

KSN 2016 Abstract Submission

Transplantation & Immunology

KSN2016ABS-1374

Long-term outcome of randomized trial comparing cyclosporine and tacrolimus therapy with steroid withdrawal in living-donor renal transplantation: 10-year follow-up

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Background: The use of steroid withdrawal protocols after kidney transplantation has been increasing because of well-known adverse effects of steroids and the introduction of new effective immunosuppressants. Long-term efficacy and safety of tacrolimus plus mycophenolate mofetil (TAC group) compared with cyclosporine A plus MMF (CsA group) for 10 years were analyzed in renal transplantation patients with low immunologic risk who underwent steroid withdrawal at 6 months after operation.

Methods: Overall 10-year follow-up data of patients who underwent their first living-donor renal transplantation at Samsung Medical Center between September 2000 and August 2003 were retrospectively analyzed. Patients were randomized to CsA or TAC groups and underwent steroid withdrawal at 6 months after renal transplantation. End points were patient and graft survival, and the incidence of acute rejection and post-transplant de-novo comorbidity such as diabetes mellitus.

Results: A total of 117 patients who successfully discontinued steroid treatment were included (55 in CsA group vs. 62 in TAC group). The 10-year patient survival was 96.2% in the CsA group and 98.4% (61/62) in the TAC group ($p=0.495$). The 10-year graft survival rate did not differ between groups (81.3% in CsA vs 91.2% in TAC; $p=0.412$). The cumulative incidence of acute rejection for 10 years after transplantation was 24.5% and 15.6% in the CsA and TAC groups, respectively ($p=0.201$). The incidence of post-transplantation diabetes mellitus was higher in the TAC group compared to the CsA group (10.0% vs 23.3%, respectively; $p=0.046$).

Conclusion: Long-term graft and patient survival, and the incidence of acute rejection were similar between CsA- and TAC-based regimens combined with MMF in low immunologic risk patients who underwent steroid withdrawal 6 months after kidney transplantation.

Keywords: Graft outcomes, Kidney Transplantation, Steroid withdrawal regimen