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Efficacy of antifungal prophylaxis with micafungin in patients receiving HLA-haploidentical bone marrow transplantation (Haplo-BMT)

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Haplo-BMT recipients are at high risk for invasive fungal infections (IFI) involving yeasts and molds. The echinocandin micafungin has shown antifungal activity against both *Candida* and *Aspergillus* species.

Objectives: the aim of this observational study was to investigate the efficacy and safety of micafungin for antifungal prophylaxis (AP) in patients undergoing haplo-BMT.

Methods: between April 2010 and October 2013, 32 patients with hematologic malignancies have been enrolled, the majority (62%) of whom were in advanced phase of disease at the time of transplant. Seven patients received a previous allogeneic stem cell transplant. Reduced intensity preparative regimen was administered to 9 patients, conventional myeloablation was administered to 23 patients, followed by T-cell replete bone marrow in all patients. Postgrafting immunosuppression consisted of Cyclophosphamide (50 mg/Kg/day on days +3 and +4); at 24 h after Cyclophosphamide administration, GVHD prophylaxis continued with mycophenolate mofetil and tacrolimus. Primary AP was administered to 23 patients: 10 patients received fluconazole 400 mg ev/po from day-1 until day 100 after transplant; 13 patients received micafungin 50 mg once daily as a 1-h infusion from day-1 until neutrophil engraftment (median duration 20 days, range 11-35 days) followed by fluconazole 400 mg po until day +100. Seven patients had a history of possible aspergillosis before haplo-BMT and received secondary AP with Liposomal-AmB (n=3), posaconazole (n=3) or voriconazole (n=1). Two patients were not evaluable due to the presence of IFI at the time of transplant requiring antifungal treatment.

Results: according to the revised EORTC/MSG definitions, 3 of the 10 patients receiving AP with Fluconazole developed probable aspergillosis based on CT scan of the lung and positive galactomannan antigenemia >0.5 (n=2 in the serum; n=1 in the bronchoalveolar lavage). None of the patients who received micafungin developed proven of probable IFI; 1 patient had possible IFI based on CT scan suggestive of pulmonary aspergillosis. None of the 7 patients who received secondary AP developed IFI. Empirical antifungal treatment has been administered to 3 patients receiving micafungin and 1 patient receiving fluconazole as AP. Only one patient discontinued prematurely the administration of micafungin due to the presence of side effects (cutaneous rash). Micafungin was not associated with any hepatotoxicity. After a median follow-up of 498 days (range 30-908 days) 14 patients (44%) were alive, 13 patients (41%) died of disease progression and 5 (15%) because of transplant-related complications; none of the deaths was associated with an IFI.

Conclusions: the results of present study suggest that micafungin is a safe and effective drug for AP in patients undergoing haplo-BMT and provide support for further prospective clinical trials to confirm our preliminary data.