Poster

[P26-6] P26-6: Immunosuppressive drugs (5): Clinical practice

Chair: Hege Christensen, Norway

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[P26-6-2] MeltDose® tacrolimus clinical pharmacokinetics in adult renal transplant recipients in the early transplant period

Pilar Salvador-Garrido[1], Maria Outeda-Macias[2], Constantino Fernandez-Rivera[3], Angel Alonso-Hernandez[4], Isaura Pedreira-Vazquez[5], Isabel Martin-Herranz[6] (1.A Coruna University Hospital Complex, 2.A Coruna University Hospital Complex, 3.A Coruna University Hospital Complex, 4.A Coruna University Hospital Complex, 5.A Coruna University Hospital Complex, 6.A Coruna University Hospital Complex)

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Background

A new once-daily prolonged-released tacrolimus formulation with a MeltDose® technology (LCP-Tacro, Envarsus®) has become available. The aim of this study was to determine the clinical pharmacokinetic profile of this LCP-Tacro formulation in a population of adult renal transplant recipients at 15 days after transplantation.

Methods

Retrospective observational study of 12 Caucasian cadaveric renal transplant patients who were co-treated with mycophenolic acid and steroids. All patients received the same LCP-Tacro dosage for at least 3 days before each profile.

Blood levels were measured by CMIA on an Architect-C8000 Analyzer.

Pharmacokinetic profiles were obtained at two weeks post-transplant. Blood samples were taken predose and 1, 2, 3, 4, 6, 8 and 12 h after the oral morning dose. The area under the concentration-time-curve from 0 to 24 h (AUC_{0-24}) was calculated using the linear trapezoidal rule.

Statistical analysis was performed using SPSS 19.0. The correlation between individual concentrations and the AUC_{0-24} was evaluated by Spearman's Rho coefficient.

Results

12 patients, age 54±10 years, weight 82±12 kg were included. These patients were receiving a total and weight-adjusted daily dose of 10.29±5.19 mg and of 0.12±0.05 mg/kg, respectively, obtaining an AUC_{0-24} of 354.76±46.19 ng.h/mL. LCP-Tacro was associated with a peak concentration (C_{max}) of 25.16±6.43 ng/mL, which was achieved approximately at 6 h (T_{max}) at steady state, and a trough level (C_{trough}) of 7.23±2.37 ng/mL, being the peak-to-trough (C_{max}/C_{trough}) ratio of 3.5. There was a good correlation between the C_{trough} and AUC0-24 at steady state: Spearman's Rho= 0.821 (p=0.023).

Conclusions

This new LCP-Tacro formulation (Envarsus®) was associated with a steadier concentration time profile that remained within the therapeutic range for almost 24 h.

For LCP-Tacro, the trough level monitoring gave a good indication of overall drug exposure ($AUC0-_{24}$).