INDUCTION THERAPY IN RENAL TRANSPLANTATION WITH ANTITHYMOCYTE GLOBULIN AND BASILIXIMAB- A SINGLE CENTRE RETROSPECTIVE STUDY

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ABSTRACT

BACKGROUND

Renal transplantation is the best available form of renal replacement therapy. Induction therapy pre-transplant reduces the incidence of graft rejections. We present a retrospective study comparing different induction methods in living donor kidney transplantation in our institute.

MATERIALS AND METHODS

We analysed 423 live kidney transplant recipients of our center from Dec 2010 to Nov 2015, 344 of whom received basiliximab as induction and 79 r-ATG as induction. Primary outcomes like patient survival and graft survival, secondary outcomes like graft rejections, infections, PTDM, recurrence of disease were compared.

RESULTS

5yr patient survival rates were observed to be 91% and 88% respectively whereas graft survival rates were 93% and 86% respectively for ATG and basiliximab. Incidence of rejections was similar (p=0.867). Cellular rejections were more common with basiliximab (7.9% vs. 3.8%) but statistically not significant (P=0.498). Infections in the post-operative period were more common in r-ATG arm especially LRTI (P=0.011) and diarrhoeal episodes (P=0.005). Incidence of cytopenias was more in r-ATG arm during hospital stay (10.1 vs. 2.6% P=0.002) and also the later followup period (25 vs. 12.4% P<0.001). Incidence of PTDM was more in basiliximab (33.8% vs. 22.8%) arm but not significant (P=0.061).

CONCLUSION

ATG and basiliximab are non-inferior to one another as induction therapy. ATG is effective in high immunological risk groups with equivalent graft and patient survival with increased risk of Lower respiratory tract infections and diarrhoea in immediate post-transplant periods and increased risk for cytopenias compared to basiliximab. Basiliximab has slightly increased risk of post-transplant diabetes mellitus. Careful selection of the agent in an individual based on risk rather than a question of efficacy of agents is the key to successful transplantation.

KEYWORDS

Renal transplantation, Antithymocyte-globulin, Basiliximab, Immuno-Suppression.

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BACKGROUND

Renal transplantation is the best available form of Renal replacement therapy. Induction therapy has significantly reduced the incidence of acute rejection episodes and graft loss following kidney transplantation. Anti-thymocyte globulin (ATG), a polyclonal antibody preparation was licenced to use in kidney transplantation in the 1980s[1] where as basiliximab a high affinity monoclonal antibody against human IL-2 receptor was introduced in late 90s.[2] Basiliximab spares the T lymphocyte progenitors. There were many predecessors of basiliximab like 33B3.1.[3] Induction therapy has evolved over the years and has made possible transplants among individuals with little genetic matching. The choice of induction therapy was historically based on the efficacy of the different induction agents to prevent rejection. In the present era, the choice of induction therapy is based on the risk benefit ratio in individual patient.[2] We present a study comparing different induction methods in Living donor kidney transplantation using related or spousal donors in our institute.

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MATERIALS AND METHODS

Study Design

A retrospective study of 423 patients who underwent living donor renal transplantation and received either rabbit Anti-thymocyte globulin or Basiliximab (Simulect) as induction from December 2010 to November 2015. Deceased donor recipients were excluded from the study. Patients who

received no induction were excluded from the study. Patients were followed up till November 2016.

Induction Therapy

Patients received r-Antithymocyte globulin or basiliximab based on their immunological risk. High immunological risk received Antithymocyte globulin and low immunological risk received basiliximab. High immunological risk included patients undergoing second renal transplants, previous CDC crossmatch positive patients, patients with donor specific antibodies and flow cytometry crossmatch positive patients and combination of these.

r-ATG was given just before surgery through a central venous catheter over 4 hours. The initial dose is 1.5 mg/kg body weight and two subsequent doses were given on the second and fourth postoperative days respectively, a total of about 4.5 mg/kg body weight. Premedication with Inj. chlorpheniramine and hydrocortisone were given. Most of the patients received three doses of r-ATG but few patients were given lesser doses if infection was suspected or if the Absolute neutrophil count fell down to less than 1500/mm^3. Valganciclovir prophylaxis was started and continued for 3 months in all patients who received r-ATG.

Basiliximab was given through peripheral IV line. The dose used was 20 mg by slow injection just before the patient undergoes surgery. The second dose was repeated on the third postoperative day.

Written informed consent was taken from all the patients or their near relatives explaining the risks and benefits of induction therapy.

Immunosuppression

Immunosuppression with Tacrolimus 0.1 mg/kg body weight or Cyclosporine 15 mg/kg/day in divided doses and Mycophenolate mofetil 1.5 to 2 g was started 2 days before transplantation. Inj. Methyl prednisolone 500 mg was given IV intraoperatively and oral steroid 20mg was started on the first postoperative day. During the first month, the tacrolimus trough levels were maintained at 10-12 ng/ml and 8-10 ng/ml during the next 2 months, decreased to 6-8 ng/ml during the next 3 months and maintained at a stable level of 4-6 ng/ml.

Infection Prophylaxis

All the patients received prophylaxis against pneumocystis carinii for 1 year. All the patient received prophylaxis against fungal infections with either clotrimazole lozenges or clotrimazole mouth paint for atleast 6 months. Prophylaxis for CMV with Valganciclovir for 3 months is given for all patients who were given Antithymocyte globulin for induction.

Diagnostic Labelling Standards

Delayed graft function was defined as requirement of dialysis in the first week following renal transplantation surgery.

Rejection was diagnosed by clinical symptoms signs and graft biopsy showing evidence of rejection. Post-transplant Diabetes Mellitus is defined as requirement of insulin or oral hypoglycaemic agents in recipients after the 6^{th} month of transplantation when the doses of immunosuppression are stabilised. Leukopenia is defined as Total White blood cell count below 3500/mm^3 requiring treatment with GM-CSF 30 mcg subcutaneous injection.

	ATG	Basiliximab	p-Value
Age Recipient	36.66+/-10.83	36.53+/-11.6	0.987
Weight (kg)	55.37+/-11.03	56.21+/-13.3	0.645
Height (cm)	163.67+/-7.54	162.32+/-10.4	0.508
Duration of Dialysis(months)	14.15+/-9.88	12.52+/-9.2	0.12
Gender			0.49
Male	65(82.3%)	307(90.3%)	
Female	14(17.7)	33(9.7)	
CAD	3(3.8%)	16(4.7%)	0.738
Diabetes Mellitus	14(17.7)	42(12.2)	0.200
Hypertension	74(94.9%)	298(87.4%)	0.072
Previous TB	12(15.2%)	52(15.4%)	>0.05
Previous Stroke	1(1.4%)	2(0.6%)	0.494
Hepatitis B	2(2.5%)	11(3.2%)	0.754
Hepatitis C	6(7.6%)	25(7.3%)	>0.05
Dialysis Access			0.898
AV Fistula	74(93.7%)	31(91.5%)	
IJV	2(2.5%)	9(2.6%)	
Tunnelled Catheter	1(1.3%)	6(1.7%)	
CAPD	1(1.3%)	3(0.9%)	
No Access	1(1.3%)	11(3.2%)	
ABOI	6(7.6%)	15(4.4%)	0.235
Basic Disease			0.768

CGN	34(43%)	164(47.8%)	
CIN	27(34.2%)	101(29.4%)	
ADPKD	4(5.1%)	7(2%)	
DKD	11(13.9%)	40(11.7%)	
Solitary Kidney	0	8(2.3%)	
MPGN	0	5(1.5%)	
IGAN	1(1.3%)	4(1.2%)	
CIN –Obstructive Uropathy	2	2(0.6%)	
PUV		3(0.9%)	
ANCA GN		1(0.3%)	
ANCA ANTI GBM GN		1(0.3%)	
Idiopathic Crescentic		1(0.3%)	
Lupus Nephritis		1(0.3%)	
Nephrolithiasis		2(0.6%)	
Patchy Cortical Necrosis		2(0.6%)	
Multicystic Dysplastic Kidney		1(0.3%)	
Reflux Nephropathy		1(0.3%)	
Table 1			

Lower respiratory tract infection was diagnosed by clinical signs, radiological evidence and sometimes sputum culture showing organisms. UTI was diagnosed by urine examination, urine culture or radiological evidence of infection. CMV infection is defined as positive CMV PCR.BK virus nephropathy is diagnosed by positive BK Virus PCR and Viral cytopathic changes and tubulointerstitial nephritis on kidney biopsy.

Patients were discharged after they attain a stable s. creatinine and DJ stent removal.

	ATG	**Basiliximab**	
HLA MATCH	2.35+/-1.40	2.58+/-1.44	0.214
0	9(11.4%)	37(10.8%)	
1	15(19%)	48(14%)	
2	12(15.2%)	52(15.2%)	
3	27(34.2%)	125(36.4%)	
4	9(11.4%)	51(14.9%)	
5	5(6.3%)	23(6.7%)	
6	0	6(1.7%)	
Flow Cytometry			<0.001
B Cell Positive	2(2.5%)	0	
T Cell Positive	4(5.1%)	0	
Negative	22(27.8%)	146(42.6%)	
Test unavailable	51(64.6%)	197(57.4%)	
DSA			<0.001
Class 1 Positive	13(16.5%)	4(1.2%)	
Class 1, 2 Positive	2(2.5%)	0	
Negative	42(53.2%)	222(64.7%)	
Test Unavailable	22(27.8%)	117(34.1%)	
Second Transplant	11(13.9%)	1(0.3%)	
Tacrolimus	74(93.7%)	331(96.5%)	0.249
Cyclosporine	5(6.3%)	12(3.5%)	
Table 2			

Clinical Parameters

Patients were compared with respect to their graft survival and patient survival and survival rates were calculated. Incidence of infections during immediate post-transplant period during hospital stay and after discharge were calculated. Incidence of Cytopenias during hospital stay and after discharge and Post-transplant Diabetes mellitus are calculated.

Graft loss was defined as returning to maintenance dialysis. Cases lost to follow up and death of functioning graft were censored during analysis.

Statistical Analysis

The results were analysed using SPSS version 20.0. The categorical variables were analysed using Chi-square test or Fischer exact test. The non-parametric variables were analysed using the Independent samples T test. Survival was analysed through Kaplan-Meier survival analysis and the Log rank test. A significance level of 0.05 was used.

RESULTS

During Hospital Stay			
INFECTIONS DDUR HOSPITAL STAY	ATG	BASILIXIMAB NUMBER	P VALUE
CVP LINE INFECTION	4(5.1%)	7	0.128
LRTI	14(17.7%)	27(7.9%)	0.011
DIARRHOEA	7(8.9%)	8(2.3%)	0.005
URTI	1(1.3%)	5(1.5%)	0.897
UTI	8(10.1%)	24(7%)	0.348
TOTAL INFECTIONS	22(27.8%)	61(17.8%)	0.058

Table 3

Immediate Postop Hospital Stay	ATG No.	Basiliximab No.	p-Value
Cytopenias	8(10.1%)	9(2.6%)	0.002
Thrombocytopenias	7(8.9%)	11(3.2%)	0.025
Leukopenia	9(11.4%)	10(2.9%)	0.001
Methyl Prednisolone during Hospital Stay	6(7.6%)	64(18.7%)	0.001
Transient Hyperglycaemia	41(51.9%)	199(58.4%)	0.314
Delayed Graft Function	2(2.5%)	9(2.9%)	0.963
Allograft Dysfunction	19(24.1%)	104(30.5%)	0.336
Biopsy	20(25.3%)	82(24.2%)	0.884
Rejection	8(10.1%)	33(9.6%)	0.835
Recurrence of Diseases	2(2.6%)	14(4.1%)	0.182
Everolimus Conversion	1(1.3%)	8(2.3%)	

Table 4

Baseline Characteristics

The patient populations treated with Antithymocyte globulin and Basiliximab were not different from each other with respect to recipient age, BMI, time on dialysis prior to transplantation, basic kidney disease and comorbidities like coexisting CAD, Diabetes, Hypertension and hepatitis B and C seropositive status. There was no significant difference between the two populations with respect to the HLA match but the ATG group had higher proportion of patients with DSA or Flow cytometry cross-match positivity. The number of second transplants were higher in the ATG group. Donor characteristics like age, GFR, type and side of donor nephrectomy, donor kidneys with multiple vessels are not significantly different between the two groups. Immunosuppression received was also in same proportions.

Graft and Patient Survival

Graft survival rate at end of 5 yrs. was 93% in the ATG group and 86% in the basiliximab group. Patient survival rates at the end of 5 yrs. were 91% in the ATG group and 88% in the basiliximab group.

No significant difference observed between the two groups in Kaplan Meier method in patient survival (P=0.838 95% Confidence limits) and graft survival (P=0.917). S. Creatinine at 1 yr. was not significantly different between the two groups (ATG Vs Basiliximab-1.24+/-0.47 Vs 1.56+/-0.50.). There were 2 instances of delayed graft function in ATG (2.5%) whereas 9 recipients in basiliximab (2.6%). There were no significant differences between mean duration of hospital stay and the number of hospital admissions post discharge between the two groups.

Rejections

Incidence of biopsy proven acute rejections were 15.2% in the ATG group and 16.9% in the basiliximab group (p=0.867). Cellular rejections were more common with basiliximab (7.9%) when compared to ATG (3.8%) but statistically not significant (P=0.498). Basiliximab arm received more methyl prednisolone pulses during hospital stay (P=0.001) indicating more early rejections which were not proved by biopsy.

	ATG	Basiliximab	p-Value
Rejection Total	12(15.2%)	58(16.9%)	0.867
Cellular Rejection	3(3.8%)	27(7.9%)	0.498
ABMR	6(7.6%)	23(6.7%)	0.805
Mixed Rejection	2(2.5%)	8(2.4%)	0.916
Bx CNI Toxicity	2(2.5%)	9(2.6%)	0.963
CRAI	15(19%)	51(15%)	0.391
Chronic Rejection	6(7.6%)	18(5.3%)	0.417
Graft Loss	3(3.8%)	14(4.1%)	0.9
Death of Functioning Graft	0	8(2.8%)	0.171
Mortality	4(5.1%)	20(5.8%)	0.786
Total Graft Loss	7(8.9%)	26(7.58%)	0.650

Table 5

Complications

Post Discharge Infections	ATG No. 73	Basiliximab No. 317	p-Value
Invasive Fungal Infections	7(8.9%)	20(5.8%)	0.313
Fungal Skin Infections	1(1.3%)	5(1.5%)	0.897
Diarrhoeas	26(32.9%)	97(28.3%)	0.413
UTI	13(16.5%)	62(18.1%)	0.871
BKV	1(1.3%)	5(1.5%)	0.897
CMV	6(7.6%)	19(5.5%)	0.485
TB	3(3.8%)	15(4.4%)	0.819
Varicella	2(2.5%)	9(2.3%)	0.960
Deep Seated Infections	4(5.1%)	0	0.129
LRTI	10(12.7%)	45(13.1%)	>0.05
Cytopenias	25(31.6%)	42(12.4%)	<0.001
PTDM	18(22.8%)	116(33.8%)	0.061

Table 7

Infections in the post-operative period were more common in r-ATG arm especially LRTI (17.7% vs. 7.9%) (P=0.011) and Diarrhoeal episodes are also more with Antithymocyte globulin (8.9% Vs. 2.3%) (P=0.005). Incidence of cytopenias was more in r-ATG arm during hospital stay (10.1 vs. 2.6% P=0.002) and also the later followup period (25 vs. 12.4% P<0.001). The occurrence of transient hyperglycemia is equivalent (51.9% in ATG Vs 58,4% in basiliximab) in both groups. Incidence of PTDM was more in basiliximab (33.8% basiliximab vs. 22.8% ATG) arm but not significant (P=0.061). 24 deaths occurred and cause of death was sepsis in most with no difference between two groups (5.1% and 5.8%, P=0.786).

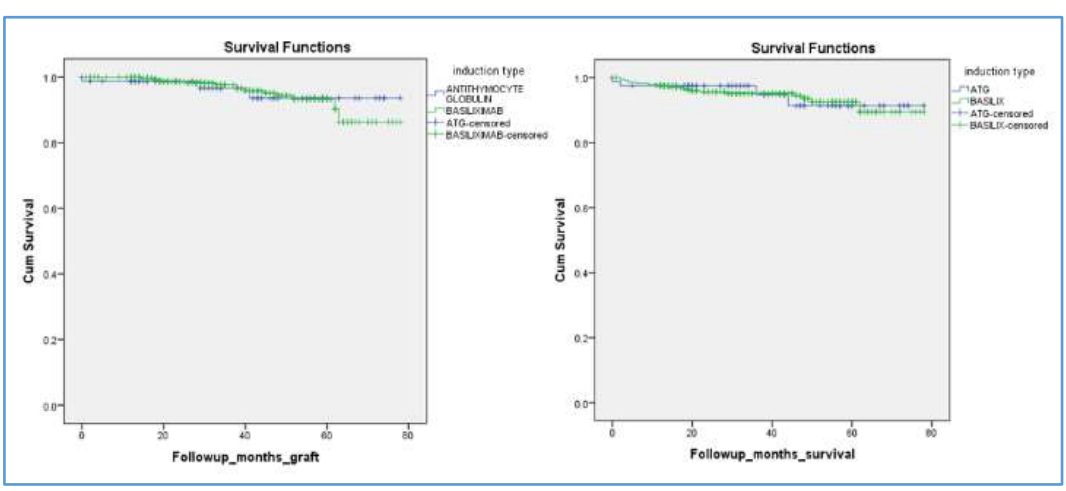

Image 1

DISCUSSION

Basiliximab had comparable efficacy with ATG in the prevention of Acute allograft rejections. The incidence of acute rejection is recognised as an important predictive factor for late allograft function. We compared the effects of induction therapy in recipients of Live related renal transplantation from 2010 to 2015 over 6 yrs. Earlier studies comparing these two induction agents included both biopsy-proven and presumed rejections but we compared only the biopsy proven rejections. There was one previous retrospective study in India comparing induction strategies with ATG and basiliximab.[4] Many randomised controlled trials[3,5,6,7,8] and retrospective trials[4,9-17] were done to compare the induction agents.

Recent studies showed that Antithymocyte globulin was more effective in the prevention of acute rejection when compared to basiliximab.[13,15] Except the Mexican study in deceased donors.[17] In our study acute rejections between the two arms were comparable (ATG 15.2% Vs. Basiliximab 16.9%, P=0.867). There was a trend of better graft and patient survival with ATG but this was not statistically significant. Worse unadjusted survival was seen in ATG group in Patlolla series probably because of selection bias.[18]

Even though the Antithymocyte globulin group had a bad patient profile in terms of number of second transplant candidates and flow cytometry and Donor specific antibody positivity, the graft and patient survivals were comparable between the two groups similar to Kim et al[14] and Sancho et al.[16] Even in paediatric renal transplantations ,both the induction agents are of comparable efficacy and early toxicities are similar.[19] This is not a head to head comparison study between induction agents because the sensitized patients in our centre received Antithymocyte globulin according to our protocol.

Haematological adverse effects were more common in the ATG group. Cytopenias were seen in 31.6% vs. 12.4% basiliximab. This includes the effects of CMV infection and Valganciclovir used for prophylaxis. This is more than previously done retrospective study in India by Kesiraju et al.[4]

The rate of bacterial, fungal and viral infections was comparable in both the groups. Similar to Liborio et al[11] The rate of Lower respiratory tract infection was higher in ATG group 15.2% vs. 10.5% in basiliximab group similar to Wang et al.[13] The incidence of UTI was similar between the two groups (13.3% vs. 12.5%) in contrast to Huang et al[20] where there was higher incidence of UTI in ATG group.

Incidence of CMV infection was slightly higher in ATG group vs. basiliximab group (7.6% vs. 5.5%) but was not significant (P=0.485). This is similar to the Huang et al study(20) where there was insignificant difference but different in Kim et al, Liborio et al., Ulrich et al and Haririan et al.[11,12,14,21] where there was significantly higher incidence in ATG group. In contrast to these studies Brennan et al.[7] found higher incidence in basiliximab group. The incidence of CMV infection is more in both groups when compared to previous studies Kesiraju et al[4] who used lesser doses of ATG and used CMV prophylaxis in both groups but less than the incidence in Ulrich et al and Kim et al.[12,14]

There were two previous studies from India Kesiraju et al[4] and Patel et al. The death censored graft loss was 3.8% in ATG group and 4.1% in the basiliximab group. Total graft loss was 8.9% in the ATG group and 7.58% in the basiliximab group less than previous studies done in India.

The main limitations of this study are the level of sensitization of the recipients could not be matched between the two groups which is inherent to retrospective studies. The lymphopenia due to ATG which contributes to its efficacy could not be evaluated because no monitoring of differential count was done routinely.

CONCLUSION

ATG and basiliximab are non-inferior to one another as induction therapy. ATG is effective in high immunological risk groups with equivalent graft and patient survival with increased risk of lower respiratory tract infections and diarrhoea in immediate post-transplant periods and increased risk for cytopenias compared to basiliximab. Use of routine CMV prophylaxis after ATG induction has decreased incidence of CMV infection so the comparable incidence to basiliximab. Basiliximab has slightly increased risk of post-transplant diabetes mellitus.

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