Is generic tacrolimus “Adoport” safe in kidney transplantation?

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OBJECTIVES

The use of generic drugs in the solid organ transplant field in Spain is lower than in other western countries. One of the most common criticisms against the use of generic drugs is their lack of clinical data on patients since a generic drug, in order to be approved, “just” needs to prove its bio-equivalence in healthy subjects.

The scope of our work has been to test the safety and efficacy of a “generic” tacrolimus (Adoport - Sandoz) versus the referenced tacrolimus (Prograf – Astellas) in a real clinical setting

METHODS

In the study, we included 60 patients treated with Adoport since the first day after the renal transplant versus a historical control group formed 60 patients treated with Prograf. This second group was selected backwards on time with, as the starting date, the day before Adoport was introduced in our Hospital. We dismissed patients treated with a combination with iMtor or patients who had been submitted to other organs transplants. The basal specifics are shown in Table 1.

For each group, we evaluated: frequency of acute rejection and DGF, renal function at 6 months after transplant, proteinuria at 6 months, tacrolimus levels at 5-7 days, at 1, 3 and 6 months from transplant, coefficient of variation of the levels between 3 and 6 months and Through Tacrolimus Concentration/dose at 6 months.

For a sub-group of patients (32 Adoport group vs 29 Prograf Group), we evaluated the results from the protocol biopsy at 6 months and the results from the immunomonitoring (% of the de novo DSA in each group).

	ADO (60)	PRO (60)	p.
Age (mean)	56.1±12.6	59.2±13.7	0.35
Sex (% M/F)	70/30	62/38	0.44
Kidney Transp. (% 1/>1)	83/17	82/18	0.81
DSA at time of KT(% Y/N)	2/98	5/95	0.30
HLA MM (Median)	3	3	0.18
Type of dialysis			
Hemodialysis (%)	82	88	
Peritoneal Dialysis (%)	10	4	0.057
Pre-emptive (%)	8	8	
Induction Therapy (%Y/N)	97/3	89/11	0.18
ATG (% Y/N)	31/69	18/81	0.09
Basiliximab (% Y/N)	43/57	78/21	0.01
Corticoid at 6 m. (% Y/N)	90/10	82/18	0.12
Age (Mean±S.D.)	59.9±15	60.4±13	0.13
CIT (Mean±S.D.)	18±6.3	17±7.3	0.24
Type of Donor			
Deceased Donor (%)	82	88	0.43
Living Donor (%)	8	10	0.36
DCD (%)	10	2	0.09

Table 1. Baseline Characteristics

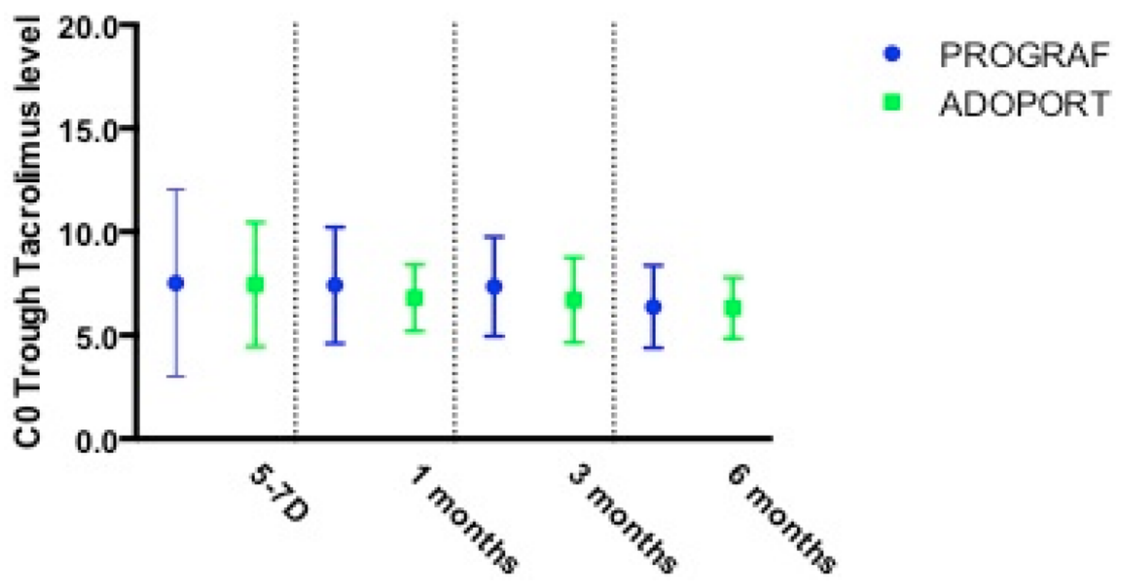

Figure 1. C0 Trough Tacrolimus Level

RESULTS

At 6 months after the renal transplant no significant difference was observed in C0 trough tacrolimus levels at different time points (Figure 1) and in kidney allograf function (figure 2). The incidence of acute rejection and DGF was the same in the two study group. (p. NS). Moreover at protocol biopses at 6 months the prevalence of banff items was the same for the two study group and the incidence of dnDSA was similar (see Figure 3)

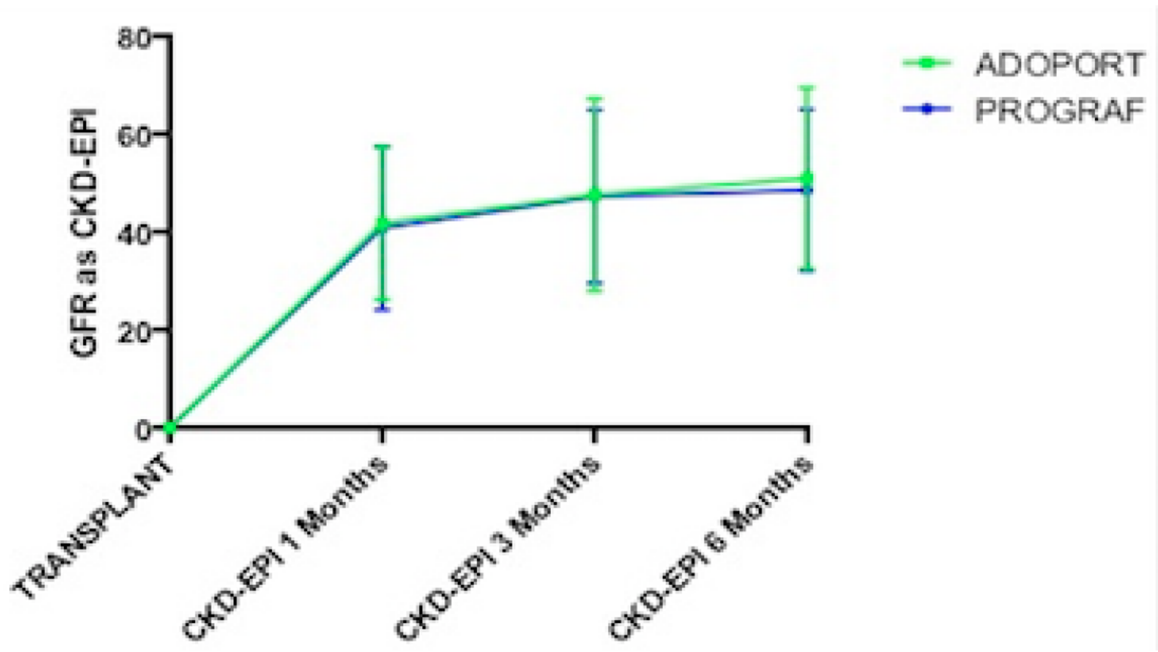

Figure 2. eGFR measured as CKD-EPI

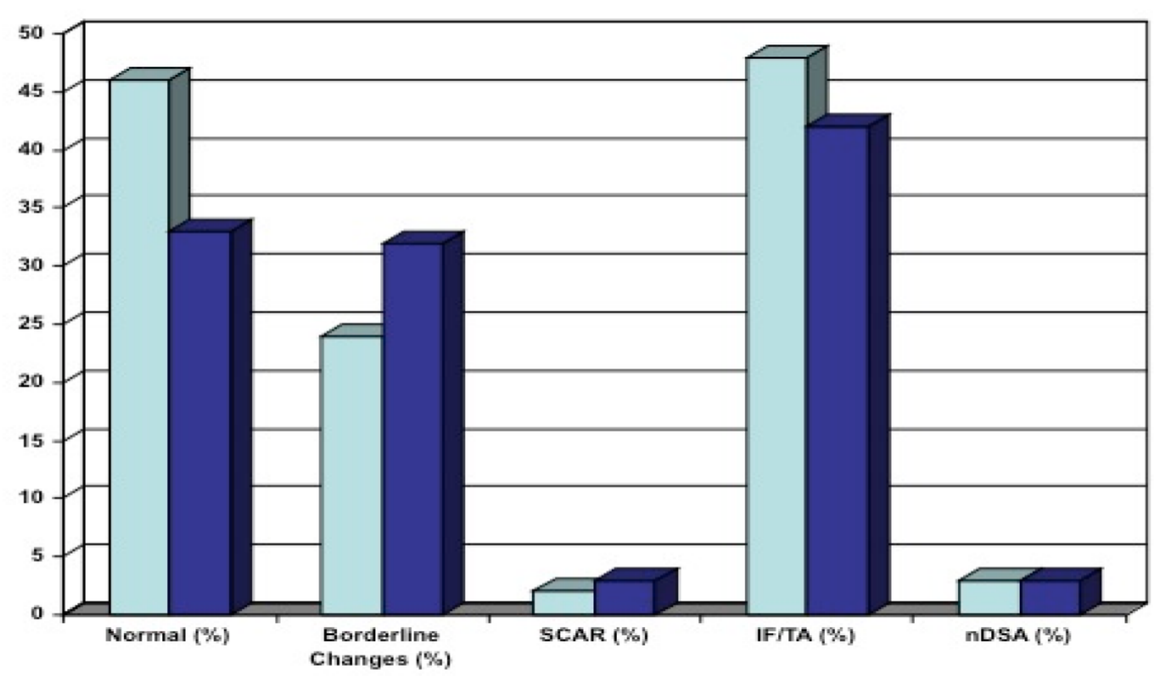

Figure 3. Histology and immunomonitoring

CONCLUSIONS

De novo use of Adoport in patients submitted to renal transplant is safe and effective.

DOI: 10.3252/pso.eu.52era.2015