(PB4228) ANALYSIS OF ADVERSE DRUG REACTIONS AND CMV INFECTIONS DURING LETERMOVIR THERAPY: A FAERS DATABASE STUDY

Topic: 31. Infections in hematology (incl. supportive care/therapy)

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Background

Letermovir is an antiviral agent approved for CMV infection prophylaxis in transplant recipients. This study aimed to evaluate adverse drug reactions (ADRs) during letermovir treatment.

Aims

We aim to explore ADRs associated with letermovir treatment using FAERS database.

Methods

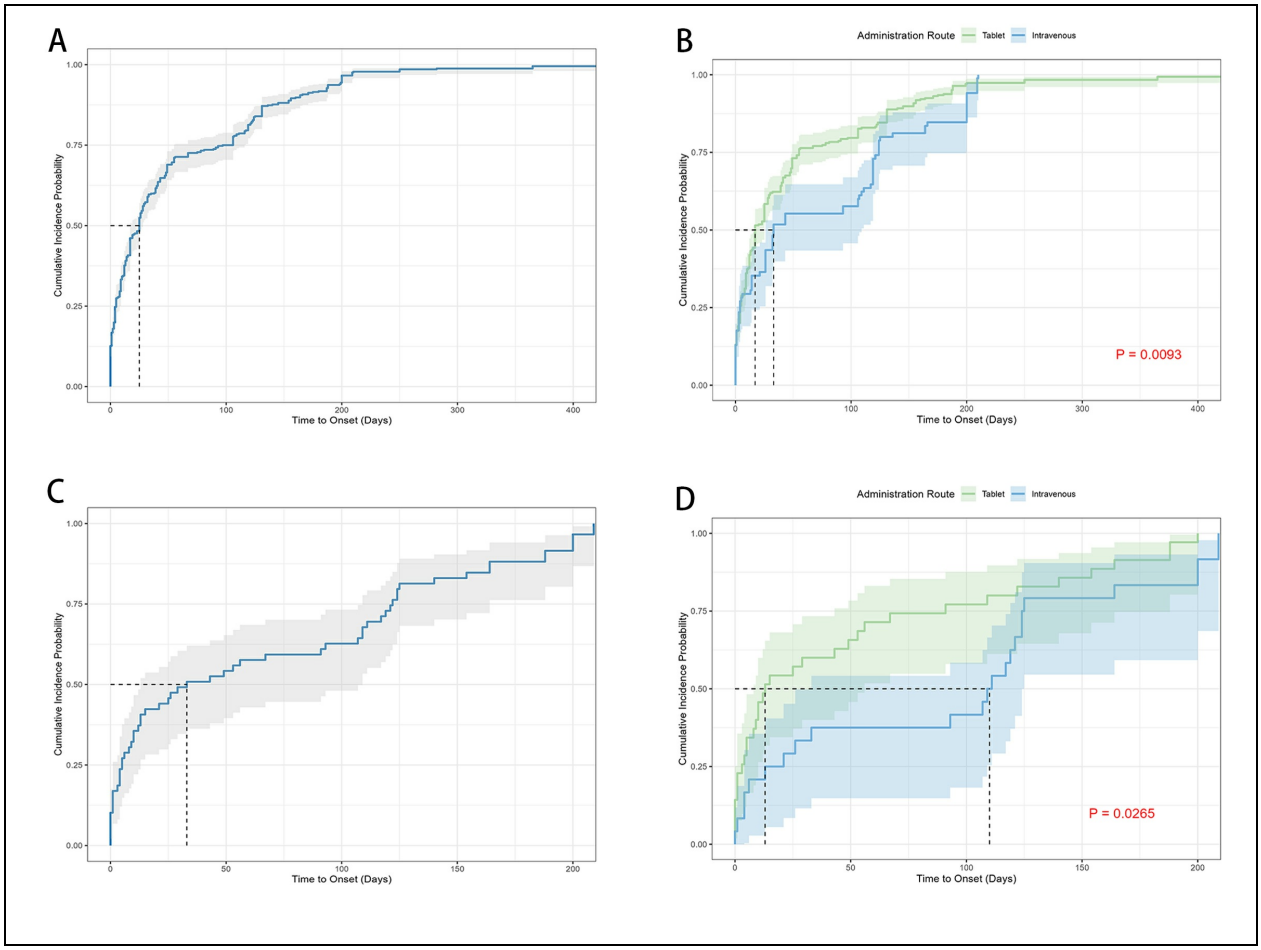
Data from October 2017 to September 2024 were extracted from FAERS database. Disproportionality analysis was performed to detect adverse events potentially associated with letermovir. Time-to-onset analysis was conducted, logistic and cox regression were performed to identify risk factors.

Results

The most frequently reported ADR was infections and infestations at SOC level, CMV infection at HLT level and CMV infection reactivation at PT level. Novel safety signals included cardiac disorder (cardiac arrest, heart failure), gastrointestinal/hepatobiliary disorder (colitis, hematochezia, hepatic failure), renal failure, various CMV-related events and transplant-related complications. The median time to onset for overall ADRs was 25 days (Figure A), and 33 days for events associated with CMV infections (Figure B), with both showing significantly delayed onset time for intravenous formulations compared to tablets (Figure C, D). Older age was identified as a protective factor against CMV infections, while geographic disparities revealed increased risks in Europe and decreased risks in North America.

Summary/Conclusion

Severe cardiac, hepatic and renal complications were found to be associated with letermovir. CMV breakthrough infections remain a concern, and leukemia relapse risk requires further investigations.



Cumulative incidence probability of ADRs associated with letermovir. Panels (A) and (C) showed cumulative incidence probability of overall ADRs (A) and CMV infections (C) during letermovir treatment. Panels (B) and (D) illustrated stratification by administration route (tablet vs. intravenous) for overall ADRs (B) and CMV infections (D) during letermovir treatment. ADRs: adverse drug events.