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/

dia, ocorrendo suspensão completa no dia +57. Durante a internação, a paciente apresentou episódios de dor abdominal intensa, epigástrica, relacionada principalmente com a dieta, associada a diarreia, necessitando internação em UTI pediátrica por 26 dias para controle da dor, período em que recebeu morfina, metadona, cetamina e clonidina, e substituição da dieta enteral para fórmula de aminoácidos livres. A pesquisa de patógenos fecais foi negativa. Exames de imagem demonstraram pneumatose intestinal colônica, sem evidências de perfuração e atribuída ao uso de corticoide, ausência de alterações pancreáticas, e com exame endoscópico evidenciando gastrite hemorrágica de fundo gástrico. Foi otimizado o tratamento com inibidor de bomba de prótons, com aumento de dose do omeprazol para 2 mg/kg/dia; entretanto, porém sem melhora dos quadros álgicos e da diarreia. Diante deste quadro, foi solicitado pesquisa de gordura fecal, com resultado negativo, e quantificação de elastase fecal, com resultado abaixo do valor esperado (36,0 ug/g; referência normal: maior ou igual a 200 ug/g). Diante dessa situação, foi iniciada terapia de reposição de enzimas pancreáticas (TREP), com a paciente evoluindo com redução da frequência e intensidade dos episódios álgicos, acompanhada de redução da analgesia, boa aceitação de dieta, e resolução da diarreia. Paciente recebeu alta hospitalar em fevereiro de 2025, assintomática. Em abril de 2025, após a suspensão da TREP, reiniciou diarreia e dor abdominal, com resolução completa da sintomatologia após sua reintrodução. Até agosto de 2025, a paciente não apresentou novos episódios semelhantes ao relatado. **Conclusão:** Estudos demonstraram a ocorrência IPE tardiamente no TCTH, geralmente associada à atrofia pancreática, que pode ser secundária à toxicidade medicamentosa, infecções virais e DECH crônico. No caso relatado, houve uma apresentação precoce e atípica, com dor abdominal e diarreia, pesquisa de gordura fecal negativa e sem alterações pancreáticas em exames de imagem, mas com elastase fecal bastante reduzida. Assim, reforçamos a importância de considerar IPE como diagnóstico diferencial de quadros de dor abdominal de etiologia incerta associada a diarreia, mesmo em casos de pesquisa de gordura fecal negativa, independente do período pós-transplante.

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JOINT USE OF SOLE, CALCINEURIN INHIBITOR-FREE GRAFT-VERSUS-HOST DISEASE PROPHYLAXIS WITH RABBIT ATG AND POSTTRANSPLANT IMMUNOSUPPRESSION WITH CYCLOPHOSPHAMIDE FOR HLA-MATCHED, PERIPHERAL BLOOD TRANSPLANTATION – THE NCT06299462 JURASSIC TRIAL

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Introduction: A phase III trial showed that sole posttransplant cyclophosphamide (PTCy) is feasible in HLA-matched bone marrow (BM) hematopoietic cell transplants (HCT) but leads to high graft-versus-host disease (GVHD) rates with peripheral blood grafts (PBSC). We hypothesized that adding low-dose ATG could reduce GVHD. **Aim:** Assess the feasibility of HLA-matched PBSC HCT using only ATG and PTCy, without calcineurin inhibitors, sirolimus, or antimetabolites for GVHD prophylaxis. **Material and methods:** Prospective, single-center phase I/II trial (NCT06299462) involving patients aged 18–60 years with acute leukemia in CR1/CR2, myelodysplasia with less than 20% blasts, or lymphoma; HLA 8/8 donor; PBSC graft. Exclusion: liver dysfunction. Primary endpoint: grades III–IV acute GVHD. ATG 4–5 mg/kg was given before HCT, and PTCy 50 mg/kg on days +3 and +4. No other GVHD prophylaxis was used. Minimum follow-up was 3 months, ensuring all patients were eligible for acute GVHD assessment. **Results:** Ten patients were enrolled; six received myeloablative conditioning, and four received reduced-intensity conditioning. All engrafted; one experienced secondary graft failure amid a cluster of failures under investigation. Early after infusion, 40% developed grade 3–4 CRS, all of which responded to treatment. Three patients developed grade II acute GVHD, all steroid-responsive: one after donor lymphocyte infusion (DLI) for immune reconstitution, another after protocol violation (CD34 dose 6.7×10^6/kg). One patient died from mesenteric thrombosis, while another with refractory Hodgkin lymphoma experienced disease progression; all others are alive in complete remission. One DLI-treated patient developed moderate, steroid-refractory chronic GVHD, now managed with sirolimus. Six-month overall survival (OS) and progression-free survival (PFS) were 100% and 83%. CMV reactivation occurred in 80%, without CMV disease. Three patients experienced hemorrhagic cystitis (one grade 2, two grades 3–4). At 6 months, median CD4+ and B-cell counts were 225/mm^3 and 135/mm^3, respectively. **Discussion and conclusion:** This ATG+PTCy-only regimen for HLA 8/8 PBSC HCT was feasible, with no grades III–IV acute GVHD. Avoiding calcineurin inhibitors may lower toxicity and expenses (> R$25,000 for tacrolimus and monitoring over 3 months), potentially allowing resources to be redirected to patient care. Despite frequent viral reactivations, immune reconstitution was adequate at 6 months. Letermovir and tocilizumab were unavailable; CRS cases were managed with high-dose dexamethasone, which may have contributed to viral reactivations. Strategies to address CRS and viral reactivation are in development, and we plan to move to phase II of the trial soon. These early results support the potential of sole ATG +PTCy prophylaxis in HLA 8/8 PBSC HCT.

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