

describe a serious vapor ST failure, as well as the improvements implemented in the storage procedure to increase the safety and quality of cryopreserved CT products. **Method:** This is a case report of a vapor ST failure (CBS, isothermal V5000-AB series). The records were reviewed to obtain information regarding the frozen units. **Results:** On 07-dec-2021, the technical staff observed the accumulation of liquid nitrogen (LN2) at the bottom of the ST. The engineering team was contacted and adjusted the ST's maximum LN2 level. The problem recurred on 23-dec-2021. The engineering and maintenance company carried out a series of tests on the ST. On 06-Jan-2022, it was requested emptying and defrosting of the ST for 48 hours for corrective maintenance of the LN2 level sensor. Planning to transfer the inventory to another ST was started, including bags with serology/NAT reagent overwrapping. However, on 23-Jan-2022 (Sunday), the LN2 level sensor stuck at level zero leading the automated LN2 filling of the ST to start and not stop. There was an overflow of LN2 inside the vapor ST, and 3 of 4 rack positions were submerged in LN2. The engineering team performed the filling interruption manually, after being called by the concierge. There were 553 frozen bags from 307 patients/donors stored in the ST at the time of failure. Out of the 553 bags, 87 (15.7%) had positive serology or NAT tests. Of these, 11 (1.9%) were anti-HIV positive (NAT HIV negative) and two (0.3%) were HBsAg and NAT HBV reagents. Out of the 553 bags, 10 (1.8%) had a positive microbiological test, including four (0.7%) for multi-sensitive *Salmonella* sp. Excess of LN2 was manually removed from the ST and the actions to transfer the inventory to the backup ST were intensified, including changing the bags with positive tests (PT) to positions A or B of the racks, as well as finishing these bags overwrapping. The inventory was transferred and stored in the backup ST for approximately 72 hours. Surveillance actions were performed, including virtual meeting and discussion with the Brazilian National Health Surveillance Agency, visual examination to disclose leaking or breakage of seals, thawing of the unit with positive HBV NAT (authorized disposal) to confirm the absence of leaking or breakage of seals, monitoring external signs of vacuum loss, and discussion of the possibility of cross-contamination with the bag supplier. **Discussion:** The data provided by this study are unique and should be considered when evaluating the cryopreserved cell therapy products storage procedure, including ST monitoring, detection of a failing ST, and contingency plan. After this ST failure, improvement actions in the storage procedure were implemented in our institution, including the modification of the storage location of the bags in quarantine and those with PT (positions A and B of the rack) and implementation of the routine use of overwrap in bags with PT. All activities conducted to resolve the issue and the improve actions were documented in non-compliance. **Conclusion:** Vapor ST may fail, leading to an unexpected accumulation of LN2. Improvements in the storage procedure can avoid the serious consequences of this failure, including cross-contamination.

**TRANSPLANTE DE CÉLULAS-TRONCO
HEMATOPOIÉTICAS NO HAPLOIDÊNTICO:
PERCEPÇÃO E DESAFIOS DAS ENFERMEIRAS
FRENTE AO CUIDADO DE ADOLESCENTES
ACOMETIDOS POR ANEMIA APLÁSICA SEVERA
- RELATO DE EXPERIÊNCIA DE UM HOSPITAL
FEDERAL DO ESTADO DO RIO DE JANEIRO**

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Objetivo: Relatar a experiência de trabalho de enfermeiros(as) de uma unidade de Transplante de Células-Tronco Hematopoiéticas com adolescentes acometidos pela Anemia Aplásica Severa. **Material e Métodos:** Trata-se de um relato de experiência de abordagem qualitativa e descritiva de enfermeiras assistenciais de uma unidade de internação de um Centro de Transplante de Células-Tronco Hematopoiéticas do Estado do Rio de Janeiro. **Resultados:** Pode-se perceber que o trabalho do(a) enfermeiro(a) dentro de um centro de transplante tão especializado é notadamente diferenciado pois o mesmo absorve a internação da criança até o idoso. Nesta perspectiva percebe-se a forma especial que o adolescente precisa ser abordado e requer níveis diferentes de atenção e cuidados. O tempo de internação, a gravidade do tratamento, as diversas perspectivas como o medo e a insegurança no sucesso do TCTH são situações que aumentam a carga emocional e de trabalho do enfermeiro (a) frente ao paciente gerando desgastes e desafios diários na evolução do transplante. Dessa forma torna-se necessária, a implantação de estratégias de alívio do estresse de ambos os lados para que a relação paciente e enfermeiro(a) seja a melhor possível, ocasionando o alívio da dor emocional, do sofrimento, do acolhimento, enfim gerando um relacionamento de cumplicidade com o objetivo final do sucesso do tratamento físico e mental. **Discussão:** É relevante entender que a carga emocional que recai sobre os enfermeiros (as) encontra-se em patamar semelhante da sua articulação intelectual para efetuar os cuidados com essa clientela adolescente. Considerando a saúde mental do trabalhador como uma demanda de extrema importância na atualidade vale ressaltar que propostas devem ser criadas e implementadas como suporte para essa realidade. As fases a serem ultrapassadas neste tipo de transplante por um adolescente é bastante difícil, pois recai na sua sobrevivência, sonhos, autoimagem, estudos enfim tudo o que se espera de uma vida plena e saudável. Em contrapartida o(a) enfermeiro(a) está presente para identificar cada fase que está surgindo a fim de que não haja progressão das reações advindas do TCTH, movimento esse que causa grande tensão diária ao profissional que necessita de cooperação do adolescente assim como de sua destreza para não aumentar a ansiedade natural do curso do tratamento. **Conclusão:** As vivências do enfermeiro(a) sendo aquele(a) que está sempre a frente do cuidado demonstram a importância da saúde do trabalhador juntamente com a instituição em identificar esses profissionais e suas demandas. Principalmente num setor onde trata-se as

diversas faixas etárias num tratamento bastante específico, neste interim vale ressaltar que a adolescência é marcada por diversas problemáticas internas que se intensificam quando passadas por um tratamento bastante agressivo. Outrossim, a abordagem tende a ser diferenciada para este público-alvo requerendo observação e táticas de abordagem diferenciadas sobrecarregando emocionalmente e intelectualmente o(a) enfermeiro(a) assistencial.

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THE DEFIFRANCE REGISTRY STUDY: EFFECTIVENESS AND SAFETY OF DEFIBROTIDE IN PATIENTS WITH VENOCCLUSIVE DISEASE/SINUSOIDAL OBSTRUCTION SYNDROME FOLLOWING CHEMOTHERAPY

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Objectives: Venocclusive disease/sinusoidal obstruction syndrome (VOD/SOS) is a potentially life-threatening complication of haematopoietic cell transplantation (HCT) that can also occur after high-dose chemotherapy. Defibrotide is approved in Brazil and the US for treatment of VOD/SOS with renal or pulmonary dysfunction post-HCT in adult and paediatric patients (pts), and in the EU for treatment of severe hepatic VOD/SOS post-HCT in pts aged >1 month. This analysis presents outcomes in pts who received defibrotide treatment for VOD/SOS post-chemotherapy from the DEFIFrance registry study. **Material and methods:** This post-marketing registry study collected retrospective and prospective real-world data on pts receiving defibrotide at 53 HCT centres in France. VOD/SOS diagnosis was per the investigator's typical clinical practice. Disease severity was categorised using adult EBMT severity criteria in adults; paediatric pts (<18 years) were retrospectively/prospectively categorised using paediatric EBMT severity criteria. Survival and complete response

(CR; total serum bilirubin < 2 mg/dL and multiorgan failure [MOF] resolution per investigator's assessment) rates by Day 100 post-VOD/SOS diagnosis were calculated. Treatment-emergent serious adverse events (TESAEs) of interest were haemorrhage, coagulopathy, injection-site reactions, infections, and thromboembolic events, irrespective of relationship to treatment. **Results:** Overall, 46 pts (19 [41%] paediatric and 27 [59%] adults) received defibrotide for VOD/SOS post-chemotherapy. Median age was 5.8 years (range: 2, 17) in paediatric pts and 56.6 years (range: 18, 72) in adults. Paediatric pts were more likely than adults to have a primary diagnosis of ALL (paediatric: 53%; adult: 22%) or neuroblastoma/solid tumour (32%; 0%), while AML (11%; 63%) was more common in adults. Paediatric pts were less likely to have prior exposure to gemtuzumab ozogamicin and inotuzumab ozogamicin (11% and 0%, respectively) than adults (41% and 15%). VOD/SOS was severe/very severe in all paediatric pts and 22 (81%) adults. MOF was present in 5 (26%) paediatric pts and 10 (37%) adults, including renal failure (paediatric: 60%; adult: 70%), respiratory failure (100%; 80%), and cerebral failure (20%; 70%). By Day 100 post-VOD/SOS diagnosis, the Kaplan-Meier (KM)–estimated survival rate was 74% in paediatric pts and 37% in adults, and the CR rate was 68% in paediatric pts and 37% in adults. Of 5 paediatric pts who died within 100 days of VOD/SOS diagnosis, all 5 had very severe VOD/SOS (4 with MOF). Of 17 adults who had died by Day 100, 10 had very severe VOD/SOS (9 with MOF). By Day 100, 2 paediatric pts and 6 adults had died due to relapse/progressive disease and there were no VOD/SOS-related deaths. TESAEs of interest occurred in 15% of pts with VOD/SOS post-chemotherapy (paediatric: 11%; adult: 19%), including infection and haemorrhage (each 9% in the overall group). **Discussion:** In this real-world DEFIFrance study, the majority of pts who received defibrotide for VOD/SOS post-chemotherapy had severe/very severe VOD/SOS and a notable proportion had MOF, indicating advanced disease in this pt population. **Conclusion:** These data indicate that VOD/SOS is a concern outside the HCT setting and suggest a need for continuous vigilance for signs and symptoms of VOD/SOS among those monitoring pts after chemotherapy, to facilitate earlier diagnosis.

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ESTUDO FENOTÍPICO E FUNCIONAL DE QUERATINÓCITOS EXPOSTOS AO SORO DE PACIENTES COM ESCLEROSE SISTÊMICA SUBMETIDOS A TRANSPLANTE AUTÓLOGO DE CÉLULAS-TRONCO HEMATOPOÉTICAS

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