## IS PERIPHERAL BLOOD STEM CELL MOBILIZATION VIABLE IN CROHN'S DISEASE PATIENTS UNDERGOING AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION?

MA Ruiz [a,b], RL Kaiser-Junior [a,b], L Piron-Ruiz [a], LG Quadros [b], G Piron-Ruiz [c]

[a] *Associação Portuguesa de Beneficência de São José do Rio Preto, São José do Rio Preto, SP, Brazil*
[b] *Kaiser Clinica, Centro Médico Avançado de São Jose do Rio Preto, São José do Rio Preto, SP, Brazil*
[c] *Faculdade Faceres, São Jose do Rio Preto, SP, Brazil*

**Background:** Crohn's disease is a chronic, inflammatory disease of the gastrointestinal tract. As an autoimmune disorder, treatment with high doses of chemotherapy followed by autologous hematopoietic stem cell transplantation is promising for refractory Crohn's disease patients with no other therapeutic option and at imminent risk of further surgeries. **Objectives:** To evaluate the feasibility and efficacy of hematopoietic progenitor cell mobilization in a group of Crohn's disease patients preparing for autologous unselected hematopoietic stem cell transplantation in a single institution. This is the first study to evaluate mobilization in Crohn's disease. **Methods:** Patients were selected according to criteria of the European Bone Marrow Transplant Society. **Results:** All patients mobilized with the mean number of hematopoietic progenitor cells obtained and infused being $16.17\times10^6$/CD34 +/kg. Most (23/29) patients required only one leukapheresis session to reach the ideal number of cells. Grafting occurred around ten days after cell infusion. Complications and adverse events during the mobilization period were rare with only one patient presenting sepsis as a relevant event in the period. Most patients 20/29 (70%) had anemia from the beginning of the mobilization but only 11 (37.9%) received packed red blood cell transfusions. **Conclusion:** Mobilization in patients with Crohn's disease is effective; almost all patients in this series were good mobilizers. **Clinical trial register:** NCT 03000296.

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## AVALIAÇÃO DE EFICÁCIA E TOXICIDADE DO PROTOCOLO DE CONDICIONAMENTO LACE EM PACIENTES COM LINFOMA SUBMETIDOS AO TRANSPLANTE AUTÓLOGO DE MEDULA ÓSSEA

R Portugal, M Nucci, G Cuquetto

*Universidade Federal do Rio de Janeiro (UFRJ), Rio de Janeiro, RJ, Brasil*

**Objetivos:** O objetivo foi avaliar a toxicidade do protocolo LACE e sua aplicação como protocolo alternativo em nosso meio. **Materiais e métodos:** Realizamos uma análise retrospectiva de 29 pacientes submetidos a transplante autólogo de medula óssea com o protocolo LACE (lomustina, citarabina, ciclofosfamida e etoposídeo) no Hospital Universitário Clementino Fraga Filho (UFRJ) entre 2018 e 2022. Foram coletados dados de variáveis demográficas, tratamentos prévios e parâmetros para avaliação de toxicidade, como neutropenia febril, mucosite, disfunção orgânica, necessidade de terapia intensiva e mortalidade. **Resultados:** Foram identificados 29 pacientes, com idade mediana de 36 anos (variando de 23 a 62 anos), com diagnóstico de linfoma (17 Hodgkin e 12 não Hodgkin. A mediana de linhas de tratamentos anteriores foi de 2 (variando de 1 a 4 linhas) e o GDP (gencitabina, dexametasona e cisplatina) foi utilizado em 41% dos casos de resgate anterior ao TAMO (n = 12). A maioria dos pacientes – 82,8% - apresentava doença sensível à quimioterapia (n = 22) e apenas 6,9% dos pacientes foram considerados resistentes ao tratamento de resgate (n = 2). Nenhum paciente apresentou mucosite grau 3 ou 4 e 1 paciente necessitou de nutrição parenteral total devido a enterocolite neutropenica (3%). Toxicidades não hematológicas (hepáticas, renais ou cardíacas) grau 3 ou 4 ocorreram em 4 casos (13,7%), destes, 2 casos foram de elevações assintomáticas de enzimas hepáticas. A mortalidade associada ao transplante foi de 3% (n = 1). A sobrevida mediana no total de pacientes foi de 45 meses, sendo que na população de linfoma de Hodgkin não foi atingida e na população de linfoma não Hodgkin foi de 28 meses (p = 0,169). **Discussão:** O transplante autólogo de células tronco hematopoiéticas é uma modalidade de tratamento frequentemente empregada nos linfomas recaídos ou refratários à primeira linha de tratamento. O BEAM (carmustina, etoposideo, citarabina e melfalano) está entre os protocolos tradicionalmente utilizados como condicionamento, entretanto, faltam dados comparativos na literatura em relação ao regime com maior eficácia e segurança. No período do estudo, houve desabastecimento de carmustina, medicação utilizada no protocolo BEAM. O cenário de desabastecimento de quimioterápicos a nível nacional não é infrequente e salienta a importância da investigação de regimes alternativos, principalmente no âmbito do Sistema Único de Saúde, onde a importação de fármacos não é uma realidade para a maioria das instituições. Os resultados encontrados sugerem um baixo perfil de toxicidade, tanto do ponto de vista hematológico quanto de outros sistemas. A sobrevida mediana sugere que pacientes com Linfoma de Hodgkin possam contar com benefício adicional em termos de resposta, o que precisa ser confirmado em análises posteriores. **Conclusão:** O condicionamento com o protocolo LACE apresentou perfil de toxicidade baixo, colocando-o como alternativa aos protocolos convencionais. Os resultados obtidos não diferem dos reportados na literatura com o mesmo protocolo.

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## HIV INFECTION IS ASSOCIATED WITH DELAYED PLATELET ENGRAFTMENT AFTER AUTOLOGOUS PERIPHERAL BLOOD STEM CELL TRANSPLANTATION

AR Belisário, LT Mendonça, RK Andrade, MC Martins, LA Costa, KL Prata

*Centro de Tecidos Biológicos de Minas Gerais – Fundação Hemominas, Belo Horizonte, MG, Brazil*

**Aim:** Hematopoietic Stem Cell Transplantation (HSCT) stands as a cornerstone in the treatment of various disorders. The kinetics of hematopoietic recovery after Autologous Stem Cell Transplantation (ASCT) may be affected by clinical characteristics, including the coexistence of infectious diseases. In 2022, data from the World Health Organization estimated that approximately 39 million people were living with Human Immunodeficiency Virus (HIV) worldwide. The interplay between HIV infection and HSCT outcomes requires better understanding. In this study, we evaluated the association of HIV infection with ASCT outcomes in Minas Gerais, Brazil. **Methods:** This nested case-control study included individuals with hematological and non-hematological diseases who underwent ASCT. Cryopreservation was conducted at a single processing facility between 2014 and 2023, and patients received clinical care at six transplant centers. Covariates and outcome data were retrieved from participants' records. HIV-positive participants were compared to age, gender, center, and disease-matched HIV-negative participants (ratio 1:5). Infusion-related adverse effects were recorded using standard forms. Time of engraftment refers to the interval between cell infusion (Day 0) and the first day with a neutrophil count higher than $0.5\times10^9$ per L or a platelet count higher than $20\times10^9$ per L, respectively. Delayed engraftment was defined as unsuccessful recovery within 14-days after the infusion. **Results:** Fourteen HIV-positive participants were included. Most of the HIV-positive participants had multiple myeloma (35.7%; n = 5) followed by Hodgkin's lymphoma (28.6%; n = 4), and non-Hodgkin lymphoma (21.4%; n = 3); eleven (78.6%) were male, and the mean age was 47 ± 20 years. As expected, the HIV-positive and HIV-negative groups were similar with respect to the matching variables of age, gender, disease, and transplant center. The median time to platelet engraftment was 14 days for participants with HIV and 11 days for those without HIV (p = 0.017). HIV-positive participants had significantly five times higher odds of delayed platelet engraftment compared to the HIV-negative group (OR = 5.0; 95% CI 1.3–19.9; p = 0.028). The association between HIV infection and time to platelet engraftment, as well as delayed platelet engraftment, remained significant after adjusting for infused CD34+ cell dose (p = 0.008 and p = 0.024, respectively). There was no association between HIV infection and time to neutrophil engraftment or delayed neutrophil engraftment. The frequency of adverse effects during infusion was similar in HIV-positive and HIV-negative participants. **Discussion:** HIV infection may delay platelet engraftment after ASCT due to immunosuppression, direct effects of HIV on bone marrow cells, chronic inflammation, potential myelosuppressive effects of antiretroviral therapy, co-infections, and pre-existing bone marrow damage. Understanding the dynamics between HIV infection and HSCT outcomes is imperative for optimizing transplant strategies and post-transplant care, including transfusion support. **Conclusion:** In summary, HIV infection was associated with an increased risk of delayed platelet engraftment in patients undergoing ASCT.

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## 10-YEARS ANALYSIS OF CRYOBAG FRACTURE IN A LARGE INVENTORY OF CELLULAR THERAPY PRODUCTS: RATES AND RISK FACTORS

AR Belisário, LT Mendonça, RK Andrade, MC Martins, LA Costa, KL Prata

*Centro de Tecidos Biológicos de Minas Gerais – Fundação Hemominas, Belo Horizonte, MG, Brazil*

**Aim:** Cryobags are crucial for the freezing, storage and transport of cellular therapy products. Despite their widespread use and importance, cryobags are vulnerable to damage, and fractures can significantly impact both patient outcomes and the operational efficiency of cellular therapy facilities. To date, there have been no reported studies on Peripheral Blood Stem Cell (PBSC) bag fractures. This study aimed to investigate the incidence and determinants of cryobag fractures within a large inventory of cellular therapy products in Brazil. **Methods:** This retrospective cohort study included cryobags from individuals referred for hematopoietic stem cell transplantation or immunotherapy. Cryopreservation was performed at a single processing facility between 2015–2024, with clinical care provided at nine transplant centers. The products were centrifuged, and plasma was removed to adjust the buffy coat to achieve the final Total Nucleated Cell (TNC) concentration of $\leq7.5\times10^8$ cells/mL after adding the cryopreservation solution. Cryobags (CryoStore CS500N, OriGen Biomedical, Austin, TX, USA) were frozen at an uncontrolled rate in a -80°C mechanical freezer and stored in a vapor phase storage tank. The frozen cryobags underwent macroscopic evaluation in the vapor phase through visual inspection to check for fractures and leaks. Records were reviewed to gather information on covariates and outcomes. **Results:** During the study period, 2,078 PBSC collections were performed for 1,637 patients (911 [55.7%] male) with ages ranging from 1- to 75-years. Multiple myeloma was the most common diagnosis (59.8%), followed by lymphoma (27.9%). Among the 2,078 products collected, 514 (24.7%) were processed from components collected in two consecutive apheresis procedures, and 1,564 (75.3%) were processed after a single apheresis procedure, resulting in 1,821 cryopreservation procedures. Each cryopreservation procedure resulted in one to seven cryobags being frozen, totaling 4,144 cryobags studied. Out of these, 15 (0.4%) experienced fractures. Of the 15 fractures, 13 (86.7%) were detected during macroscopic evaluation in the processing facility, and two (13.3%) occurred after the cryobags were released to the transplant center. The incidence rate of cryobag fractures was 0.41 (95% CI 0.23–0.66) per 100 bag-years. The cumulative incidence of fractures after 3.16-years of storage was 1% (95% CI 0.7%–1.3%). Multivariate analysis identified two independent predictors of cryobag fracture: the initial TNC count (OR = 1.002, 95% CI 1.001–1.003; p < 0.001) and hematocrit (OR = 0.55, 95% CI 0.34–0.90; p = 0.018). When compared to products with an initial TNC ≤ $10\times10^8$ cells/mL, those with TNC > $10\times10^8$ cells/mL had 10.8 times higher odds (95% CI 3.3–35.9; p < 0.001) of triggering a cryobag fracture. **Discussion:** This study provides critical insights into cryobag fractures incidence and determinants. Our findings highlight two key predictors of cryobag fractures.