Oral pH-modified release budesonide for preventing recurrence of IgA nephropathy in kidney transplant recipients: a single center experience

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Introduction

- Recurrence rate of IgA nephropathy (IgAN) after kidney transplantation (KT) varies between 13 - 58%;
- IgAN recurrence is associated with a higher risk of kidney graft loss;
- There are no known preventive therapies for IgAN recurrence so far;
- Oral budesonide has demonstrated promising results in patients with IgAN on native kidneys, but studies on recurrence management after KT are lacking;
- We sought to evaluate the effect of oral pH-modified release budesonide in preventing recurrence of IgAN in KT recipients;

Methods

Study type: prospective, open-label

Number of patients: 19 KT recipients

Enrollment period: 2021-2023

Inclusion criteria:
- Biopsy-proven IgAN on native kidneys
- Age >18 years
- KT performed in Fundeni Clinical Institute, Department of Kidney Transplantation
- Follow-up for at least 6 months

Follow-up period (median): 15 months (10-22)

Treatment: 3mg of oral pH-modified release budesonide from day 45 after KT

IgAN recurrence diagnosis: kidney graft biopsy at indication
- SCr increase ≥ 25% from baseline *or*
- A/C >500mg *or*
- Persistent hematuria

Primary endpoint: clinically significant and biopsy-proven IgAN recurrence

Secondary endpoints:
- Mean change of eGFR from baseline
- Percentages of proteinuria ≥ 0.5 g/24h, hematuria, creatinine increase ≥ 25% from baseline
- Incidence of graft loss
- Incidence of rejection
- Drug tolerability

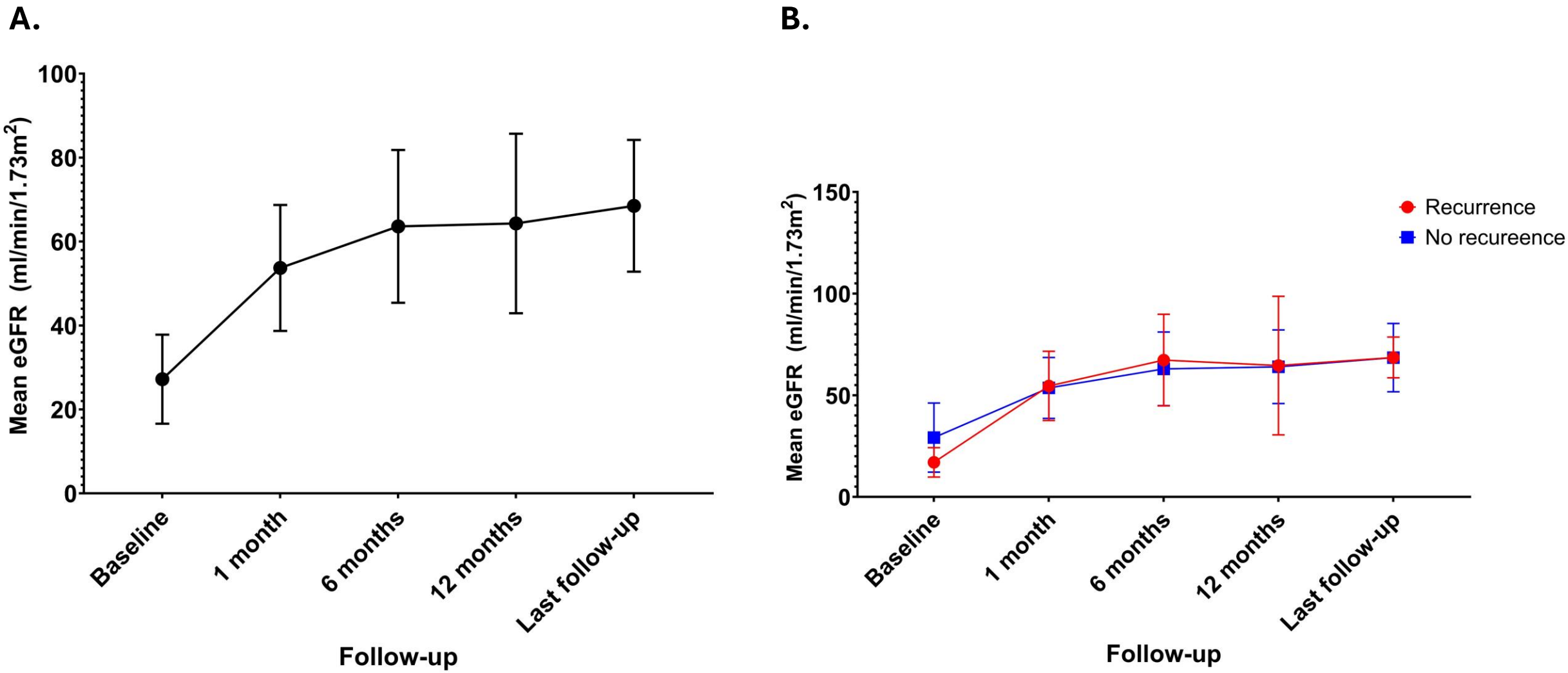
Results

Table 1. Patients' characteristics and outcomes

Recipient variables		Outcomes	
Age (mean, years)	42.4± 7.5	IgAN recurrence (%)	3 (15.8%)
Male gender (%)	14 (73.7%)	Proteinuria≥ 0.5g/24h (%)	4 (21.1%)
Dialysis before KT (%)	13 (68.4%)	Hematuria	7 (36.8%)
Previous KT (%)	1 (5.3%)	Creatinine increase ≥ 25% from baseline	4 (21.1%)
IgAN recurrence on previous graft (%)	1 (5.3%)	Graft loss (%)	0 (0%)
HTN (%)	19 (100%)	Rejection (%)	1 (5.3%)
Diabetes (%)	1 (5.3%)	Adverse events (%)	0 (0%)
Obesity (%)	3 (15.8%)	**Biopsy reasons**	
Serum creatinine in the first 48h after KT (mean, mg/dl)	3.4± 1.5	Proteinuria	1 (5.3%)
eGFR in the first 48h after KT (mean, mg/dl)	27.3± 10.6	Proteinuria and hematuria	1 (5.3%)
Preformed HLA-DSA (%)	2 (10.6%)	Creatinine increase	2 (10.6%)
Donor variables		Creatinine increase and proteinuria	1 (5.3%)
Age (mean, years)	52.5%± 14.2	**MEST-C score (IgAN recurrence)**	
Male gender (%)	15 (78.9%)	M0	1 (33.3%)
Living donor type (%)	11 (57.9%)	M1	2 (66.7%)
Transplant variables		E0	3 (100%)
HLA compatibility (mean, %)	50.8± 17.0	E1	0 (0%)
CIT (median, mins)	60 (30- 700)	S0	3 (0%)
WIT (mean, mins)	25.0± 5.6	S1	0 (0%)
Induction immunosuppression (%) ATG Basiliximab	 7 (36.8%) 12 (63.2%)	T0 T1 T2	3 (100%) 0 (0%) 0 (0%)
Maintenance immunosuppression (%) Tacrolimus, mycophenolate, prednisone	19 (100%)	C0 C1 C2	3 (100%) 0 (0%) 0 (0%)

Results

Figure 1. eGFR evolution in the entire cohort (A) and according to recurrence status (B)



Conclusion

- The recurrence rate of IgAN after KT was 15.8% under preventive treatment with oral pH-modified release budesonide;
- None of the patients experienced graft loss;
- The incidence of rejection was 5.3%;
- No difference regarding eGFR change was observed between patients with and without recurrence;
- No adverse events have been observed;