

LIVE DONOR RENAL TRANSPLANTS IN INDIA
OUTCOME and COMPARISON of DIFFERENT INDUCTION THERAPIES
WITH a FOCUS on GENDER BIAS IN LIVE DONOR RENAL TRANSPLANTATION

by

MARYAM IDREES KHAN

DISSERTATION

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DEDICATION

To my parents, Dr. Muhammad Idrees Khan and Samina Idrees Khan, who encouraged me to pursue my dreams. To my siblings Hamza, Omar, and Zainab for helping me stay grounded throughout it all.

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ABBREVIATIONS

ESRD	End Stage Renal Disease
DM	Diabetes Mellitus
RRT	Renal Replacement Therapy
HD	Hemodialysis
PD	Peritoneal Dialysis
RT	Renal Transplant
IL2-RA	Interleukin-2 receptor alpha chain
LDRT	Live Donor Renal Transplant
r-ATG	Rabbit Anti-Thymocyte Globulin
CKD	Chronic Kidney Disease
GFR	Glomerular Filtration Rate
GBM	Glomerular Basement Membrane
WHO	World Health Organization
PRA	Panel Reactive Antibody
HLA	Human Leukocyte Antigen
CMV	Cytomegalovirus

ABSTRACT

Background

Diabetes mellitus (DM) is the leading cause of end stage renal disease (ESRD) in both developed countries, like the United States, and developing countries like India. India is a particularly interesting country to observe given their vast population base, rapid growing economy, genetic predisposition to DM and increased insulin resistance. It is estimated that 100,000 patients develop ESRD each year in India with DM as the main underlying cause (44% of all ESRD cases). Once a patient develops ESRD, renal replacement therapy (RRT) is required to sustain life. RRT consists of three options: 1) hemodialysis (HD), 2) peritoneal dialysis (PD), or 3) renal transplant (RT). Of the three options, RT is considered the best in terms of quality of life and cost effectiveness, but only about 5% of Indian patients with ESRD end up receiving RT. Most RT in India come from living donors rather than cadaveric donors as compared to developed nations. Induction therapy with interleukin-2 receptor alpha chain (IL2-RA) is recommended as a first line agent in living-donor renal transplant (LDRT) however comparative outcomes of induction therapy remains controversial in Indian LDRT population.

Objective

To evaluate patient survival and allograft function in LDRT with a specific focus on the Indian population between 2010 and 2014 and to assess the impact of different induction therapies on the outcomes of Indian LDRT patients.

Methods

A single center (Medanta Medicity, Gurgaon, India) dataset was retrospectively studied for patients receiving LDRT from 2010 to 2014 (N=901), to compare effectiveness of IL2-RA to other induction options (no-induction and rabbit anti-thymocyte globulin [r-ATG]). IL2-RA and no induction were chosen for immunologically low risk patients. R-ATG was primarily given to the recipient with panel reactive antibody (PRA) >20% and human leukocyte antigen (HLA) mismatch of 5 antigen out of 6.

Patient paper charts were analyzed for dates not included in the Medanta database, which included follow-up dates with corresponding creatinine levels (at 3 months, 6 months, 1 year, and last follow up), date and type of rejection if applicable, graft loss and death. Patients included in the data set had their last follow up at Medanta within the last 6 months from the time data was collected. The patient data was used to calculate rejection rate, graft failure, and hazard ratio for overall graft failure. The main outcomes were the risk of acute rejection at one-year and overall allograft failure (graft failure or death) post-transplantation through the end of follow-up.

Results

Similar Kaplan Meier curves for overall graft survivals were observed among induction categories. Rejection rate was higher in no-induction and IL2-RA groups (~25%) compared to r-ATG induction. On univariate Cox analysis, compared to no-induction therapy, overall allograft failure was similar among induction categories. Most of the rejections were borderline or Banff Type I acute cellular rejections. Among the LDRT patients in our study,

we noted a distinct prevalence of females as donors (70.4%) with a large portion of recipients being males (76.7%).

Conclusion

Compared to no-induction therapy, IL2-RA induction was not associated with better outcomes in Indian LDRT recipients. R-ATG appears to be an acceptable and possibly preferred induction alternative for IL2-RA in high rejection risk Indian patients. We may attribute the gender bias in LDRT present in India to the developing status of the country, but these statistics hold true for developed countries such as the United States as well.

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CHAPTER 1

AN INTRODUCTION

1.1 Defining End Stage Renal Disease (ESRD)

Under the National Kidney Foundation Kidney Disease Outcomes Quality Initiative classification of chronic kidney disease (CKD), ESRD refers to persons with a glomerular filtration rate (GFR) less than 15 mL per minute per 1.73 m² body surface area or those needing dialysis irrespective of GFR.¹ ESRD usually occurs 10-20 years after the diagnosis of CKD, but this process is often accelerated due to uncontrolled causative factors such as diabetes mellitus and hypertension.

It is well recognized that diabetic nephropathy, alone or in combination with hypertensive nephropathy, is the most common cause of ESRD in developing and developed countries. According to a recent population-based survey, DM was the cause of CKD in 41% of cases in India.² These numbers are likely underreported as there is no central ESRD reporting system in India such as USRDS in the United States. The exact prevalence and incidence of CKD is therefore unknown, making it hard to know the exact burden on the Indian health care system.

1.2 Pathophysiology of Diabetes Mellitus (DM) Leading to ESRD

The key histological changes that occur in the glomeruli of patients with diabetic nephropathy are mesangial expansion, thickening of the glomerular basement membrane (GBM), and glomerular sclerosis.³ The severity of diabetic glomerulopathy is often predicted by the thickness of the GBM, mesangium, and matrix. These three factors lead to augmentation of the cellular matrix in turn causing renal hemodynamic alterations. Secondary to renal

hemodynamic alterations, patients with poorly controlled DM will often develop systemic hypertension. The hypertension in turn damages vasculature and microvasculature and exacerbates the underlying diabetic nephropathy. Progression of diabetic nephropathy, coupled with systemic hypertension, exacerbates disease progression, and eventually results in decline in glomerular filtration rate leading to ESRD.

1.3 Diabetes Mellitus as a Growing Global Issue

As of 2014, an estimated 9% of the global population aged over 18 years was affected by DM.¹ The World Health Organization (WHO) also estimated around 2.5% of deaths were attributed to DM in 2012 and more than 80% of those deaths occurred in low-middle income countries.⁴ Type 2 diabetes mellitus, an increasingly common, preventable, non-communicable disease, and its complications are becoming a global issue. DM is the leading cause of ESRD in both developed countries and developing countries, including India.¹

1.4 Diabetes Mellitus in India

The rapidly changing socio-economic landscape of India has laid the foundations for increased prevalence of DM in the population. These factors include, but not limited to, improved modes of transportation leading to decreased physical activity and changes in diet habits. It is estimated that 100,000 patients develop ESRD each year in India with DM as the main underlying cause (44% of all ESRD cases).⁶ Indians have shown to have a set of factors which make them particularly vulnerable to DM. Genetic predisposition and low thresholds for diabetogenic factors including age, obesity, and body fat content contribute towards this

vulnerability.

Indians develop DM at a young age, 10-15 years earlier, relative to their white counterpart. According to the national urban diabetes survey, more than 50% of Indians had onset of DM under the age of 50.⁵ Along with age, central obesity shows a higher association with glucose intolerance than generalized obesity in the Indian population. In spite of having low BMI, Indian adults are more predisposed to having abdominal obesity which likely contributes to insulin resistance in non-obese Indians. This high body fat content may lead to the higher insulin resistance seen in the Indian population. Given these factors, the Indian population faces high risk for DM and its associated complications, particularly ESRD.

1.5 Treatment of ESRD in India

Once a patient develops ESRD, RRT is required to sustain life. RRT consists of three options: 1) hemodialysis (HD), 2) peritoneal dialysis (PD), or 3) renal transplant (RT). With no existing governmental reimbursement for dialysis or transplantation it is estimated that less than 10% of all Indian ESRD patients receive any meaningful RRT.⁶ Of the three options, renal transplant is considered the best in terms of quality of life and cost effectiveness, but only about 5% of Indian patients with ESRD end up receiving RT. ⁶ Most RT in India come from living donors rather than cadaveric donors, compared to the United States. Cultural and religious factors, availability of live donors, and poorly organized utilization of cadaveric kidneys, contribute to the low numbers of cadaveric organ utilization in India.

1.6 Hemodialysis for the Indian ESRD Population

Hemodialysis centers in India exist in urban centers, while the majority of the ESRD population lives in remote rural areas where access to dialysis centers is often not available. Along with transportation, another limiting factor for continuing HD is often the ability to pay. Many patients are started on HD but soon realize it is only a means to an end and will likely bankrupt their families. Indian ESRD patients who are fortunate enough to see a nephrologist are started on hemodialysis as 30-40 % require immediate dialysis because of critical symptoms including encephalopathy, metabolic acidosis, and pulmonary edema. Near 60% of patients who are started on HD are lost to follow up while only 4% of patients remain on maintenance hemodialysis.⁶ Given the mechanics of HD in combination with poor living conditions, malnutrition, and inadequate dialysis present in undeveloped countries, patients are prone to various infections.⁶ The predominant cause of death in the Indian dialysis cohort continues to be infection and cardiac disease.⁷

1.7 Peritoneal Dialysis for the Indian ESRD Population

Peritoneal dialysis is a preferred option over hemodialysis as it provides greater independence, mobility, and overall quality of life. Peritoneal dialysis is becoming the preferred modality in countries with limited resources and fixed annual health care budgets because of its cost-effectiveness. Though there are limited resources in India, the self-payer health care model has prevented widespread use of peritoneal dialysis in the past. Recent studies published in 2012 have shown minimal difference in monthly cost of peritoneal dialysis as compared to hemodialysis.⁸ Although this study was conducted at a single center pilot study the cost of

peritoneal dialysis is comparable across the country.⁸ Since the majority of the ESRD population lives in remote rural areas without access to hemodialysis centers, transportation is a large cost that must be taken into account when comparing overall costs of hemodialysis versus peritoneal dialysis. Given the inconsequential difference in cost and improvement in quality of life that peritoneal dialysis can afford to ESRD patients, peritoneal dialysis should be offered as an alternative to hemodialysis for qualifying patients in the Indian ESRD population.

1.8 Renal Transplantation for the Indian ESRD Population

The absence of dialysis facilities in rural communities often makes renal transplant the best chance for survival for Indian ESRD patients. Renal transplantation has been shown to improve overall survival rate, quality of life, and is a more affordable treatment compared to dialysis.¹¹ The cost of transplantation can range from \$1500 USD in government hospitals to \$7000 USD in private settings.⁶ The monthly cost of hemodialysis and peritoneal dialysis varies geographically but generally ranges between \$300 USD and \$600 USD.⁶ The long term cost of renal transplantation is significantly less than that of continued dialysis and provides a higher quality of life.

Most underdeveloped nations lack structured cadaveric transplant programs making very poor utilization of cadaveric kidneys. Despite having a large cadaveric donor base due to mortalities from traffic accidents, the majority of renal transplants in India are live donor. Of the estimated 3000 renal transplants performed in India each year, only about 100 are from cadaveric donors.⁹ Inadequate education of the general public and health care professionals of

the importance of cadaveric donations also contributes to the low rates of cadaveric donation in India.

1.9 Induction Therapy for Renal Transplantation

Induction therapy is the short term use of immunosuppressive agents to mask the donor kidney from sensitization by the recipient's immune system. This helps to prevent acute rejection and often includes the use of corticosteroids and T cell-directed therapy. The T cell directed therapy is generally divided into two categories: T cell depleting versus nondepleting. These agents include the polyclonal rabbit antithymocyte globulin, the humanized anti-CD52 mAb alemtuzumab, and mAbs directed at the IL2 receptor (most notably basiliximab). The two former agents are T cell depleting and often require a protracted recovery of T cells counts while the latter is a nondepleting agent and functions by inhibiting T cell response to IL2. Currently, induction therapy with IL2 receptor antagonists, such as basiliximab, are the preferred first line agents in living donor renal transplantation however comparative outcomes of induction therapy remains controversial in Indian LDRT population.¹⁰

1.10 Current Challenges in Renal Transplant in India

The lack of a structured cadaveric transplant program often leads patients and families to pursue ethically questionable routes of obtaining a donor. In developing countries, lack of appropriate legal restrictions make the sale of organs commonplace. It is estimated that 50% of kidneys transplanted in India are provided by living unrelated donors.⁶ Although an organ transplant act was enforced in 1994, living unrelated donors who are selling their kidneys

continue to make up the majority of the donor population. Studies have shown that selling a kidney does not provide long-term economic benefits and is often associated with a deterioration in health.¹² Many private hospitals have implemented strict genetic testing protocols to help curb this practice, but with rampant poverty and lack of legal ramifications present people continue to be exploited by middlemen to sell their kidneys.

1.11 Gender Disparity in Live Donor Renal Transplant in India

In India, living donors are the main source of obtaining kidneys for renal transplantation with women donating more often than men and less likely to receive a live kidney from men.¹³ Although men are more likely to have ESRD and require RRT, studies adjusted for ages, ethnicity, income, and dialytic modalities show females are less likely to receive renal transplant than men.¹⁴ In India, and other developing countries, the society is still very male-oriented and health of the men in the family of great importance. Women are often dependent, socially and economically, on the male members of their family in these developing countries. Along with these factors, women in India are often first to volunteer for kidney donation as they have an elevated inclination towards sacrifice.

CHAPTER 2

OBJECTIVES

The objective of this study is to evaluate patient survival and allograft function in live donor renal transplants with a specific focus on the Indian patient population between 2010 and 2014 and assess the impact of different induction therapies on the outcomes of Indian live donor renal transplant patients. A permanent electronic database of patient records was also established to help Medanta keep long terms records for further research purposes.

CHAPTER 3

MATERIALS and METHODS

3.1 Study Population

A single center (Medanta The Medicity, Gurgaon, India) dataset was retrospectively studied for patients receiving live donor renal transplant from 2010 to 2014 (N=901) to compare effectiveness of IL2-RA to other induction options (no-induction and r-ATG). IL2-RA and no induction were chosen for immunologically low risk patients. R-ATG was primarily given to the recipient with PRA>20% and HLA mismatch >5 antigen out of 6.

3.2 Study Protocol

Patient paper charts were analyzed for dates not included in the Medanta database which included follow-up dates with corresponding creatinine levels (at 3 months, 6 months, 1 year, and last follow up), date and type of rejection if applicable, graft loss and death. Patients included in the data set had their last follow up at Medanta within the last 6 months from the time data was collected. The patient data was used to calculate rejection rate, graft failure, and hazard ratio (HR) for overall graft failure. The main outcomes were the risk of acute rejection at one-year and overall allograft failure (graft failure or death) post-transplantation through the end of follow-up.

CHAPTER 4

RESULTS

	No-induction	IL2-RA	r-ATG	P
N (%)	316 (35.1)	550 (61)	35 (3.9)	
DONOR				
Age	47.4±11.5	48.2±10.8	39.9±12.5	<0.001
Gender (male), %	30.7	24.7	32.3	0.13
Race (Indian), %	95.9	97.1	97.1	0.63
Relationship (family member), %	82.9	73.8	86.4	<0.001
DTPA measured GFR (ml/min)	94.7 ±10.6	94.7 ±10.5	98.7 ±11.3	0.81
RECIPIENT				
Age	38.2±12.6	41±13.2	37.1±9.3	0.01
Gender (male), %	82.6	81.8	65.7	0.05
Race (Indian), %	95.9	97.1	97.1	0.63
DM, %	17.7	27.8	20	<0.001
Pre-emptive transplant, %	14	19.9	12.5	<0.001
TRANSPLANT				
Maintenance immunosuppression (TAC/MPA/Pred), %	94.3	86.8	82.1	<0.001
Rejection rate, %	26.4	22.6	8.2	0.92
Graft failure, %	3.3	1	0	0.11
Mortality, %	2.2	2.3	4	0.85
Hazard Ratio (HR) for overall graft failure (95% CI)	1 (Reference)	0.76 (0.31-1.83)	1.24 (0.16-9.82)	

Table 1. Donor, recipient, and transplant characteristics of three induction categories including no induction, IL2-RA, and r-ATG.

Donor, recipient, and transplant characteristics are shown in Table 1. Similar Kaplan Meier curves for overall graft survivals were observed among induction categories, shown in Figure 1. Rejection rate was higher in no-induction and IL2-RA groups (~25%) compared to r-ATG induction. On univariate Cox analysis, compared to no-induction therapy, overall allograft failure was similar among induction categories.

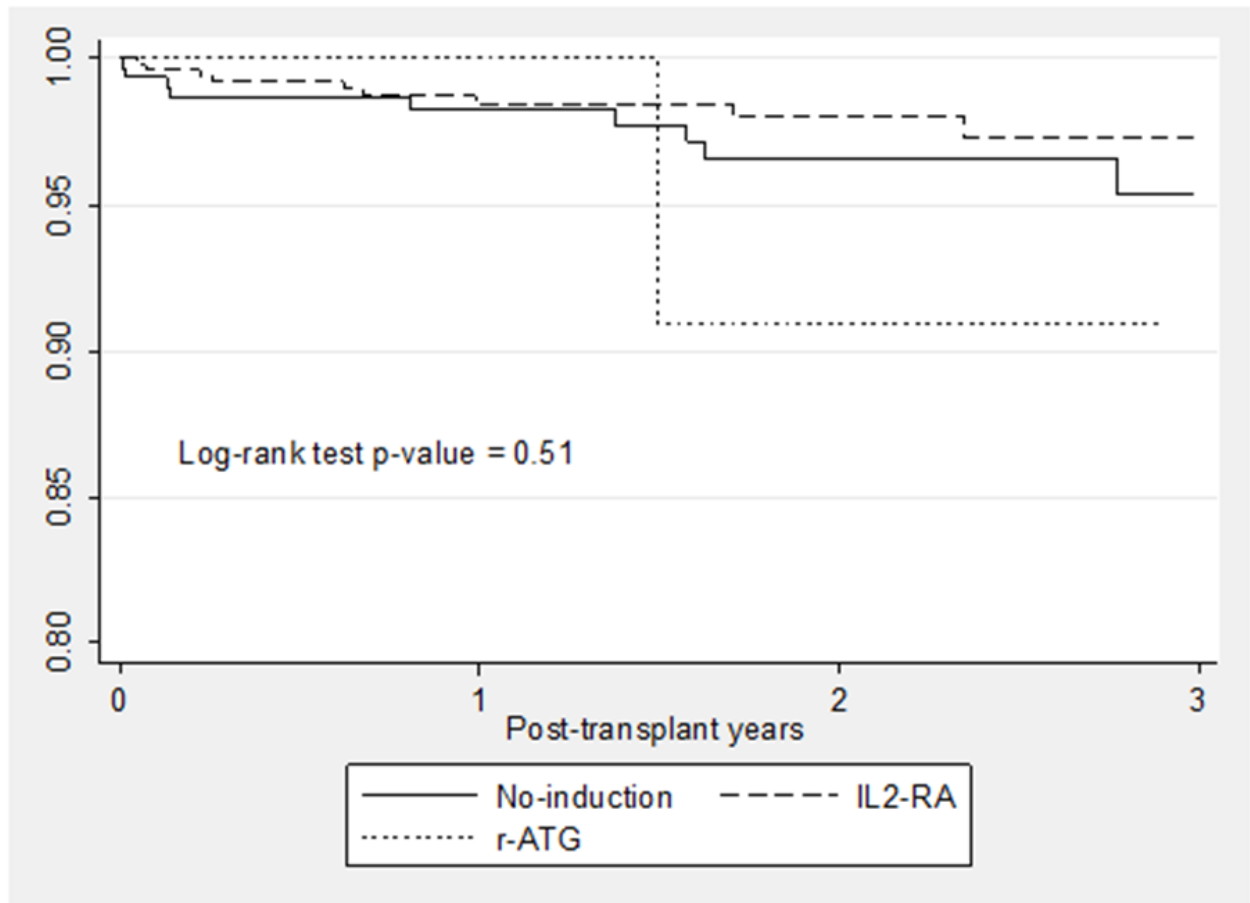


Figure 1. Similar Kaplan Meier curves for overall graft survivals were observed among induction categories.

4.1 Age and Gender Data Analysis

The mean age of recipients was 38.7 years old. In general, Indian patients are younger (mean age 42) than their United States counterparts (mean age 61) at the time of ESRD detection.⁵ Among LDRT patients in our study, we noted a distinct prevalence of females as donors (70.4%) with a large portion of recipients being males (76.7%) as shown in Figure 2.

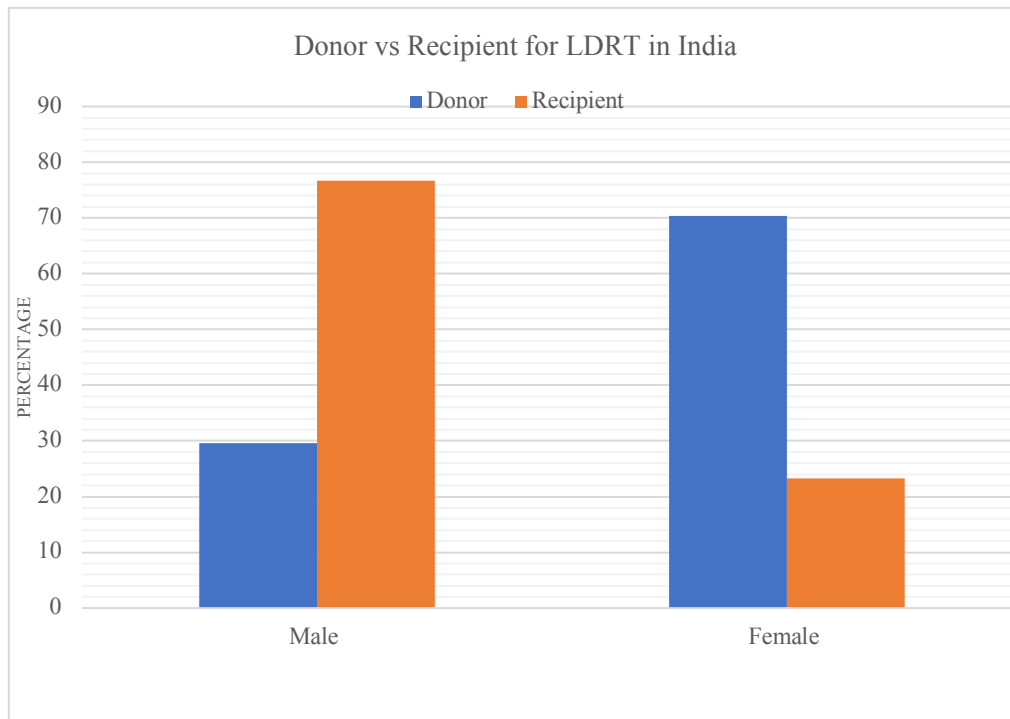


Figure 2. Prevalence of females as donors and males as recipients of live donor renal transplants.

CHAPTER 5

DISCUSSION

5.1 Induction Therapies Analysis

Compared to no-induction therapy, IL2-RA induction was not associated with better outcomes in Indian LDRT recipients. R-ATG appears to be an acceptable and possibly preferred induction alternative for IL2-RA in high rejection risk Indian patients as it offers lower rejection rates and probably better graft survival long term.

There was no difference between rATG and IL2-RA in the incidence of the composite endpoint, allograft loss, delayed graft loss, and death. rATG was associated with a significantly lower acute rejection rate (16 versus 26 percent) and incidence of acute rejection that required antibody treatment (1.4 versus 8 percent). Although overall adverse event and serious adverse event rates were similar, rATG was associated with a higher incidence of infection (86 versus 75 percent) but lower incidence of cytomegalovirus (CMV) disease (8 versus 18 percent). Thus, although the primary endpoint was similar in both arms, a significantly lower incidence of acute rejection was noted with rATG.

At five-year follow-up, the incidence of acute rejection and need for antibody treatment of acute rejection remained lower among those treated with rATG compared to IL2-RA (16 versus 30 percent and 3 versus 12 percent, respectively). Patients treated with rATG also had a significantly lower composite endpoint of acute rejection, graft loss, and death at five years (39 versus 52 percent) and incidence of treated CMV infection (7 versus 17 percent); however the incidence of malignancy did not differ. Thus, the relative benefits of rATG were sustained over a five-year period after surgery.

As the global prevalence of DM is estimated to increase, with the largest increases occurring in developing regions such as India (151%), the gap between ESRD development and RRT accessibility is going to widen.⁶ DM prevention and education should be stressed early on and RRT, particularly transplants, should be facilitated through a nationalized program.

5.2 Age Analysis

Given the younger age, ESRD is creating a burden on Indian society as it is affecting people, often males who are the providers for their families, during the most productive years of their lives. Not only are Indian patients younger at time of detection, but 2/3 of the patient population seeks a treatment from a nephrologist only after they have reached the ESRD stage.⁶ This delayed treatment pattern suggests an inability to access renal services earlier when damage to the kidneys can potentially be reversed.

5.3 Gender Disparity in India

Among the LDRT patients in our study, we noted a distinct prevalence of females as donors (70.4%) with a large portion of recipients being males (76.7%). These results match those from a state funded LDRT facility that noted 66.4% of donors were female while 83.2% of recipients were male.¹³ In a retrospective study conducted at a tertiary care facility in Northern India, it was found that mothers (32.1%) often form the largest group of donors followed by wives (15.7%).¹³ In the spousal group of donors, there is a higher ratio of female to male donors in India. The disproportionate amount of female donors could be contributed to the cultural

obligations and undue burden placed on females in the Indian society.

We may attribute the gender bias in LDRT present in India to the developing status of the country, but surprisingly these statistics hold true for developed countries such as the United States as well. According to the United Network for Organ Sharing (UNOS), 62.9% of LDRT in the United States in 2017 were from female donors. Gender disparity persists even where women are economically, educationally, and socially on par with their male counterparts.

5.4 Follow Up

Given that the gender disparity among LDRT patients in our study persists even in countries where women are on par with their male counterparts, it is important to initiate measures to ensure women do not suffer unintentional bias. These measures should include campaigns promoting mass education of the public and health care workers, public awareness, and proactive interventions. Future studies to examine gender differences in patient preference of transplantation over dialysis may provide a better idea of the gender disparity that exists among LDRT patients.

There are limitations to drawing conclusions as half of the patients in our study did not have follow up data within six months of our collection time. For those patients who did not have this data, we assumed no new events transpired since their last follow-up. The process of follow-up at Medanta proved difficult as there is no standard procedure, many patients are international, and patients often take their patient charts in order to switch providers for follow-up care.

Our intent is to return to Medanta to update and gather missing data for patients who do

not have follow-up data within the last six months as this will allow us to increase the power of analysis. Additionally, we would like to expand our study by comparing induction therapies in LDRT between Indian and United States cohorts. There is also possibility to examine our existing dataset for infection rates, outcomes of ABO incompatible transplants, and a comparative cost analysis of transplantation.

This research project has given us a better understanding of the Indian healthcare system and the limitations present for healthcare in developing countries. These same limitations to accessing medical care are present in underserved/immigrant/refugee populations in the United States. We will continue to use the invaluable lessons we have learned about limitations to accessing healthcare, communication, and research during our international clinical research experience for future involvement in global health projects and care for indigent communities in the United States. This trip has instilled in us that we still have much to learn from our colleagues abroad.

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VITAE

Maryam Khan (July 6 1993 -present) is a first generation Pakistani-American born and raised in Texas along with her three younger siblings. Over the course of her medical school career, she has had the opportunity to work with physicians at Medanta Hospital in Gurgaon, India and at The Faculty of Medicine at Khon Kaen University in Khon Kaen, Thailand. She has a vested interest in pursuing global health given the multitude of opportunities present for collaboration with our colleagues abroad. In her free time she enjoys baking, photography, international travels, Taekwondo, and working with refugees. She will be moving to Phoenix, Arizona to start her general surgery residency at The University of Arizona College of Medicine – Phoenix and plans to pursue a fellowship in academic global surgery.

Permanent Address:
101 Majestic View
Harker Heights, Texas 76548