(PB4055) FIRST-LINE MARIBAVIR TREATMENT FOR PATIENTS WITH CMV INFECTION INTOLERANT TO CONVENTIONAL ANTIVIRAL DRUGS

Topic: 23. Stem cell transplantation - Clinical

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Background

Maribavir is an anti-viral drug approved for the treatment of resistant or refractory cytomegalovirus (CMV) infection after allogeneic stem cell transplantation. Recently, ECIL-10 guidelines recommended its consideration as a first-line treatment for patients with neutropenia (BI) or renal function impairment (BII).

Aims

Our objective was to describe the efficacy and safety of maribavir as a first-line antiviral agent in patients with CMV infection intolerant to conventional antiviral therapies.

Methods

We retrospectively analyzed clinical characteristics and outcomes of patients with CMV infection or disease treated with maribavir as a first-line antiviral therapy at the University Clinical Center of Serbia between July 2022 and January 2026. Descriptive statistical analyses were performed.

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Results

A total of 12 patients were eligible for the study. The median follow-up from maribavir administration was 21 months (range 3-39). Nine patients (75%) received a transplant from matched
unrelated donor, while one patient each received a transplant from a matched related donor, a mismatched unrelated donor, and a haploidentical donor. All but one patient with a haploidentical
donor received anti-T-lymphocyte globulin before the transplant. Myeloablative conditioning was used in seven patients (58%). Eight patients (67%) had a CMV seronegative donor. All of the patients received CMV prophylaxis with letermovir for 100 days and only one patient had a breakthrough infection while still receiving it. CMV infection or disease were diagnosed after a mean of 126 days after transplantation (range 90-168). Three cases (25%) were diagnosed with CMV disease, all of them had CMV colitis. All patients received maribavir monotherapy in a standard dose (400mg twice daily) for a duration of eight weeks, with no cases of premature discontinuation of the drug. Before the administration of maribavir, grade I-IV neutropenia was present in eleven (92%) patients, while grade I-III renal impairment was present in seven (58%) patients. The median peak blood CMV copy number was 16145 copies/mL (range 1305-1864500). The infection resolved in all cases during maribavir treatment, and viremia clearance was achieved after a median of 18.5 days (range 11-31). Four reinfections were documented after discontinuation of the drug, occurring at a median of 20 days (range 17-79). Patients who did not experience CMV reinfection had a viremia clearance in a median of 16.5 days, compared to 28 days in those developing reinfection. Three patients (25%) needed a hospitalization for the initial CMV episode, while additional two cases of hospitalization were needed for the treatment of reinfection. Among four patients with CMV reinfection, one achieved successful treatment with valganciclovir and another with maribavir retreatment. The remaining two patients did not respond to multiple lines of therapy, including valganciclovir, foscarnet, cidofovir, and maribavir. During treatment with maribavir, two patients (17%) had a grade II dysgeusia, while only one case of neutropenia worsening was documented. Seven (58%) out of twelve patients are alive, with two deaths related to CMV, two to relapse and one to acute graft-versus-host disease. Drug resistance testing by next-generation sequencing was not performed.

Summary/Conclusion

Maribavir is an effective and safe treatment option for CMV infection in patients with neutropenia and/or renal impairment after allogeneic stem cell transplantation.

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