The appropriate dose of thymoglobulin induction therapy in kidney transplantation

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Introduction and Objectives

Thymoglobulin is used effectively as an induction agent in kidney trans- plantation, but there is no consensus on the optimal dose. In order to delineate the safest effective dose, an open-labeled randomized clinical trial was designed.

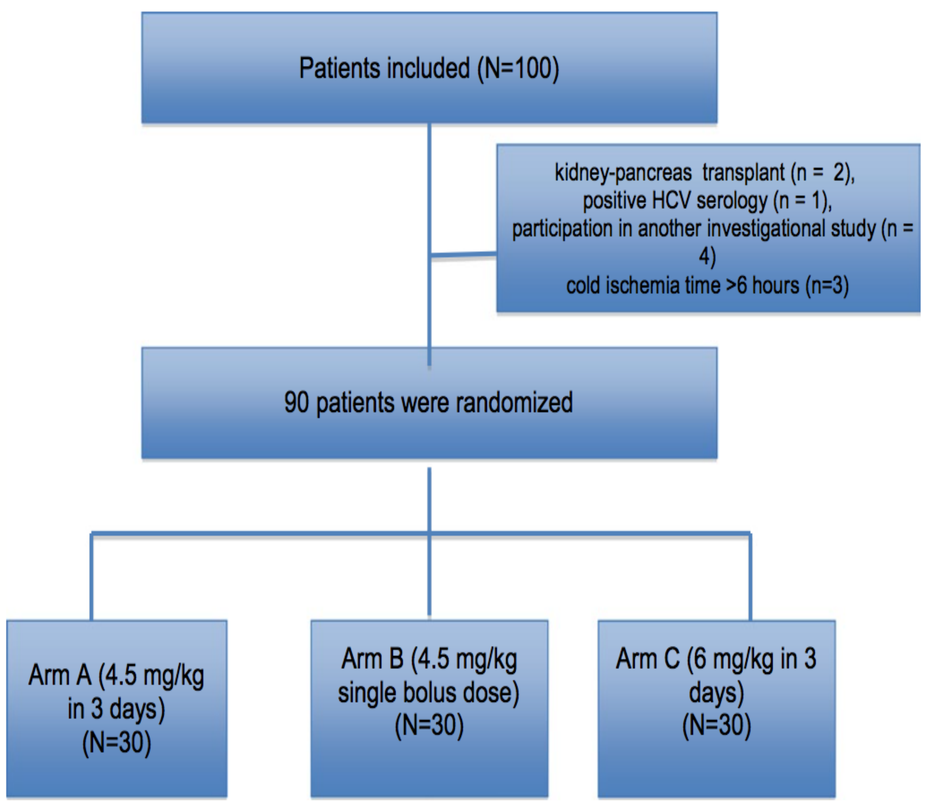
Methods

In this study, 90 adult kidney transplant recipients (KTR) were randomized before transplantation in three groups to receive thymoglobulin: Arm A (4.5 mg/kg in 3 days), Arm B (4.5 mg/kg single bolus dose), and Arm C (6 mg/kg in 3 days). Renal function, infections, and rate of readmissions were evaluated during the first post transplantation year.

Box 1 Inclusion and exclusion criteria

Inclusion Criteria
Positive PRA (> 0%) at the time of transplantation
History of previous transplantation
Age between 18 and 65 years
Extended criteria donor (ECD)
Cold ischemia time > 6 hours
Exclusion Criteria
Multiple organ transplants
Serological evidence of human immunodeficiency virus or active
hepatitis B and C in recipients or donors

PRA, panel reactive antibodies.



Results

Ninety adult kidney recipients were enrolled (51% deceased donor). No sig- nificant statistical difference was found in acute rejection episodes or type of rejection between these groups, although patients in Arm A showed more severe histopatho- logic changes according to Banff 2013 criteria, in renal biopsies (*P*=.03). At the first month after transplantation serum Cr was lower (*P*=.001) and GFR was higher (*P*=.04) in Arm A, but there was no significant difference among the three groups at 3, 6, and 12 months post-transplant.

Conclusion

Although all regimens showed the same efficacy regarding the rate of re- jection episodes, 3-day 4.5mg/kg Thymoglobulin had significantly fewer complications.

	Arm A (n=30)	Arm B (n=30)	Arm C (n=30)	P-value
Serum creatinine (mg/dL)				
Baseline	7.5±0.6	9.5±1.2	8±1.1	.125
1 mo	1.5±0.2	2±0.5	1.9±0.5	.001
6 mo	1.3±0.3	1.5±0.7	1.6±0.3	.343
12 mo	1.5±0.3	1.5±0.8	1.6±0.5	.331
GFR (mg/mL)				
Baseline	9.3±1.6	10.5±2	9.8±1.8	.346
1 mo	59.5±6	55.3±8	56±7	.002
6 mo	68.5±6	66±10	65±7	.432
12 mo	64.5±7	63.5±7	64±8	.631
Rejection types				
Cellular	1	1	1	.1
Humoral	1	1	1	
Histologic evidence (%)				
g	2 (7%)	1 (4%)	1 (4%)	.03
ptc	2 (7%)	0	1 (4%)	

Mean ± SD.

GFR, glomerular filtration rate; g, glomerulitis; ptc, peritubular capillary.

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