacted OS (HR 1.02, $p = 0.004$) via higher NRM; TBI and age were not significant. In patients ≥ 50 ($n = 116$), RIC reduced NRM (HR 0.49, $p = 0.032$) without affecting relapse; TBI lowered relapse (HR 0.413, $p = 0.046$) without increasing NRM. Country of transplant was not significant in any model. **Discussion and conclusion:** These findings demonstrate that allogeneic HCT for ALL in LA yields survival outcomes comparable to international benchmarks despite marked heterogeneity in practice. TBI-based conditioning and more recent transplant periods were associated with improved disease control without increasing NRM, while donor age remains an important predictor of adverse outcomes. RIC regimens reduced toxicity in older patients without apparently compromising relapse risk. These results highlight the importance of optimizing conditioning strategies, careful donor selection, and regional collaboration to improve HCT outcomes in LA.

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INITIAL EXPERIENCE WITH ANTI-CD19 CAR-T CELL THERAPY IN PATIENTS WITH RELAPSED/ REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA: A SERIES OF CASES IN A BRAZILIAN CANCER CENTER

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Introduction: B-cell Acute Lymphoblastic Leukemia (B-ALL) has a 90% overall survival (OS) rate in children and young adults. However, in the relapsed/refractory (R/R) setting, 5-year OS drops to 50% after the first relapse, falling to 20–30% in R/R B-ALL post-allogeneic hematopoietic stem cell transplantation (allo-HSCT). Given this scenario, the ELIANA trial evaluated the CD19-targeting CAR T-cell therapy Tisagenlecleucel (Tisa-Cel) in R/R B-ALL, reporting complete response (CR) rates of 81%. A 3-year follow-up showed event-free survival and OS rates of 44% and 63%, respectively. Among grade 3 or 4 adverse events, Cytokine Release Syndrome (CRS) occurred in 48% of cases and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) in 13%, though real-world studies report lower rates of 16% for CRS and 9% for ICANS. Another less frequent, but more serious, adverse event is Macrophage Activation Syndrome (MAS). Tisa-Cel was approved in Brazil in 2022 for R/R B-ALL patients up to 25 years of age, including post-allo-HSCT. Therefore, this study aims to retrospectively report the cases of patients with R/R B-ALL treated with Tisa-Cel at our institution between 2022 and 2024, based on the analysis of medical records. **Case report:** We report a series of three R/R B-ALL cases, aged 15 to 24, all heavily pre-treated with a median of 3 therapy lines; two had relapsed post-allo-HSCT. Following leukapheresis, all patients received Fludarabine and Cyclophosphamide lymphodepletion and a Tisa-Cel infusion. With a median follow-up of 10 months (10-13), two of the three patients remain alive and in CR without cytopenias. Patient 1: A 15-year-old male with Philadelphia (Ph)-like B-ALL, refractory to two lines (including use of Blinatumomab), and relapse in central nervous system post-allo-HSCT, received CAR-T therapy while in CR. He had no CRS or ICANS and remains with no evidence of disease. Patient 2: A 23-year-old male with lymphoblastic lymphoma Ph negative localized in the tibia (no medullary involvement), refractory to two lines and not yet submitted to allo-HSCT, received CAR-T in a partial response (PR). He developed grade 1 CRS without ICANS and achieved PR at D30, and CR at D60. Patient 3: A 24-year-old female with Ph positive B-ALL, refractory after more than 3 lines of therapy lines and relapsed post-allo-HSCT, received CAR-T with active disease (7.6% blasts in bone marrow). She developed grade 3 CRS and grade 1 ICANS, managed with IL-1 and IL-6 inhibitors, intensive care and dexamethasone. She achieved CR at D+30 but died at D+55 from complications, including severe fungal infection, occlusive-venous-disease and MAS. **Conclusion:** Despite the

small cohort, this real-world data contributes to a better understanding of treatment responses and adverse effects. The reported outcomes were similar to those found in the literature, particularly in real-world studies. Therefore, anti-CD19 CAR-T appears to be a potentially curative option in R/R B-cell ALL, even in cases of relapse after allo-HSCT, with the advantage of not requiring an RC prior to its administration.

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INITIAL EXPERIENCE WITH ANTI-CD19 CHIMERIC ANTIGEN RECEPTOR T-CELL THERAPY IN PATIENTS WITH RELAPSED/ REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA IN A BRAZILIAN CANCER CENTER

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Introduction: Chimeric antigen receptor T-cell (CAR-T) therapy anti-CD19 has emerged as a promising therapeutic modality for patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL). Since the approval of axicabtagene ciloleucel (axi-cel) and tisagenlecleucel (tisa-cel) in Brazil in 2022, access to cellular therapy has significantly expanded. However, real-world data regarding their feasibility, outcomes and associated toxicities remain limited. This study aims to describe a initial institutional experience with CAR-T cell therapy in patients with R/R DLBCL, comparing the 2 anti-CD19 products available at the time. **Case report:** 23 patients were included, 11 treated with tisa-cel (47.8%) and 12 with axi-cel (52.2%). The median age was 56 (tisa-cel) and 52 (axi-cel), with a male predominance in both groups (14 vs 9 female). Functionality was assessed by ECOG: most axi-cel patients were ECOG 0 (91.7%), while tisa-cel patients were split between ECOG 0/1 (45.5% each). Advanced stage disease (Ann Arbor III/IV) and elevated lactate dehydrogenase (median value: 321 U/L; upper limit:227) were similar between groups. Bulky disease was more common in patients submitted to tisa-cel (36,4% *vs* 16,7% axi-cel). Most patients received ≥ 3 prior therapy lines, with 4 lines predominant in axi-cel (50%) and 3 in tisa-cel (45.5%). At infusion, progressive disease (PD) was more frequent in tisa-cel (81.1%), while partial response (PR) predominated in axi-cel (50%). Median brain-to-vein time was 109 days (tisa-cel) *vs* 122 days (axi-cel). Hematologic toxicity risk (CARHEMATOTOX > 2) was higher in the tisa-cel group, with 18.2% scoring 6. Infections were more frequent with tisa-cel (90.9% *vs* 66.7%). ICU admission was similar (63.6%), but stays were longer with axi-cel (16 *vs* 4 days). Intubation was also more common with axi-cel (25% *vs* 9.1%). Grade 2 CRS predominated in both groups; grade 3 occurred only with tisa-cel. Tocilizumab use was similar. ICANS was more frequent with axi-cel (75%), leading to greater anakinra use (50%), while 72% of tisa-cel patients had no ICANS. At day 30, 34% achieved CR (75% tisa-cel, 25% axi-cel), 13% PR (66% axi-cel, 34% tisa-cel), and 21% PD (40% tisa-cel, 60% axi-cel). At day 60, CR was 30% (57% tisa-cel, 43% axi-cel), 1 PR (axi-cel), and 30% PD (28% tisa-cel, 72% axi-cel). At day 180, 13% were in CR (66% tisa-cel, 34% axi-cel), 1 PR (axi-cel), and 17% (n = 4) in PD - all axi-cel. There were 7 deaths: one at day 30 (axi-cel), one at day 60 (tisa-cel), and three at day 180 (2 tisa-cel, 1 axi-cel). Follow-up was unavailable for 20% at day 30, 8% at day 60, and 30% at day 180. **Conclusion:** Both products are feasible but differ in efficacy and toxicity. Tisa-cel showed superior early responses despite higher-risk disease, while axi-cel was associated with more neurologic toxicity and early mortality. However, it's important to highlight the limitations of our data, considering the small sample size, missing follow-up registries and the heterogeneity in baseline characteristics, precluding a robust comparative analysis between products. Finally, real-world challenges, such as the prolonged brain-to-vein time and high ICU utilization, underscore logistical and toxicity management hurdles in middle-income countries like Brazil.

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INSUFICIÊNCIA PANCREÁTICA EXÓCRINA APÓS TRANSPLANTE DE CÉLULAS-TRONCO HEMATOPOIÉTICAS ALOGÊNICO: RELATO DE CASO

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Introdução: A insuficiência pancreática exócrina (IPE) é uma complicação rara do transplante de células-tronco hematopoiéticas (TCTH), usualmente de apresentação tardia e considerada uma forma de manifestação atípica da doença do enxerto contra hospedeiro (DECH) crônica. O objetivo deste trabalho é relatar um caso de IPE precoce após TCTH alogênico. **Relato de caso:** Paciente feminino, 12 anos, com diagnóstico prévio de anemia falciforme, foi submetida em dezembro de 2024 a TCTH alogênico haploidêntico, ABO compatível, com condicionamento mieloablativo (tiotepa, fludarabina e melfalano), e profilaxia contra DECH com timoglobulina, ciclofosfamida pós-transplante, micofenolato e sirolimo. O enxerto apresentou critérios para pega neutrofílica no dia +26, e pega plaquetária no dia +31. A paciente fez uso de nutrição parenteral do dia +13 ao +27, com reintrodução de dieta enteral a partir do dia +23. Dentre as complicações pós-transplante, apresentou neutropenia febril, mucosite grau 3 e colite por *Clostridium difficile*. No dia +17, a paciente desenvolveu síndrome de encefalopatia posterior reversível (PRES), atribuída ao sirolimo, com suspensão temporária do mesmo e início de metilprednisolona 1,5 mg/kg/