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Research article

A RETROSPECTIVE STUDY ON PHARMACOTHERAPEUTIC MANAGEMENT OF URINARY TRACT INFECTION IN POST RENAL TRANSPLANT RECIPIENTS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Renal transplant recipients should receive immunosuppressants to prevent graft rejection. By suppressing the immune response of the recipient, it increases the risk of opportunistic infections. Among all infections urinary tract infections (UTI) are the most common. So, our study deals with the nature of post transplantation urinary tract infections, its management. A retrospective observational study was carried out to retrieve data of renal transplantation patients to evaluate the incidence of Post renal transplant UTI. This study also focuses on Nature of UTI including relapse UTI, recurrent UTI. As post transplantation requires maintenance immunosuppression, there is a chance for ADRs associated with the therapeutic regimens. So, these reports were also analyzed for ADRs, Causality, Severity and preventability assessment.The available data from the medical records of 87 renal transplantation patients suggests that 42.46% of 73 males and 50% of 14 females had developed UTI during their follow up.UTIismostly observed in 21-40 age groups. Recurrent UTI is observed in 3 patients. Linezolid (12.19%) was mostly used as an antibiotic therapy in UTI. Our study revealed 48 of 87 patients had experienced ADR after transplantation andcausality assessment of ADRs showed 90.9% are probable. In our study, 37.66% of ADRs are mild, 59.74% are moderate and 2.59% are severe. Preventability assessment showed 35% of ADRs are definitely preventable, 22% are probably preventable, and 43% are not preventable.UTI are one amongst the opportunistic infections, untreated UTI may lead to significant mortality. Hence patientsshould be monitored throughout the post transplant treatment period including Immunosuppressive therapy and Antibiotic treatment..

Key Words:-Urinary tract infection, Post renal transplantation, Immunosuppressant, New onset of diabetes after transplantation.

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INTRODUCTION

Currently the best method for treating the patients with end-stage renal disease (GFR<15 ml/min) is renal transplantation and dialysis is of secondary importance (Ostaszewska A *et al*., 2014). The patient survival after renal transplantation is determined by multiple factors, including pre-transplant co-morbidities, type of graft, degree of immunosuppression (Kumar A *et al*., 2016). Immunosuppressant are used to prevent transplant rejection by making the immune system less efficient, unfortunately all immunosuppressant reduce resistance to infection as well as reducing the rejection(Mohan MVNLR *et al*., 2017). Renal transplant

recipients are at high risk of infections. The infections may be nosocomial or arise De-novo in the recipient, reactivated latent infection or graft contamination. Among all infections urinary tract infections are the most common and the other infections are Tuberculosis, Hepatitis B, Hepatitis C, Cytomegalovirus, Pneumocystis. The global prevalence of post- renal transplantation UTI varies between 6% and86%, and they commonly occur within the 1st year, especially the first 3–6 months following renal transplantation (Karunanayakey L *et al*., 2018).Underlying causes and predisposing factors contribute to increase in the development of urinary tract infections include excessive immunosuppression, female gender, deceased donor, instrumentation of the urinary tract (e.g: urethral catheters and ureteric stents) (Souza RMD, Jonathanolsburgh, 2008).The most common pathogens causing urinary tract infections are Escherichia coli, klebsiella , Staphylococcus aureus, Pseudomonas, Enterococcus, Streptococcus. The pathogenesis of UTI typically begins ascending to the bladder from the urethra. Pathologic invasion of the urothelium can then occur and is aided by bacterial virulence structures, such as P fimbriae, that promote adhesion (Parasuraman R, Julein K, 2013).The suggested management for urinary tract infection is Empiric oral therapy: Ciprofloxacin+/- Amoxicillin OR ceftriaxone OR Ampicillin-sulbactam, OR Piperacillin – Tazobactam and the treatment duration is 5-7 days .Early diagnosis and appropriate treatment of urinary tract infection are critical in renal transplant recipient.

The current study deals with the pharmacotherapeutic management of urinary tract infections and we aimed to study the causative organisms of urinary tract infections and the risk factors associated with it and to study the adverse drug reactions based on the use of immunosuppressants, antibiotic therapy.

METHODOLOGY

A Retrospective Observational Study was carried out in the department of Nephrology, Sri Venkateswara Institute of Medical Sciences, Tirupati from August 2018 to January 2019.This study was approved by institutional ethics committee(Roc.No.AS/11/IEC/SVIMS/2017).A total number of patients who underwent renal transplantation from the year 2000 including men and women with all age groups and patients with urinary tract infections are included in the study.Non-Renal Transplant recipients with urinary tract infections are excluded in this study. Adverse drug reactions associated with past medication, Induction therapy, Immunosuppressive therapy and antibiotic therapy were studied. The nature of adverse drug reactions was collected and recorded in suspected adverse drug reaction reporting form designed by Indian pharmacopoeia commission under Pharmacovigilance programme of India. The assessment of causality, severity and preventability of ADRs by using World Health Organisation - Uppsala Monitoring Centre (WHO-UMC) scale,Naranjo's scale[7],Modified Hartwig and Siegel severity scale[8], Modified Schumock and Thorton's preventability scale[9]respectively.The further data is assessed and analysed in the form of numbers and percentages using Microsoft excel sheet.

RESULTS

Out of 87 post kidney renal transplant patients ,3 patients between 0-20 age group,62 patients between 21-40 age group, 22 patients between 41-60 age group and zero patients above 61 age groups were observed. In these post renal transplant recipients 73 were men and 14 were women respectively. In 87 renal transplants, 67 patients(77.01%) are with Hypertension, followed by 2 patients(2.29%) with Diabetes mellitus and 5 patients (22.98%)with both Hypertension and Diabetes mellitus, 1 patient(1.14%) with both HTN and CAD,1 patient (1.14%) with HTN+DM+CAD,1 patient(1.14%) with vesicoureteral reflux(1.14%) and the rest of 10 patients(11.49%) have no comorbidities. Among the total renal transplants,19 patients (21.8%) were received kidney from deceased donor (9 were females and 10 were males) and the rest of 68 patients (78.16%) received live related kidney (63 were men and 5 were women).Out of 87 renal transplants 31 received induction therapy i.e.,Basiliximab (87.09%), ATG(9.67%) and Combination of both basiliximab and ATG(3.22%). The most common triple regimen: Tacrolimus plus Mycophenolatemofetil plus Prednisolone was given to 60 patients(68.96%) and remaining are listed below in table:1. Table 1 shows the demographic data of the patients who underwent renal transplantation.

Among the renal transplant patients, 31 males(42.46%) and 7 females(50%) were developed urinary tract infections (UTI) during their follow up.Out of 38 post kidney renal transplant patients with UTI ,1 patient between 0-20 age group, 23 patients between 21-40 age group, 14 patients between 41-60 age group and zero patients above 61 age groups are recorded. A total 41 episodes of UTI were occurred (38 single episodes and 3 recurrent episodes).

In our study, the most common pathogens causing UTI are E.coli (39.5%), Klebsiella (16.6%), Pseudomonas (10.41%), *Staphylococcus aureus* (10.41%), Enterococcus (6.25%) and the rest of the pathogens are mentioned below in the Table.2

Documented risk factors contributing to the development of UTI in renal transplant recipients are mentioned in Table 3 and the most common risk factors are increase in immunosuppression (12.19%), Indwelling urethral catheterisation (12.19%), Deceased donor (9.75%), Female gender(7.31%) , Duration of bladder catheterisation (7.31%). Induction therapy was given to

31 patient, among those 15 patients developed UTI and without taking induction therapy 23 patients developed UTI. Among 38 patients who had developed UTI, 5 received Linezolid as antibiotic therapy(12.19%), 4 received piperacillin+Tazobactam(9.75%),3 received Amikacin(7.31%) and remaining antibiotics are listed in Table.4.

Out of 87 renal transplant recipients, 24 UTI patients (19 men & 5 women) experienced 42 ADRs and 25 patients without UTI (22 men & 3 women) experienced 35 ADRs.48 renal tranplants patients experienced 77 ADRs..Amongst the 77 ADRs, cytomegalovirus infection(15.58%) was the most frequent followed by NODAT (14.28%) and Diarrhoea(6.49%) pancytopenia (6.49%)and remaining ADRs are listed in Table.5. Out of the 77 ADRs, 16 (20.77%) of ADRs were due to Tacrolimus, followed by 13 (16.88%) were due to Tacrolimus + Prednisolone+MMF, 11 (14.28%) were related to Tacrolimus+MMF and 10 (12.98%) were due to MMF. Prednisolone alone induced 6 (7.79%) ADRs, Co-trimoxazole induced 5 ADRs (6.49%) and the remaining ADRs are listed in Table 6.

Causality assessment of ADRs by Naranjo scale showed 70 (90.9%) ADRs were probably related to the immunosuppressant therapy and antibiotic therapy whereas 7 (9.09%) were possibly related. WHO causality assessment showed that 30 (38.96%) ADRs were probably related to the immunosuppressant therapy and antibiotic therapy whereas 47(61.03%) ADRs were possibly related (Table 7).

Of all 77 ADRs, preventability assessment by Modified Schumock and Thorton scale revealed that 27 (35.06%) ADRs Definitely Preventable, 17(22.07%) ADRs are Probably Preventable and 33(42.8%) ADRs are Not Preventable (Figure 2). As patient safety is the utmost priority, all the ADRs were managed appropriately.

Severity assessment of ADRs by Modified hartwig and siegel scale, Out of 77 ADRs , 37.66% of reactions are assessed as mild, 59.74% as moderate and 2.59% as severe (Figure.3).

The action taken for the management of ADRs are drug withdrawn (20.7%), dose reduced (16.8%), no change in dose (59.7%), others(2.59%) comprises of splitting the dose.

Outcomes of ADRs are almost recovered (90.9%) and some of the are recovering (5.19%) as it is NODAT and 3(3.89%) as they are antecedent causes of death.

Graph 1. Occurrence of UTI episodes after renal transplantation

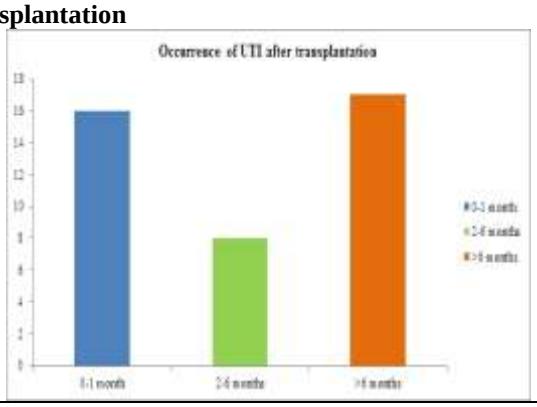

Fig 1. Microbiological profile of UTI in renal transplant recipients

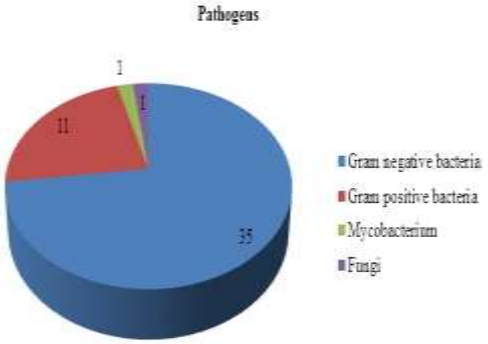

Fig 2. Preventability assessment by modified Schumock and Thorton scale

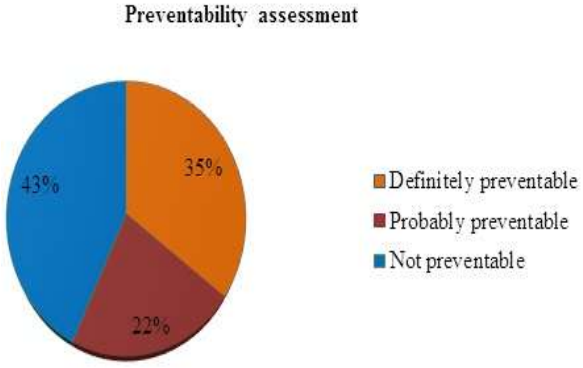

Fig 3. Severity assessment by Modified Hartwig and Siegel scale

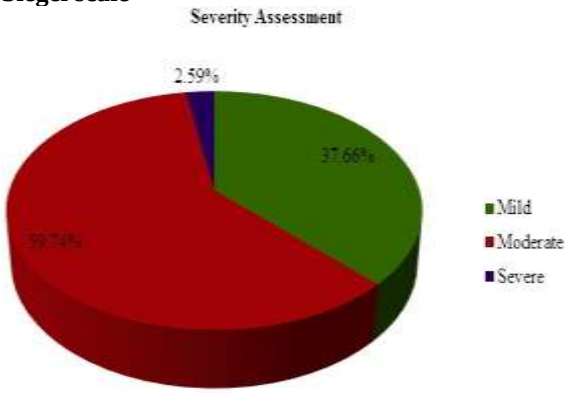

Table 1. Demographic data of patients who underwent renal transplantation

S.No	Variable	Percentage		
1	**Age**	< 20 years	03	3.44%
		21-40 years	62	71.26%
		41-60 years	22	25.28%
2	**Gender**	Males	73	83.91%
		Females	14	16.09%
3	**Source of Allograft**	Deceased related	19	21.8%
		Live related	68	78.16%
6	**Induction therapy**	Basiliximab	27	87.09%
		Anti-thymocyte globulin	3	9.67%
		Basiliximab+ATG	1	3.22%
7	**Maintenance therapy**	Tacrolimus+Prednisolone+MMF	60	68.96%
		Cyclosporine+Prednisolone+MMF	09	10.34%
		Everolimus+Prednisolone+MMF	05	5.74%
		Everolimus+Prednisolone+Tacrolimus	03	3.44%
		Azathioprine+Prednisolone	03	3.44%
		Azathioprine+Prednisolone+Tacrolimus	03	3.44%
		Azathioprine+Prednisolone+Cyclosporine	01	1.44%
		Sirolimus+Prednisolone+MMF	01	1.44%
		Sirolimus+Prednisolone	01	1.44%
		Tacrolimus+Prednisolone	01	1.44%

Table 2. Microbiological profile of UTI in renal transplant recipients

	Pathogen	Frequency	Percentage
Gram negative bacteria	Escherichia coli	19	39.5%
	Klebsiella	08	16.6%
	Pseudomonas	05	10.41%
	Acinetobacter	01	2.08%
	Morganella	01	2.08%
	Citrobacter	01	2.08%
Gram positive bacteria	Staphylococcus aureus	05	10.41%
	Enterococcus	03	6.25%
	Coagulase negative staphylococcus aureus	02	4.16%
	Non haemolytic streptococcus	01	2.08%
Mycobacterium	Koch's	01	2.08%
Fungi	Candidal hyphae	01	2.08%
Total		48	100%

Table 3. Risk factors for occurrence of UTI

S.No	**Risk factors**	**Frequency**	**Percentage**
1	Increase in immunosuppression	5	12.19%
2	Indwelling urethral catheterisation	5	12.19%
3	Deceased donor	4	9.75%
4	Female gender	3	7.31%
5	Duration of bladder catheterisation	3	7.31%
6	Female gender + Deceased donor	3	7.31%
7	Deceased donor+ Delayed graft function	2	4.87%
8	Delayed graft function	1	2.43%
9	Acute rejection episodes	1	2.43%
10	Female gender+ Duration of bladder catheterisation	1	2.43%
11	Deceased donor+Acute rejection episodes+Delayed graft function	1	2.43%
12	Indwelling urethral catheter+Delayed graft function+Deceased donor	1	2.43%
13	No Risk factors	11	26.82%
	TOTAL	41	100%

Table 4. Various antimicrobial agents used in the treatment of Urinary tract infections in renal transplant recipients

Medications	Frequency	Percentage
Linezolid	5	12.19%
Piperacillin+Tazobactum	4	9.75%
Amikacin	3	7.31%
Ciprofloxacin	2	4.87%
Cefixime	2	4.87%
Meropenem+Metronidazole	2	4.87%
Imipenem+Ceftazidime	2	4.87%
Faropenem	1	2.43%
Meropenem Imipenem	1 1	2.43% 2.43%
Cefuroxime	1	2.43%
Ceftriaxone	1	2.43%
Tigecycline	1	2.43%
Fluconazole	1	2.43%
Co-trimoxazole	1	2.43%
Cefperazone-sulbactum	1	2.43%
Imipenem+Co-trimoxazole	1	2.43%
Meropenem+ Co-trimoxazole	1	2.43%
Ofloxacin+Meronidazole	1	2.43%
Metronidazole+ Cefperazone-sulbactum	1	2.43%
Co-trimoxazole+Cefixime	1	2.43%
Piperacillin-Tazobactum+Norfloxacin	1	2.43%
Piperacillin-Tazobactum +Tigecycline	1	2.43%
Ciprofloxacin+Amoxicillin	1	2.43%
Tigecycline + Cefalexin	1	2.43%
Meropenem+Linezolid+piperacillin-Tazobactum	1	2.43%
Imipenem+Ampicillin+Ciprofloxacin	1	2.43%
TOTAL	41	100%

Table 5. Frequency of ADRs

Reaction	Frequency	Percentages
Cytomegalo virus infection	12	15.58%
NODAT	11	14.28%
Diarrhoea	05	6.49%
Pancytopenia	05	6.49%
Anaemia	04	5.19%
Leucopenia	03	3.89%
Herpes zoster infection	03	3.89%
Hyponatremia	03	3.89%
Raised renal parameters	03	3.89%
Pancreatitis	02	2.59%
Fungal infections	02	2.59%
Varicella zoster infection	02	2.59%
Seizures	02	2.59%
Hypokalemia	02	2.59%
Acneform eruption	01	1.29%
Bicytopenia	01	1.29%
Pure red cell anaemia	01	1.29%
Neutrophilicleucocytosis	01	1.29%
Thrombocytopenia	01	1.29%
Vitamin D deficiency	01	1.29%

Nausea	01	1.29%
Hepatitis C infection	01	1.29%
Left patellar bursitis	01	1.29%
Optic neuropathy	01	1.29%
Parvo virus infection	01	1.29%
BK viremia	01	1.29%
Hypotension	01	1.29%
Refractory septic shock	01	1.29%
Raised liver enzymes	01	1.29%
Proteinuria	01	1.29%
Central serous retinopathy	01	1.29%
Increased serum creatinine and Total leucocyte count	01	1.29%
TOTAL	**77**	**100%**

Table 6. Contribution of drugs with respect to ADRs

Suspected drug	No. of ADRs	Percentage
Tacrolimus	16	20.77%
Tacrolimus+Mycophenolatemofetil+Prednisolone	13	16.88%
Tacrolimus+Mycophenolatemofetil	11	14.28%
Mycophenolatemofetil	10	12.98%
Prednisolone	6	7.79%
Co-trimoxazole	5	6.49%
Everolimus	2	2.59%
Azathioprine	2	2.59%
Methyl prednisolone	2	2.59%
Tacrolimus+prednisolone	2	2.59%
Anti-thymocyte globulin	2	2.59%
Valganciclovir	2	2.59%
Nitroglycerin	1	1.29%
Levofloxacin	1	1.29%
Prednisolone+everolimus	1	1.29%
Fluconazole	1	1.29%

Table 7. Causality assessment of ADRs by WHO and Naranjo scale

Parameters	No. of ADRs	
	WHO Scale	Naranjo Scale
Certain/Definite	0 (0%)	0 (0%)
Probable/Likely	30 (38.96%)	70 (90.9%)
Possible	47 (61.03%)	07 (9.09%)
Unlikely/Doubtful	0 (0%)	0 (0%)
TOTAL	**77 (100%)**	

Table 8. Comparative assessment for UTI

Parameter	**Our study**	**Shams et al**	**Deepa R et al**	**MariosPapasotiriou et al**	**B.Maraha et al**	**Agata et al**
Sample size	87	247	50	122	192	100
No. of patients with UTI	38	56	21	74	71	55
Risk factors	Indwelling urethral catheterisation (12.19%)	Not mentioned	Not mentioned	Delayed graft function (31.1%) Acute rejection	Not mentioned	Delayed graft function (31.3%)

	Deceased donor (9.74%) Female gender (7.31%)			episodes (5.7%)		
Pathogens	Escherichia coli (39.5%) Klebsiella (16.6%) Staphylococcc usaureus (10.41%)	Escherichia coli (55.3%)	Escherichia coli(33.3%) Klebsiella (23.8%) Proteus vulgaris (9.52%)	Escherichia coli (32.2%)	Escherichia coli (31.6%)	Not mentioned
Treatment	Linezolid (12.9%) Piperacillin(9.75%) Amikacin (7.31%)	Not mentioned	Not mentioned	Ciprofloxacin (35.2%)	Amoxicillin(29.8%) Ciprofloxacin (14.2%)	Not mentioned

Table 9. Comparative assessment of Adverse drug reactions

Study	Causality by Naranjo scale			Severity by modified Hartwig and Siegel scale			Preventability by Modified Schumock and Thorton scale		
	Definite	Probable	Possible	Mild	Moderate	Severe	Definitely preventable	Probably preventable	Not preventable
Lingal amane esha*et al*.,	0 (0%)	65 (91.5%)	6 (8.5%)	8 (11%)	42 (59%)	21 (30%)	0 (0%)	2 (2.9%)	69 (97.1%)
Sharma love *et al*.,	4 (4.76%)	47 (55.95%)	33 (39.29%)	49 (58.33%)	34 (40.47%)	1 (1.19%)	0 (0%)	4 (4.77%)	80 (95.23%)
Our study	0 (0%)	70 (90.9%)	7(9.09%)	29 (37.66%)	46 (59.74%)	2 (2.59%)	27 (35%)	17 (22%)	33 (43%)

DISCUSSION

Renal transplantation prolongs the life span of the patients with end-stage renal disease (GFR<15 ml/min) and dialysis is of secondary importance. Allograft rejection is a major challenge that patients do usually encounter during the post transplantation. Immunosuppressant's helps to prevent transplant rejection by making the immune system less efficient, unfortunately they all reduce resistance to infection as well as reducing the rejection, so renal transplant recipients are at high risk of infections. Among all infections urinary tract infections are the most common and the other infections are Tuberculosis, Hepatitis B, Hepatitis C, Cytomegalovirus, Pneumocystis. Our study mainly focuses on the UTI in renal transplant recipients.

In our study, out of 87 renal transplants 38 were experienced UTI with 41 episodes (In them 15 were received induction therapy). Compared with related articles, an Iranian article Shams et al., documented that in 247 renal transplants only 56 patients got UTI (Shams SF *et al*., 2017). The common causative organisms involved are *Escherichia coli* (39.5%), *Klebsiella* (16.6%), *Staphylococcus aureus* (10.41%), *Pseudomonas* (10.41%), *Enterococcus* (6.25%). Compared to other related studies conducted by Deepa R et al., documented that the common pathogens are *Escherichia coli* (33.3%), *Klebsiella* (23.8%), *Proteus vulgaris* (9.52%) (Deepa R *et al*., 2017). We identified the risk factors contributing to the occurrence of UTI in renal transplant recipients i.e., Indwelling urethral catheterisation (12.19%), Deceased donor (9.74%), Female gender (7.31%). Compared to other related studies, a Greece article Mariospapasotiriou et al documented that the risk factors for the development of UTI are Delayed graft function(31.1%),Acute rejection episodes (5.7%) (Papasotiriou M *et al*., 2011). The current study focused on the antibiotic treatment for UTI. In 38 patients , UTI was treated with antimicrobial agents such as Linezolid (12.19%), Piperacillin-tazobactum(9.75%), Amikacin(7.31%), Ciprofloxacin (4.87%).Compared to other studies a Netherlands article B. Maraha et al., documented that the antimicrobial agents used are Amoxicillin-clavulanic acid(29.8%),Ciprofloxacin(14.2%)(Maraha B *et al*., 2001).

Our study results determined that only 55.17% of patients had experienced at least one ADR during the studyperiod and 44.82% patients have no any such complaintswith the immunosuppression therapy, past medications and antibiotic therapy. Out of the 77 ADRs, 16 (20.77%) of ADRs were due to Tacrolimus, followed by 13 (16.88%) were due to Tacrolimus + Prednisolone+MMF, 11 (14.28%) were related to Tacrolimus+MMF and 10 (12.98%) were due to MMF. Other related studies Sharma love et al, also concluded that incidence of ADRs are more in renal transplant recipients due to Tacrolimus and MMF (73.8%) (Love S *et al*., 2012)

In our study the assessment of ADRs by Naranjo and WHO scale showed that 90.9% of ADRs are probable and 9.09% of ADRs are possible followed by severity assessment our study results showed that 37.66% of ADRs are mild, 59.74% are moderate and 2.59% are severe. Preventability assessment showed 35% of ADRs are definitely preventable, 22% are probably preventable, 43% are not preventable. Our study findings similar to LingalaManeesha et al documented that Naranjo and WHO scale showed 91.5% of ADRs are probable, Severity assessment showed 5.9% of ADRs are moderate and 30% of ADRs are severe and preventability assessment showed 97.1% of ADRs are not preventable in their study (Maneesha L *et al*., 2016) and other studies conducted by Sharma love at al documented that Naranjo and WHO scale assessment showed 40.47% ADRs are moderate and preventability assessment showed 93.45% ADRs are not preventable (Love S *et al*., 2012).

Outcomes of ADRs are almost recovered (90.9%) and some of the are recovering (5.19%) as it is NODAT and 3(3.89%) as they are antecedent causes of death.

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CONCLUSION

We concluded that urinary tract infections after renal transplantation may occur within a short period due to indwelling urethral catheters and increase in immunosuppression.Immunosuppression is recommended to reduce the rejection after transplantation. Though it prevents rejection, it increases the risk opportunistic infections in renal transplantation patients. UTI are one amongst the opportunistic infections, unless treated UTI may lead to significant mortality, this favours the Poly pharmacy. Hence patients are at high risk to get experienced with Adverse Drug Reactions. Hence patients should be monitored throughout the post transplant treatment period including Immunosuppressive therapy and Antibiotic treatment. A proper monitoring of given treatment through the treatment period can reduce the incidence of preventable ADRs such that the term patient safety is the utmost priority can be justified.

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CONFLICT OF INTEREST

Nil

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