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THE BRAZILIAN REGISTRY OF HEMATOPOIETIC CELL TRANSPLANTATION AND CELLULAR THERAPY: A MODEL FOR COLLABORATIVE ADVANCEMENT AND DATA MANAGEMENT

CMCR da Silva ^a, AJ Simone ^b, FF Costa ^c, AMTD Yamada ^d, HRA das Neves ^e, SO Ferreira ^c, AR de Almeida ^f, VADN Varjão ^g, AMQ Cavilha ^e, AV de Macedo ^h, A Seber ^g, N Hamerschlag ^a, FB Duarte ⁱ

^a Hospital Israelita Albert Einstein, São Paulo, SP, Brazil

^b Hospital Amaral Carvalho, Jaú, SP, Brazil

^c Hospital Sirio Libanês, São Paulo, SP, Brazil

^d Rede DO'r, São Paulo, SP, Brazil

^e Universidade Federal do Paraná, Complexo Hospital de Clínicas, Curitiba, PR, Brazil

^f Hospital Casa Premium, Rio de Janeiro, RJ, Brazil

^g Instituto de Oncologia Pediátrica, São Paulo, SP, Brazil

^h Hospital da Polícia Militar, Belo Horizonte, MG, Brazil

ⁱ Hospital Universitário Walter Cantídio, Fortaleza, Fortaleza, CE, Brazil

Introduction: Establishment in 2019 through a strategic collaboration between the Brazilian Society of Bone Marrow Transplantation and Cellular Therapy (SBTMO) and the Center for International Blood and Marrow Transplant Research (CIBMTR), the Brazilian Registry of Hematopoietic Cell Transplantation and Cellular Therapy was designed to consolidate national data and foster multicenter clinical research. Concurrently, SBTMO created the Data Managers Working Group (GTGD-SBTMO) to develop national standards, ensure data quality, and support safe and effective cellular therapies (CT), including Hematopoietic Cell Transplants (HCT) and CAR-T cell therapies (CAR-CT). **Aim:** To describe the development and impact of the Brazilian Registry of Hematopoietic Cell Transplantation and Cellular Therapy (RBTCH-TC) and the GTGD-SBTMO, focusing on their strategies to expand national reporting capacity, standardize data collection, and strengthen research infrastructure for HCT and CAR-T therapies in Brazil. **Material and methods:** A comprehensive historical and documentary review was performed, incorporating institutional records, collaborative projects, training initiatives, and database activities related to both RBTCH-TC and the GTGD-SBTMO. **Results:** Between 2016 to 2024, the number of Brazilian centers actively reporting data to the CIBMTR increased by 191% (from 11 to 32), while reported HCT procedures rose by 204% (from 628 to 1,909). The ongoing multicenter study (CAAE 65575317.5.1001.0071) comprises 90 centers authorized by the National Ethics Commission, with 60 centers approved by their respective institutional review boards. The 2025 summary slide consolidates data from 14,331 transplants across 45 centers (2012–2024). The CT section includes 11 centers, 104 CAR-T cell infusions, and two published summary slides (2024 and 2025). To support growing data

demands, 95 analysis requests have been recorded through an established request workflow. Since its formation, GTGD-SBTMO developed a mission, vision, and operational subcommittees (administrative, scientific, educational, etc.), adopting tools like Trello and AI-assisted minute generation. It has organized 59 training events with a 4.9/5 satisfaction rate and led the standardization of data submissions to CIBMTR, expanding reporting centers from 10 to 92. The group has published 7 scientific papers (5 on HCT, 2 on CAR-CT), created a "Knowledge Trail for Data Managers," and released a Data Management Guide, also available in Spanish. In 2024, 71 database queries were logged 82% from physicians with a 92% resolution rate; 63% supported abstract submissions to scientific conferences. **Discussion and conclusion:** The RBTCH-TC and GTGD-SBTMO represent a robust and scalable model for collaborative registry development and data governance in cellular therapy. Their coordinated efforts have significantly enhanced data integrity, research capacity, and national integration, contributing to improved clinical outcomes, public health policymaking, and international collaboration. Sustained investment in digital infrastructure, human resource development, and adaptive strategies will be critical to maintaining and expanding these achievements.

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THERAPEUTIC IMPACT OF POST-TRANSPLANT CYCLOPHOSPHAMIDE IN ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION: A SYSTEMATIC REVIEW

IM de Almeida ^a, LM Pinheiro ^a, CM Lucini ^a, MFGM Fernandes ^a, JM Marchetti ^a, IP Dall Agnol ^a, GD Chiesa ^b, GA Lopes ^c, JWO Romanov ^d

^a Pontifícia Universidade Católica do Rio Grande do Sul, Porto Alegre, RS, Brazil

^b Universidade de Caxias do Sul, Caxias do Sul, RS, Brazil

^c Centro Universitário Cesumar, Maringá, RS, Brazil

^d Hospital São Lucas da Pontifícia Universidade Católica do Rio Grande do Sul, Porto Alegre, RS, Brazil

Introduction: Post-transplant cyclophosphamide (PTCy) is a key strategy to prevent graft-versus-host disease (GVHD) after allogeneic hematopoietic stem cell transplantation (allo-HSCT). By targeting proliferating alloreactive T cells while preserving immune reconstitution, it enables safer use of haploidentical, unrelated, and mismatched related donors. Its growing use warrants updated evidence on efficacy, safety, and applicability. **Aim:** To synthesize evidence on PTCy in allo-HSCT, assessing its effects on acute and chronic GVHD, survival, relapse, infection, graft failure, and its performance versus alternative prophylaxis across donor types, conditioning regimens, graft sources, and special populations. **Material and methods:** A systematic review was performed following

PRISMA guidelines, searching PubMed (2015–2025) with terms on cyclophosphamide, GVHD, allo-HSCT, and systematic reviews/meta-analyses. Inclusion: studies assessing PTCy as GVHD prophylaxis in allo-HSCT and reporting outcomes (GVHD incidence, survival, relapse, infections, graft failure). Eighteen articles met criteria. **Results:** Post-transplant cyclophosphamide (PTCy) is a key GVHD prophylaxis in allogeneic HSCT, effective across haploidentical, unrelated, and matched donor settings. In unrelated donor HSCT, PTCy reduced grade II–IV aGVHD (RR = 0.68; HR = 0.63) and grade III–IV aGVHD (RR = 0.32; HR = 0.35) versus ATG, with no significant difference in cGVHD. OS was higher (RR = 1.29; HR = 0.62), PFS improved (HR = 0.76), and NRM lower (RR = 0.67; HR = 0.59) without relapse increase (RR = 0.95). In haploidentical HSCT, PTCy achieved similar aGVHD to ATG but improved OS (HR = 0.70), LFS (HR = 0.66), GRFS (HR = 0.79), and reduced relapse (HR = 0.69). ATG+PTCy further lowered aGVHD (RR ≈ 0.52) and improved OS/GRFS over either alone. Compared to methotrexate, PTCy regimens had lower severe oral mucositis (55.4% vs 83.4%). In aplastic anemia, engraftment reached 97.3%, with reduced aGVHD (12.8% vs ≥ 27.8%), CMV viremia (10.4% vs ≥ 38.6%), and CMV disease (0% vs up to 33%). In pediatric thalassemia, haplo-HSCT achieved OS 92.4%, TFS 84.5%, graft failure 8.1%, TRM 7.4%, with no PTCy vs non-PTCy difference. Haplo-HSCT with PTCy lowered cGVHD risk by ~50% vs matched sibling donors but had higher NRM; versus unrelated donors, OS was similar but GVHD rates lower. Graft source analysis in haplo-HSCT showed PBSCs lowered relapse (HR = 0.84) and improved engraftment but increased acute/chronic GVHD; bone marrow had lower GVHD rates. Myeloablative conditioning reduced relapse (HR = 0.70) and improved PFS but increased NRM versus RIC, with no OS difference. Overall, PTCy provides robust GVHD control, improved survival, reduced infection rates, and broad applicability, especially in haploidentical HSCT. **Discussão e conclusão:** This review confirms PTCy as a versatile and effective GVHD prophylaxis in allo-HSCT, improving survival, reducing NRM, and maintaining relapse control across donor types. Outcomes vary with graft source and conditioning, underscoring the need for individualized approaches. Post-transplant cyclophosphamide (PTCy) is an effective and versatile GVHD prophylaxis across donor types in allogeneic HSCT. It consistently reduces acute and chronic GVHD, lowers non-relapse mortality, and improves overall survival without increasing relapse rates. Benefits extend to special populations, such as aplastic anemia and pediatric thalassemia, and can be enhanced when combined with ATG. Graft source and conditioning intensity influence outcomes, allowing tailored approaches.

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TRANSPLANTE AUTÓLOGO DE CÉLULAS-TRONCO HEMATOPOÉTICAS A FRESCO: RESULTADOS INICIAIS DE UMA ESTRATÉGIA VIÁVEL NO SUS

RDS Oliveira,
AC Martins Oliveira Menezes Silva,

CG Miranda, KA Da Silva, LS Dos Santos,
PC Da Silva

Instituto Estadual de Hematologia Arthur de
Siqueira Cavalcanti (Hemorio), Rio de Janeiro, RJ,
Brasil

Introdução: O transplante de células-tronco hematopoéticas (TCTH) autólogo é amplamente utilizado no tratamento de neoplasias hematológicas, sendo a criopreservação o método padrão para armazenar células coletadas. No entanto, essa prática envolve custos elevados e riscos associados ao uso do DMSO. Em 2024, o Instituto Estadual de Hematologia Arthur de Siqueira Cavalcanti (HEMORIO) realizou os primeiros TCTH a fresco no SUS, buscando avaliar a eficácia e a viabilidade dessa estratégia alternativa. **Objetivos:** Descrever a eficácia e a viabilidade do transplante autólogo de células-tronco hematopoéticas (TCTH) a fresco (não criopreservado), em comparação ao modelo tradicional de criopreservação, nos primeiros procedimentos realizados no Instituto Estadual de Hematologia Arthur de Siqueira Cavalcanti (Hemorio). **Material e métodos:** Estudo retrospectivo descritivo, realizado mediante análise de prontuários físicos e eletrônicos de seis pacientes com diagnóstico de mieloma múltiplo submetidos ao TCTH entre 2024 e 2025. Foram comparados dois grupos: três pacientes que receberam infusão de células-tronco a fresco (em até 48 horas após a coleta) e três pacientes que receberam células criopreservadas. As variáveis analisadas incluíram: tempo de internação, tempo para pega medular (neutrófilos ≥ 500/ μ L por dois dias consecutivos) e parâmetros hematológicos na alta hospitalar (hemoglobina, hematócrito, leucócitos totais e neutrófilos absolutos). **Resultados:** O tempo médio de internação foi de 18,3 dias no grupo a fresco, em comparação a 29 dias no grupo criopreservado, evidenciando uma redução significativa de aproximadamente 11 dias na hospitalização. Quanto ao tempo para a pega medular, a média foi de 9,6 dias no grupo a fresco e 11 dias no grupo criopreservado, indicando uma tendência de recuperação hematológica mais rápida nos pacientes que receberam células não criopreservadas. Os parâmetros hematológicos na alta hospitalar apresentaram-se semelhantes entre os grupos. No grupo à fresco, a hemoglobina variou entre 8,6 e 9,2 g/dL; leucócitos entre 7,8 e 9,97 $10^3/\mu$ L e neutrófilos entre 2,36 e 7,52 $10^3/\mu$ L. No grupo criopreservado, a hemoglobina variou entre 8,0 e 10 g/dL; leucócitos entre 5,56 e 8,97 $10^3/\mu$ L e neutrófilos entre 3,71 e 6,85 $10^3/\mu$ L. Esses dados indicam que a recuperação hematológica foi equivalente em ambos os grupos, sem impacto negativo decorrente da ausência de criopreservação. **Discussão e conclusão:** Além dos aspectos clínicos, o TCTH à fresco apresenta vantagens operacionais e econômicas relevantes. A redução no tempo de internação diminui a exposição a infecções hospitalares e as complicações associadas, favorecendo o retorno precoce ao ambiente domiciliar e ambulatorial. Institucionalmente, há a otimização do uso de leitos e a redução de custos relacionados à internação prolongada, à aquisição de insumos como o dimetilsulfóxido (DMSO) e à necessidade de equipamentos e profissionais especializados em criopreservação. Os resultados preliminares sugerem que o TCTH autólogo à fresco é uma alternativa eficaz, segura e economicamente viável ao modelo