

# 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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## Introduction & Objects

### Introduction

- Because of well-known adverse effects of steroids and introduction of new effective immunosuppressants
- The use of steroid withdrawal protocols after kidney transplantation has been increasing

### Objects

- To compare the long-term efficacy and safety of tacrolimus plus mycophenolate mofetil (TAC group) versus cyclosporine A plus MMF (CsA group) after steroid withdrawal 6 month after living-donor renal transplantation in low immunologic risk patients; 10-year follow up

## Methods

### Study design

- Retrospective single center study, Samsung Medical Center
- Follow up period : From September, 2000 to March, 2015 or patient death

### Study subjects

- 1<sup>st</sup> living-donor renal transplantation with low immunologic risk
- Between September 2000 and August 2003
- 131 patients were randomized to CsA or TAC groups
- 117 patients (55 in CSA group vs 62 in TAC group) satisfied **the criteria for steroid withdrawal** (no biopsy-proven rejection episode and serum creatinine <2.0mg/dl 6 months after transplantation )

### Outcomes

- Patient and graft survival, and the incidence of acute rejection and post-transplant de-novo comorbidity such as diabetes mellitus

## 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

## Reference

- Lee YJ et al. *Randomized trial of cyclosporine and tacrolimus therapy with steroid withdrawal in living-donor renal transplantation: 5-year follow-up.* *Transplant Int.* 2010 Feb;23(2):147-5
- Pelletier RP et al. *Prospective, randomized trial of steroid withdrawal in kidney recipients treated with mycophenolate mofetil and cyclosporine.* *Clinical transplantation* 2006; 20: 10-8.
- Rizzari MD et al. *Ten-year outcome after rapid discontinuation of prednisone in adult primary kidney transplantation.* *Clinical journal of the American Society of Nephrology : CJASN* 2012; 7: 494-503.

## Results

Table 1. Baseline characteristics

	CsA group (n=55)	TAC group (n=62)	P value
Recipient Male(%)	26(47.3%)	39(62.9%)	0.09
Donor Male(%)	20(54.5%)	36(58.1%)	0.69
Recipient age(Years)*	38.5±9.5	38.8±9.2	0.67
Donor age(years)*	39.7±10.2	38.9±11.5	0.70
Donor source Living related	35(63.6%)	36(58.1%)	0.79
Number of HLA mismatches			
0	10(18.2%)	7(11.3%)	0.10
1	5(9.1%)	5(8.1%)	
2	12(21.8%)	9(14.5%)	
3	17(30.9%)	22(35.5%)	
4	8(14.6%)	14(22.6%)	
5	1(1.8%)	2(3.2%)	
6	2(3.6%)	3(4.8%)	
Median(IQR)†	3.0(1.0-3.0)	3.0(2.0-4.0)	0.13
Panel reactive antibody			
0%	53(96.4%)	59(95.2%)	0.56
<50%	2(3.6%)	2(3.2%)	
>50%	0(0%)	1(1.6%)	
Body weight(kg)	58.0±7.6	62.6±11.0	0.01
Body mass index(kg/m2)	22.0±2.4	23.0±3.2	0.06

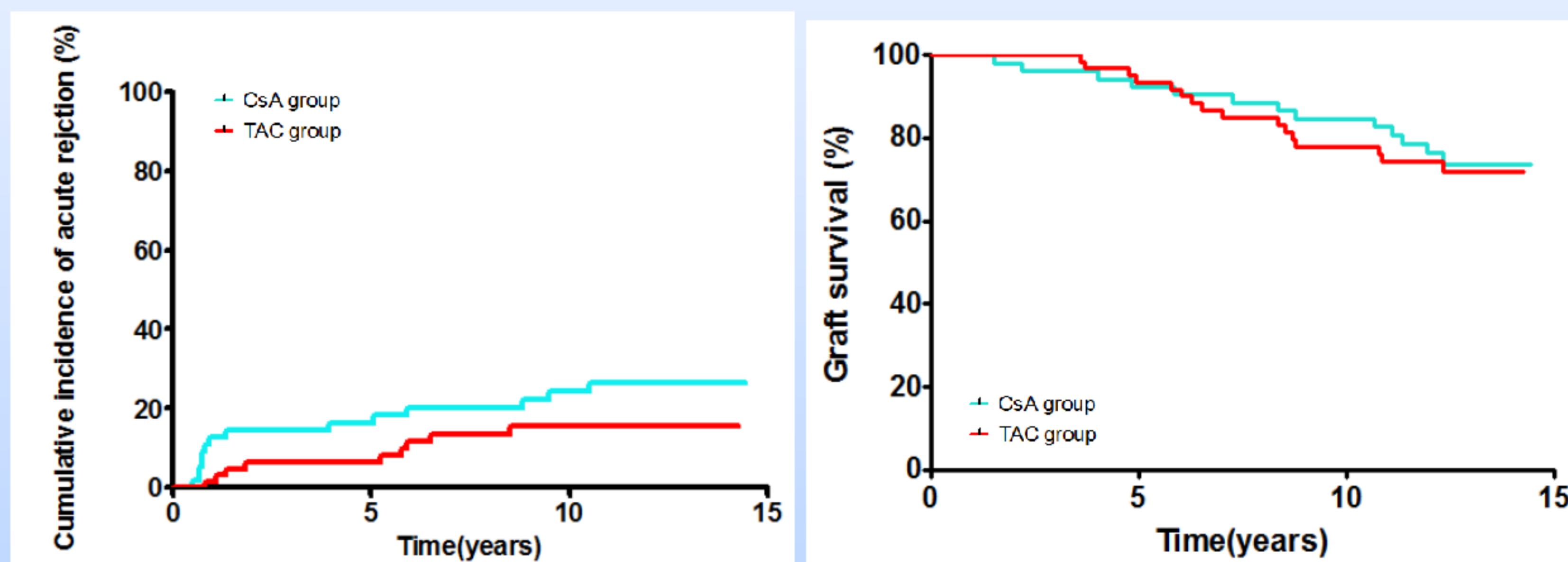
HLA, human leukocyte antigen

\*Mean ± SD. †Median(interquartile range).

### Patient and graft survival, Incidence of acute rejection

- The 10-year patient survival rate ;**  
96.2% in the CsA group(53/55) and 98.4% (61/62) in the TAC group (p=0.495)
- The 10-year graft survival rate ;**  
81.3% in CsA group vs 91.2% in TAC group (p=0.412)
- The cumulative incidence of acute rejection for 10 years after transplantation ;** 24.5% and 15.6% in the CsA and TAC groups, respectively (p=0.201)

Figure 2. Graft survival and Cumulative incidence of acute rejection



### Post-transplant de-novo comorbidity

- 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)
- Incidence of other de-novo comorbidities** such as dyslipidemia, hypertension, ischemic heart disease, opportunistic infection did not differ between two groups.

