ATG-Fresenius or daclizumab induction therapy in immunologically high risk kidney recipients: a prospective randomized pilot trial

Min Jeong Kim, Dimitrios Tsinalis, Stefan Franz, Isabelle Binet, Lorenz Gürke, Michael J Mihatsch, Jürg Steiger, Gilbert Thiel & Michael Dickenmann

BACKGROUND: Despite all the advantages in the immunosuppressive therapy, kidney transplantation in immunologically high risk patients remains a challenge. Ideally, an induction therapy should provide maximal graft protection, while adverse events rate and costs remain as low as possible.

MATERIAL & METHODS: Immunologically high risk kidney recipients with CDC-PRA ≥ 25% within the last 3 years, a positive B-cell CDC-crossmatch or graft loss due to rejection within 3 years following a prior transplantation, were randomized 1:1 to receive ATG-Fresenius (ATG-F) (9 mg/kg day 0; 3 mg/kg day 1-4) or Daclizumab therapy (1 mg/kg day 0, 14, 28, 42, 56) in a pilot study. Additional immunosuppression consisted of cyclosporine, mycophenolate mofetil, and steroids. 11 patients were included in each group.

RESULTS: The patient (90% in ATG-F; 100% in Daclizumab) and graft survival (censored for death) (100% in ATG-F; 90% in Daclizumab) and the mean creatinine concentration at 24 months (139+/-68 mol/l in ATG-F; 176+/-103 mol/l in Daclizumab) were similar in both groups. More severe graft rejections (3 vascular rejections in Daclizumab) and adverse events (5.3/patient in ATG-F; 6.7/patient in Daclizumab) were observed in the Daclizumab group. The costs for hospitalization/day within 24 months were lower in ATG-F (2.32+/-3.51 USD vs. 12.25+/-9.75 USD; p=0.02) resulting in an average cost-difference of more than 10'435 USD /patient.

CONCLUSIONS: In this pilot trial, both treatments were comparably successful regarding graft and patient outcome.

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