Abstract

To compare the efficacy and safety of tacrolimus and cyclosporine in heart transplantation, this single-center, prospective, randomized, open-label clinical trial was undertaken. METHODS: Seventy-three adult patients were randomly assigned at the time of transplantation to receive either tacrolimus (n=43) or cyclosporine (n=30) as the primary immunosuppressant. Ten of the 43 patients in the tacrolimus group received the drug intravenously in the perioperative period; all other patients received only oral tacrolimus. RESULTS: With a mean follow-up of 27 months, patient survival rates (tacrolimus 83%, cyclosporine 81%) were similar. Fewer patients experienced acute rejection in the tacrolimus group (79%) than in the cyclosporine group (100%), but the difference was not statistically significant. The number of infections and dialysis and insulin requirements were similar for the 2 treatment groups, but the proportion of patients requiring multidrug antihypertensive regimens was lower in the tacrolimus group (12.5% vs 50.0% at month 6; p=.025). The interpatient variance in pharmacokinetic parameters in a subset of 10 patients was much higher after the first oral dose of tacrolimus than at steady-state (eg, first-dose time at which maximal concentration is reached (t(max)): 3.5+/−2.5h, steady-state t(max): 2.0+/−0.7h), and patients treated with intravenous tacrolimus (n=13) rather than oral tacrolimus (n=30) reached target concentrations faster and with less interpatient variability (eg, at day 0: 9.72+/−10.9 ng/mL intravenously vs 3.31+/−8.1 orally). CONCLUSIONS: Tacrolimus was associated with similar efficacy and safety profiles compared with cyclosporine. The higher interpatient variance in absorption associated with oral tacrolimus during the first few days after transplantation would suggest that intravenous tacrolimus should be used during the perioperative period.