Title of the Contribution:
Four-year data after pediatric renal transplantation: a randomized trial of tacrolimus vs. cyclosporin microemulsion.

Abstract:
This study was undertaken to compare the efficacy and safety of tacrolimus (Tac) with cyclosporin microemulsion (CyA) in pediatric renal recipients. A 6-month, randomized, prospective, open, parallel group study with an open extension phase was conducted in 18 centers from nine European countries. In total, 196 pediatric patients (<18 yr) were randomly assigned (1:1) to receive either Tac (n = 103) or CyA (n = 93) administered concomitantly with azathioprine and corticosteroids. The primary endpoint was incidence and time to first acute rejection (intent-to-treat). Baseline characteristics were comparable between treatment groups. Excluding deceased patients (n = 9) and patients lost to follow-up (n = 31, mostly transferred to adult care), 95% of 2-yr data (159 of 167 possible patients), 87% of 3-yr data (142 of 163) and 73% of 4-yr data (114 of 156) were retrieved. At 1 yr Tac therapy resulted in a significantly lower incidence of acute rejection (36.9%) compared with CyA (59.1%, p = 0.003). The incidence of corticosteroid-resistant rejection was also significantly lower with Tac (7.8% vs. 25.8%, p = 0.001). At 4 yr, patient survival was similar (94% vs. 92%, p = 0.86) but graft survival significantly favored Tac (86% vs. 69%; p = 0.025, log-rank test).
respectively. At 1 yr, the mean glomerular filtration rate (GFR) (Schwartz formula, ml/min/1.73 m(2)) was 64.9 +/- 20.7 (n = 84) vs. 57.8 +/- 21.9 (n = 77, p = 0.0355), at 2 yr 64.9 +/- 19.8 (n = 71) vs. 51.7 +/- 20.3 (n = 66, p = 0.0002), at 3 yr 66.7 +/- 26.4 (n = 81) vs. 53.0 +/- 23.3 (n = 55, p = 0.0022), and at 4 yr 71.5 +/- 22.9 (n = 51) vs. 53.0 +/- 21.6 (n = 44, p = 0.0001) for Tac vs. CyA, respectively. Cholesterol remained significantly higher with CyA throughout follow-up. Three patients in each arm developed post-transplant lymphoproliferative disease. Incidence of insulin-dependent diabetes mellitus was not different. Tac was significantly more effective than CyA in preventing acute rejection in pediatric renal recipients. Renal function and graft survival were also superior with Tac. Glomerular filtration rate appears to be an useful surrogate marker for long-term outcome.

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