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Efek Samping Terapi Valgansiklovir terhadap Enzim Hati dan Fungsi Ginjal pada Anak dengan Infeksi Cytomegalovirus Kongenital
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INTISARI

Latar belakang: Infeksi *Cytomegalovirus* (CMV) kongenital merupakan penyebab penting gangguan neurologis dan gangguan pendengaran pada anak. Terapi valgansiklovir terbukti memberikan manfaat klinis, namun juga berpotensi menimbulkan efek samping berupa gangguan hematologi, enzim hati dan fungsi ginjal. Data mengenai keamanan terapi valgansiklovir terhadap parameter enzim hati dan fungsi ginjal pada anak dengan CMV kongenital di Indonesia masih terbatas.

Tujuan: Mengetahui efek samping terapi valgansiklovir terhadap enzim hati dan fungsi ginjal pada anak dengan infeksi CMV kongenital.

Metode: Penelitian ini merupakan studi analitik observasional dengan desain kohort retrospektif pada pasien anak usia 0–12 bulan dengan infeksi CMV kongenital yang mendapatkan terapi valgansiklovir minimal 6 minggu di RS Sardjito periode Januari 2023–Desember 2025. Luaran yang dinilai meliputi efek terhadap enzim hati berdasarkan rasio *alanine aminotransferase* (ALT) terhadap nilai *upper limit of normal* (ULN) dan fungsi ginjal berdasarkan rasio kreatinin terhadap nilai dasar (*baseline*). Evaluasi dilakukan pada minggu ke-1, ke-2, dan ke-6 sejak terapi diberikan. Analisis dilakukan secara longitudinal menggunakan *Linear Mixed Model*, serta analisis bivariat dengan uji *Chi Square* dan multivariat menggunakan regresi logistik biner.

Hasil: Sebanyak 98 subjek penelitian dianalisis dengan hasil tidak ditemukan perubahan bermakna rasio ALT/ULN maupun rasio *Cr/baseline* selama pemberian terapi valgansiklovir pada minggu ke-1, minggu ke-2, dan minggu ke-6 berdasarkan analisis longitudinal. Pada analisis bivariat, jenis kelamin dan usia saat memulai terapi berhubungan dengan kejadian efek enzim hati, sedangkan lama terapi, prematuritas, status gizi, malnutrisi, dan penggunaan terapi nefrotoksik tidak menunjukkan hubungan bermakna. Untuk efek fungsi ginjal, tidak ditemukan hubungan bermakna antara seluruh faktor yang dianalisis. Pada analisis multivariat, hanya usia saat memulai terapi kelompok 1–6 bulan yang tetap berhubungan dengan kejadian efek enzim hati (p=0,029). Efek pada enzim hati ditemukan pada 11,2% pasien dan seluruhnya derajat ringan, sedangkan efek fungsi ginjal ditemukan pada 31,6% pasien dengan variasi derajat sedang hingga sangat berat.

Kesimpulan: Terapi valgansiklovir pada anak dengan infeksi CMV kongenital tidak menunjukkan perubahan longitudinal yang bermakna terhadap enzim hati dan fungsi ginjal selama 6 minggu terapi. Namun, efek terhadap enzim hati dan fungsi ginjal tetap ditemukan sehingga pemantauan laboratorium berkala tetap diperlukan.

Kata Kunci: Cytomegalovirus kongenital, valgansiklovir, efek samping, enzim hati, fungsi ginjal

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ABSTRACT

Background: Congenital Cytomegalovirus (CMV) infection is an important cause of neurological impairment and hearing loss in children. Valganciclovir therapy has demonstrated clinical benefits but may also cause adverse effects including hematological abnormalities, liver enzyme alterations, and renal dysfunction. Evidence regarding the safety of valganciclovir on liver enzymes and renal function among children with congenital CMV infection in Indonesia remains limited.

Aim: To evaluate the adverse effects of valganciclovir therapy on liver enzymes and renal function in children with congenital CMV infection.

Methode: This observational analytic study used a retrospective cohort design involving children aged 0–12 months with congenital CMV infection who received valganciclovir therapy for at least 6 weeks at Sardjito Hospital between January 2023 and December 2025. Outcomes included liver effects assessed using the alanine aminotransferase to upper limit of normal ratio (ALT/ULN) and renal effects assessed using serum creatinine relative to baseline (Cr/baseline). Evaluations were performed at weeks 1, 2, and 6 after treatment initiation. Longitudinal analysis was conducted using a Linear Mixed Model, followed by bivariate analysis using Chi-square test and multivariate analysis using binary logistic regression.

Result: A total of 98 subjects were included. No significant changes were observed in ALT/ULN ratio or Cr/baseline ratio during weeks 1, 2, and 6 of valganciclovir therapy based on longitudinal analysis. Bivariate analysis showed that sex and age at treatment initiation were associated with liver adverse effects, whereas treatment duration, prematurity, nutritional status, malnutrition, and nephrotoxic therapy were not significantly associated. No significant associations were found between any evaluated factors and renal adverse effects. In multivariate analysis, only treatment initiation at age 1–6 months remained associated with liver adverse effects (p=0.029). Liver adverse effects occurred in 11.2% of patients and were all classified as mild, while renal adverse effects occurred in 31.6% of patients with moderate to very severe grades.

Conclusion: Valganciclovir therapy in children with congenital CMV infection did not show significant longitudinal changes in liver enzymes and renal function during the 6-week treatment period. However, liver and renal adverse effects were still observed, indicating that routine laboratory monitoring remains necessary.

Keywords: Congenital Cytomegalovirus, valganciclovir, adverse effects, liver enzymes, renal function, children