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CYTOMEGALOVIRUS REACTIVATION IN ALLOGENEIC STEM CELL TRANSPLANT RECIPIENTS: FREQUENCY, TIME TO REACTIVATION AND DYNAMIC OF VIREMIA IN DIFFERENT TYPES OF DONORS AND IN REPEATED EPISODES

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Background: Cytomegalovirus (CMV) remains leading to high morbidity and mortality in allogeneic stem cell transplant (Allo-SCT). High immunosuppression increases the risk of reactivation and allows repeated reactivation episodes. However, immunosuppression varies in accordance to donor types. In this study, we compared CMV reactivation in different Allo-SCT: Related (RD), unrelated (URD), and haploidentical (Haplo) donor SCT and analyzed the dynamic of repeated CMV episodes. **Methods:** Prospective cohorts of Allo SCT (from 2013 to 2019). Patients were screened by CMV quantitative PCR (Taqman Sistem – artus CMV Qiagen) in plasma. The screening started on the first week after SCT, repeated once a week until D+100, and after D+100 if immunosuppression was maintained. Repeated episode was defined if at least two negative CMV CRP results were obtained after the first episode. The following variables were analyzed: time after SCT to reactivation, initial viral load, highest viral load within the event, duration of viremia, and response to treatment. **Results:** There were 123 Allo-SCT performed. Median age was 47 years (ranging 1 to 70), and acute leukemia represented 63%. RD, URD, and Haplo were 72 (58%), 30 (24%), and 21 (17%), respectively. The median duration of follow-up was 251 days. CMV reactivation was documented in 84 (68%), with a median number of 2 (1 – 9) episodes per patient. RD, URD, and Haplo had similar frequencies of reactivation (64%, 70%, and 81%; p = 0.33). URD-SCT had earlier reactivation than others (median D+6, versus D+37 and D+ 21 in RD and Haplo, p < 0.001). A total of 192 CMV reactivation episodes were analyzed: 100 in RD, 55 in URD, and 37 in Haplo. Haplo-SCT reached the highest viral loads (median of 1070 copies/mL vs., 373 and 163 copies/mL in RD and URD-SCT; p = 0.036). First CMV reactivation episode reached higher viral load (median 1897 vs. 143 copies/mL; p < 0.001) and longer viremia (median 28 vs. 14 day; < 0.001), compared with repeated ones. **Conclusions:** Reactivation of CMV occurred with different dynamics by SCT donor type and in the first or repeated episode. Treatment and preventive strategies should be adapted, considering these different scenarios.

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DEFIBROTIDE TREATMENT IN PAEDIATRIC PATIENTS WITH SEVERE/VERY SEVERE VENO-OCCLUSIVE DISEASE/SINUSOIDAL OBSTRUCTION SYNDROME AFTER HAEMATOPOIETIC CELL TRANSPLANTATION: DEFIFRANCE INTERIM RESULTS

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Objectives: Veno-occlusive disease/sinusoidal obstruction syndrome (VOD/SOS) is a potentially fatal complication of haematopoietic cell transplantation (HCT) conditioning that may also develop after high-dose chemotherapy. Defibrotide is approved in Brasil and the US for adult and paediatric patients (aged >1 month in Brasil) with hepatic VOD/SOS with renal or pulmonary dysfunction post-HCT, and in the EU for patients aged >1 month with severe hepatic VOD/SOS post-HCT. The DEFIFrance study is collecting real-world data on outcomes in patients treated with defibrotide across France. This interim analysis evaluated a subgroup of paediatric patients (<18 years) with severe/very severe VOD/SOS post-HCT who were treated with defibrotide. **Material and methods:** DEFIFrance is a multicentre, post-marketing study collecting retrospective and prospective real-world data on patients receiving defibrotide at 53 HCT centres in France since July 2014; this analysis includes data collected from 36 active HCT centres. Criteria used for VOD/SOS diagnosis were at the discretion of the treating physician based on their clinical expertise; severity was adjudicated by an expert steering committee member according to EBMT criteria. Primary endpoints included Kaplan-Meier (KM)–estimated Day 100 survival rate post-HCT and Day 100 complete response (CR; total serum bilirubin <2 mg/dL and resolution of multiorgan failure [MOF] per investigators'assessment) in patients with severe/very severe VOD/SOS post-HCT. Secondary endpoints included evaluation of adverse events (AEs) of interest, irrespective of their relationship to treatment. **Results:** As of 8 November 2018, 324 patients were included in DEFIFrance. Of these, 41 paediatric patients had VOD/SOS post-HCT, of which 23 had severe/very severe VOD/SOS and were included in this analysis. Median age was 8.5 (range, 0.4–17.5) years. MOF occurred in 5 (22%) patients. The KM–estimated Day 100 post-HCT survival rate was 85% (severe [n = 14]: 100%; very severe [n = 9]: 53%); estimated survival rates were 68% and 55% at 6 and 12 months, respectively. The Day 100 post-HCT CR rate was 81% in patients with severe/very severe VOD/SOS. Among evaluable patients with severe (n = 14) and very severe (n = 7) VOD/SOS, Day 100 CR rates were 93% and 57%, respectively.