AMERICAN JOURNAL OF PHARMTECH RESEARCH

Journal home page: http://www.ajptr.com/

A Study of An Efficacy of Tacrolimus (Generic Form) In Renal Transplant Recipients

KhajaRamizuddinMahammad[1]*, Shiv ShankerPunna[1], VenkataSravaniPolamraju[1], SrikalaPatha[2]

1.Department of Pharmacy, Bharat Institute of Pharmacy, Jawaharlal Nehru Technological University, Andhra Pradesh, India

2.PharmD,Head of Department, Department of Pharmacy, Bharat Institute of Pharmacy, Jawaharlal Nehru Technological University, Andhra Pradesh, India

ABSTRACT

This study helps to determine the efficacy of tacrolimus (generic form) in renal transplant patients in India. To assess the efficacy of tacrolimus in renal transplant recipients by using graft survival rate (primary objective) and patient survival rate (secondary objective). This is a retrospective study involving collection of data from medical records of patients who underwent renal transplantation in between JUNE 2010-JUNE 2013 at a tertiary care hospital) in India. Study population involves 65 patients between age group of 10-60 years, Male and Female gender, patients receiving tacrolimus (generic form) in their immunosuppressive regimen. Exclusion criteria involved patients with hyperacute graft dysfunction, patients who did not receive tacrolimus as a part of immuno suppressive regimen. Tacrolimus was given in combination with mycophenolatemofetil, corticosteroids. Tacrolimus was given at a dose of 0.15 mg/kg and titrated based on the graft function, trough levels of tacrolimus and other parameters. Of 65 patients,59 were men and 6 were women.86% of patients received graft from living donor, where as 14 % of patients received from cadaveric donor. Graft survival rates for the 1st, 2nd, 3rd years of transplantation were found to be 93.84%,89.23%,87.68 %.Patient survival rate was 98.46% during the 1st year, and it remained same for the succeeding years with no loss of patient lives. The main limitations of this study are inadequate sample size and retrospective nature of study. Through this study, it was concluded that tacrolimus(generic form) demonstrated efficacy in majority of renal transplant patients in preventing graft rejection and maintained favorable function for a period of 3 years.

*Corresponding Author Email: khajaramiz@gmail.com

Received 13 May 2014, Accepted 07 June 2014

Please cite this article as: Mahammad KR *et al.*, A Study of An Efficacy of Tacrolimus (Generic Form) In Renal Transplant Recipients. American Journal of PharmTech Research 2014.

INTRODUCTION

Tacrolimus, a potent calcineurin inhibitor is a widely used immunosuppressive drug in transplantation patients including renal transplantation. It`s efficacy and safety is well established through several studies that were conducted till date[1,2]. Although, there are well established evidences about it`s efficacy, there are a very few studies which indicates the efficacy of tacrolimus(generic form). The present study aims at evaluating the efficacy of tacrolimus (generic form) in renal transplant recipients in India.

To evaluate the efficacy of tacrolimus (genric form) in renal transplant patients in India. For this purpose, graft survival rate was selected as primary objective where as, patient survival rate was taken as a secondary objective.

MATERIALS AND METHODS

Design and data source:

This is a retrospective study conducted which involved collection of data from the medical records of the patients who underwent renal transplantation between the period of June 2010-June 2013 at a tertiary care hospital in India.

Subjects:

Patients between the age group of 10-60 years(Male and Female Gender),patients who has received the kidney from cadaver/living donor, patients receiving tacrolimus (generic form) in their immuno supressive regimen were included in the study .Exclusion criteria involved patients with hyperacute graft dysfunction, patients who did not receive tacrolimus (generic form) were excluded from the study.

Interventions:

Tacrolimus(generic form) was given at a dose of 0.15mg/kg along with mycophenolatemofetil at a dose of 1000 mg twice a day,oral prednisolone at a dose of 5 mg once a day. Dose of the tacrolimus (generic form) and maintenance therapy was titrated based on the requirements.

Outcome:

Graft survival rate (primary outcome) and patient survival rate (secondary outcome) were illustrated by using Kaplan Meier survival curve. A P value of less than 0.05 was considered to be statistically significant.

RESULTS AND DISCUSSION

Transplantation records of 65 patients were evaluated. Out of 65 patients, 56 were male and 9 were female. 86 %(56 subjects,50 were male,6 were female) of patients received the renal graft from

living donor whereas, 14%(09 subjects,6 were male,3 were female) of patients received the renal graft from cadaveric donor.

Table 1 :Graft And Patient Survival Rate (Kaplan Meier Survival Curve)

Survival time			Time	
Endpoint			Survival Function	
Factor			Group	
	Factors			
	Graft survival (1)		**Patient survival (2)**	
Sample Size	**65**		**65**	
Median Survival	-		-	
Survival Time	**Survival Proportion**	**Standard Error**	**Survival Proportion**	**Standard Error**
1	0.985	0.0153	0.985	0.0153
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
7	-	-	-	-
8	0.957	0.0308	-	-
9	-	-	-	-
10	0.925	0.0432	-	-
11	-	-	-	-
12	0.891	0.0535	-	-
14	0.852	0.0637	-	-
19	-	-	-	-
20	-	-	-	-
21	-	-	-	-
23	0.802	0.0772	-	-
24	0.752	0.0871	-	-
25	-	-	-	-
26	-	-	-	-
28	-	-	-	-
29	-	-	-	-
30	-	-	-	-
31	-	-	-	-
33	-	-	-	-
34	-	-	-	-
35	0.627	0.136	-	-
36	-	-	-	-
	Comparison of survival curves (Log rank test)			
Endpoint: Observed n	8.0			1.0
Expected n	4.4			4.6
Chi-squared	5.6577			
Degrees of Freedom	1			
Significance	P = 0.0174			

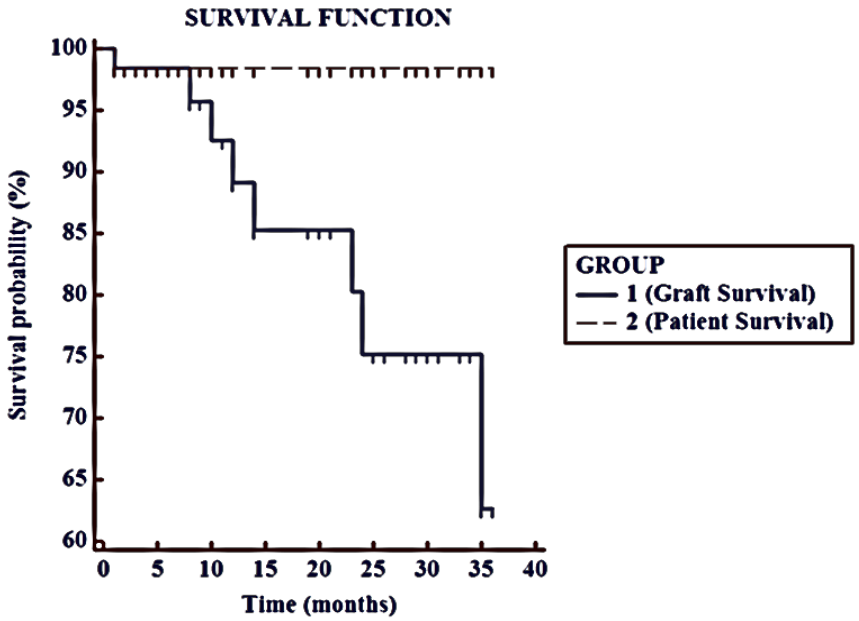

Figure 1: Graft And Patient Survival Rate (Kaplan Meier Survival Curve)

The graft survival rates of 3 years following treatment with tacrolimus (generic form) were found to be 93.84 % as there were 4 grafts which have failed in the first year, 89.23% in the second year due to failure of 7 grafts in total, by the end of second year, the graft survival rate was found to be 87.68% by the third year as the total of 8 were failed by the end of third year. One patient has expired during the first month of transplantation due to sepsis leading to survival rate of 98.46 % in the first year. No patient was expired in the second and third year of transplantation thus, patient survival rate remained same i.e., 98.46 % by the third year of transplantation.

The endpoint of time period for both the groups was selected as 36th month. Time period is defined as the time (in months) between JUNE 2010-JUNE 2013.Patients whose graft has dysfunctioned with in this time period was defined as the subjects who met the endpoint i.e., end of graft survival. Patients who did not meet the end point within the time period were selected as censored subjects because the outcome was unknown in those patients.

A graft was rejected in the first month of the transplantation and it lead to the drop in survival proportion(SP) of the graft to 0.98. Graft rejection was also seen in the 8th (SP-0.95), 10th (SP-0.92), 12th (SP-0.89), 14th (SP-0.85), 23rd (SP 0.80), 24th (SP-0.75), 25th (SP-0.62) months after transplantation. A subject was expired with in the first month of transplantation which leads to the drop in the patient survival proportion to 0.98.

P value was found to be 0.0174 and indicates that there is significant difference between the patient survival and graft survival rates. Remaining subjects did not meet the end point within the duration of study so, outcome in those patients was unknown and they were represented as

censored subjects on the graph. The main limitation of this study is small sample size, retrospective nature of study.

CONCLUSION:

Through this study, it was concluded that tacrolimus (generic form) demonstrated considerable efficacy by preventing the rejection of graft for a period of three years. Although, it is a drug with narrow therapeutic index, careful monitoring of the trough levels and dose titrations as and when needed will help to maintain favorable graft function in renal transplant patients. It`s availability in generic form makes it affordable to most of the patients.

REFERENCES

1. Webster A[1], Woodroffe RC, Taylor RS, Chapman JR, Craig JC.Tacrolimus versus cyclosporin as primary immunosuppression for kidney transplant recipients. Cochrane Database Syst Rev. 2005 Oct 19;(4):CD003961.