

Abstract

Introduction: The TRANSFORM study demonstrated that an immunosuppression based on a combination of calcineurin inhibitors and de-novo mTOR inhibitors (mTORi) is safe and effective in kidney transplant recipients. However, data that validate this approach in clinical practice are currently missing.

Materials and methods: Analysis of 401 kidney transplant recipients transplanted from June 2013 to December 2016. All patients received tacrolimus with prednisone in combination with either mycophenolate (n = 186) or mTORi (either everolimus or sirolimus, n = 215). A propensity score to receive mTORi was calculated based on the inverse probability of treatment weighting (IPTW) from the following parameters: age and sex of donor and recipient, BMI, previous transplants, diabetes, cPRA, dialysis before transplantation, dialysis vintage, type of donor, ABO-incompatibility, HLA-mismatches, induction and ischemia time. Median follow-up was 2.6 [1.9; 3.7] years.

Results: Cox-regression analysis suggests good results for mTORi versus MPA in terms of 1-year biopsy-proven acute rejection (BPAR, P = 0.063), 1-year graft loss (P = 0.025) and patient survival (P < 0.001). Results observed for BPAR and graft failure were largely attributed to those patients that would have been excluded by the TRANSFORM because of some exclusion criteria (52.9% of the population, P = 0.003 for 1-year BPAR and P = 0.040 for graft loss). In patients who met selection criteria for TRANSFORM, no effect of treatment for BPAR or graft failure was observed, while the beneficial effect on overall survival persisted.

Conclusions: In a real-life setting, a protocol based on de-novo mTORi with tacrolimus and prednisone could be employed as a standard immunosuppressive regimen and was associated with good outcomes.