(PB4022) EFFICACY AND SAFETY OF MARIBAVIR INTHE TREATMENT OF 10 PATIENTS WITH CMV END-ORGAN DISEASE AFTER ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION

Topic: 23. Stem cell transplantation - Clinical

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Background

Cytomegalovirus (CMV) end-organ disease is a severe complication after allogeneic hematopoietic stem cell transplantation (allo-HSCT). Traditional nucleoside antiviral agents as first-line treatments are limited in clinical use due to significant adverse effects. Maribavir has been increasingly used for the treatment of CMV infection in recent years. However, clinical efficacy and safety analyses in small cohorts of patients with post-HSCT CMV end-organ disease remain limited. This study analyzed the medical records of 10 patients to provide clinical evidence for clinical practice.

Aims

To evaluate the efficacy and safety of maribavir in the treatment of CMV end-organ disease following allo-HSCT, and to provide clinical evidence for antiviral management in this population.

Methods

We retrospectively analyzed the clinical data of 10 patients diagnosed with CMV end-organ disease after allo-HSCT and treated with maribavir between December 2023 and April 2025. The final follow-up date was October 31, 2025.

Results

Of the 10 patients with CMV end-organ disease, 6 were male and 4 were female, with a median age of 36 years (range, 18–68 years). Pre-transplant CMV IgG serostatus: 9 cases were D+/R+ and 1 case was D-/R+. All 10 patients received letermovir (LET) prophylaxis from day +6 to day +100 post-transplantation. No CMV infection occurred within day +100, whereas 7 patients developed late-onset CMV viremia at a median of 153 days (range, 116–180 days) after transplantation. The median peak plasma CMV DNA load was 54,000 copies/mL (range, 1100–630,000 copies/mL), and the median duration of CMV viremia was 27 days (range, 8–52 days). All 7 patients who had previously received conventional anti-CMV agents were then treated with maribavir.Among the 10 patients with CMV end-organ disease, 5 had CMV pneumonia and 5 had CMV gastroenteritis, occurring at a median of 151 days (range, 123–213 days) post-transplantation. Six patients had concurrent CMV viremia at the onset of CMV end-organ disease. Additional comorbidities included: 6 cases with concomitant overlapping GVHD/cGVHD, 4 cases with EBV-related diseases (2 EBV pneumonia, 2 EBV enteritis), 1 case with poor graft function, 1 case with capillary leak syndrome, and 1 case with severe bacterial infection. All patients treated with maribarvir when diagnosed with CMV end-organ diease. The median time to gastrointestinal symptom remission in 5 patients with CMV gastroenteritis was 19 days (range, 8–42 days). The median time to radiological resolution in 5 patients with CMV pneumonia was 4 weeks (range, 2–8 weeks). After maribavir discontinuation, CMV viremia recurred in 3 patients at a median of 81 days (range, 18–83 days) off therapy, with a median peak CMV DNA load of 1100 copies/mL (range, 770–3300 copies/mL). Sustained CMV DNA negativity was achieved in 2 patients after re-initiation of maribavir. One patient refused maribavir for personal reasons and progressed to CMV pneumonia 2 weeks after recurrent CMV viremia. One patient developed dysgeusia, which resolved after maribavir cessation. No worsening cytopenia, increased creatinine or other drug-related adverse events were observed. At the final follow-up, 9 patients alive,1 patient died due to severe pneumonia.

Summary/Conclusion

Maribavir shows favorable clinical efficacy in the treatment of CMV end-organ disease after allo-HSCT, with mild adverse effects and good tolerability. However, given the small sample size, further validation in large-scale prospective studies is warranted.

Fingure1:Clinical characteristics of 10 patients with CMV end-organ disease after allo-HSCT treated with maribavir

Clinical characteristics	Number of patients, N=10
Sex	
Male/Female	6/4
Median age (years)	36 (18-68)
Primary disease	
AML/ALL/MDS/SAA-PNH	7/1/1/1
HCT-CI score	
⩾2 points	4 (40%)
Disease Risk Stratification	
High-risk disease	4 (40%)
Immunotherapy or targeted therapy before transplant	7 (70%)
Transplant type	
Haploidentical/unrelated	8/2
Donor/recipient CMV IgG serostatus	
D−/R+	1 (10%)
D+/R+	9 (90%)
Secondary allo-HSCT	1 (10%)
Conditioning regimen	
Bu-based / TBI-based	9/1
GVHD prophylaxis	
CSA+MMF+sMTX	9 (90%)
FK506+MMF+sMTX	1 (10%)
Type of ATG	
Rabbit anti-T-cell immunoglobulin	5 (50%)
Rabbit anti-thymocyte globulin (rATG)	5 (50%)
Letermovir prophylaxis	10 (day+6 to+100)
aGVHD (grade III–IV)	4(40%)
Median lymphocyte subsets within day +100 post-transplant (cells/μL)	
CD3+/CD4+/CD8+ at day +30	47.5/11/22
CD3+/CD4+/CD8+ at day +60	104/15/62
CD3+/CD4+/CD8+ at day +100	121/66/109
CMV reactivation within day +100	0
Other viral reactivation within day +100	
EBV viremia	6 (60%) (3 treated with rituximab)
BKV viremia	2 (20%)
Post-transplant DLI	5 (50%)
High-dose steroids before CMV disease (prednisone ≥ 1 mg/kg)	4 (40%)

Late CMV viremia before CMV disease	7 (70%)
Median onset of late CMV viremia (days)	153 (116-180)
Median peak CMV DNA load (copies/mL)	54000(1100-630000)
Median duration of CMV viremia (days)	27 (8-52)
Type of CMV end-organ disease	
CMV pneumonia	5 (50%)
CMV enteritis	4 (40%)
CMV gastritis	1 (10%)
Immunosuppression at CMV disease onset	
CNI + ⩾2 agents	4 (40%)
Median time to CMV disease after HSCT (days)	151 (123-213)
Median time from CMV viremia to CMV disease (days)	5 (1-87)
Median time from aGVHD to CMV disease (days)	101 (40-164)
Median NEU at CMV disease (×10⁹/L)	0.85 (0.4-2)
Median CD4+ count at CMV disease (cells/μL)	94 (23-252)
Coinfection with other viruses	
EBV	4 (2 EBV pneumonia, 2 EBV enteritis)
Comorbidities at CMV disease	
Overlapping GVHD/cGVHD	5/1 (60%)
Poor graft function	1 (10%)
Capillary Leak Syndrome	1 (10%)
Severe bacterial infection	3 (30%)
Maribavir initiation	
First-line	5 (50%)
Second-line treatment	5 (50%)
Median creatinine at maribavir start (μmol/L)	50.3 (35.4-92)
Median NEU at maribavir start (×10⁹/L)	0.85 (0.4-2)
Median duration of maribavir	4 weeks (2-8 weeks)
Combined therapy with maribavir	
Intravenous immunoglobulin (IVIG)	10 (100%)
Foscarnet	2 (20%)
Maribavir-related adverse events	
Dysgeusia	1 (10%)
Late CMV viremia recurrence	3 (30%)
Median follow-up (days)	335 (182-810)
Vital status	
Alive	9 (90%)
Dead	1 (10%)