INTISARI

Meropenem merupakan antibiotik beta-laktam berspektrum luas yang sering digunakan untuk menangani infeksi serius pada pasien di unit perawatan intensif (ICU). *Therapeutic Drug Monitoring* (TDM) berperan penting dalam menyesuaikan dosis secara optimal, memastikan efektivitas terapi, serta mengurangi risiko toksisitas dan resistensi antimikroba. Penelitian ini bertujuan untuk mengukur kadar meropenem dalam plasma darah menggunakan teknik *Liquid Chromatography tandem Mass Spectrometry* (LC-MS/MS), serta mengevaluasi penerapannya dalam TDM pada pasien ICU. Sebanyak 40 sampel plasma dari 20 pasien yang menjalani infus kontinu meropenem dianalisis menggunakan metode LC-MS/MS yang telah divalidasi berdasarkan pedoman ICH M10 (2022). Validasi mencakup aspek selektivitas, akurasi, presisi, stabilitas, dan pengenceran sampel. Metode yang digunakan menunjukkan sensitivitas dan linearitas tinggi (r^2 = 0,993–0,996) pada rentang konsentrasi 10–2000 ng/mL, serta akurasi dan presisi yang sesuai standar (%RSD <15%). Hasil analisis menunjukkan bahwa kadar meropenem di seluruh pasien mampu mempertahankan nilai *% free time of drug concentration (% fT) > Minimum Inhibitory Concentration* (MIC) > 40%, menandakan efektivitas antibakteri yang memadai. Dosis disesuaikan berdasarkan fungsi ginjal pasien. Secara keseluruhan, metode LC-MS/MS yang divalidasi ini efektif untuk TDM meropenem pada pasien ICU dan mendukung penerapan strategi pengobatan secara individu.

Kata kunci: meropenem, TDM, LCMS/MS, validasi metode, pasien ICU

ABSTRACT

Meropenem is a broad-spectrum beta-lactam antibiotic widely used in intensive care units (ICUs) for severe bacterial infections. Therapeutic drug monitoring (TDM) is essential to optimize its dosing, ensuring effective bacterial eradication while minimizing toxicity and resistance. This study aimed to determine meropenem concentrations in human plasma using LC-MS/MS and evaluate its application in TDM for ICU patients. Meropenem concentrations in plasma samples from ICU patients were analysed using a validated liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. The study included 40 plasma samples from 20 patients receiving meropenem continuous infusion. Validation followed ICH M10 (2022) guidelines, assessing specificity, accuracy, precision, stability, and dilution integrity. The developed LC-MS/MS method demonstrated high selectivity, sensitivity, and linearity (r^2 = 0.993–0.996) over the 10–2000 ng/mL range. Accuracy and precision met ICH M10 acceptance criteria, with %CV <15%. All ICU patients maintained % time free drug concentration (% fT) > Minimum Inhibitory Concentration (MIC) > 40%, ensuring adequate bacterial eradication. Notably, patients with renal impairment required dose adjustments, while those with high creatinine clearance needed increased dosing. The validated LC-MS/MS method is suitable for meropenem TDM in ICU patients, allowing individualized dosing adjustments to optimize therapy.

Keywords: meropenem, TDM, LCMS/MS, method validation, ICU