



Outcomes of Patients **Returning after**
Receiving Live Donor Kidney Transplantation Abroad at St. Paul's Hospital Millennium
Medical College in Ethiopia: A Retrospective Chart Review Study, 2015-2022

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Outcomes of patients returning after receiving live donor kidney transplantation abroad at Saint Paul Hospital Millennium Medical College (SPHMMC), Addis Ababa, Ethiopia, 2015-2022

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ACRONYMS AND ABBREVIATIONS

CKD: Chronic Kidney Disease

ESRD: End Stage Renal Disease

KTRs: kidney transplant recipients

LDKT: Life donor kidney transplant

WHO: World Health Organization

SPHMMC: Saint Paul Hospital Millennium Medical College

ABMR: Antibody-Mediated Rejection

TCMR: T cell-mediated rejection

BKV: BK virus

CMV: Cytomegalovirus

PTDM: Post-transplant Diabetes mellitus

ATG: Anti-thymocyte globulin

eGFR: Estimated Glomerular Filtration Rate

CKD EPI: Chronic kidney disease epidemiology collaboration

DGF: Delayed Graft Function

AR: Acute rejection

KDIGO: Kidney Disease Improving Global Outcomes

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ABSTRACT

Introduction: Kidney transplant is the optimal management for patients with ESRD. The provision of transplant activity is limited in sub-Saharan African countries, including Ethiopia. The long waiting list at Saint Paul makes most patients seek kidney transplants abroad but their clinical outcomes are not known. Therefore, the information obtained from this study will allow physicians to better understand their post-transplant outcomes and provide care accordingly.

Objective: The study aimed to assess the outcomes of patients returning after receiving live donor kidney transplantation abroad at Saint Paul Hospital Millennium Medical College (SPHMMC), Addis Ababa, Ethiopia, from September 1st 2015 to December 31st 2022.

Methodology: A retrospective chart review was conducted from February 1st to April 30th, 2023 among a total of 74 live donor kidney transplant recipients from abroad and were on follow up at SPHMMC from September 1st 2015 to December 31st 2022 for at least one year. Data was summarized using frequency with proportion, mean (standard deviation), median (interquartile range), and graphs. To identify the presence of significant difference in the rate of complication between different groups, chi-square test/Fisher's exact test, independent t-test/ Mann-Whitney U test were used where p-value of <0.05 indicates a statistically significant difference.

Results: The mean age of the participants was 34.9 ± 11.3 years and 54/74 were males. The mean eGFR at 1 week, 3 months, 6 months, 1 year, 2 years, and 3 years was 100.9 ± 27.5 , 90.9 ± 22.2 , 91.7 ± 21.6 , 93.2 ± 24.7 , and 93.9 ± 23.9 ml/min/1.73 m², respectively. In the 3rd year, the median eGFR was 109.6 (IQR, 82.5-129.4) ml/min/1.73 m². Stage 3a CKD was diagnosed in 4/74, 1/23, and 1/5 cases in the 1st, 2nd, and 3rd year of follow up. Stage 3b CKD and stage 2 CKD were diagnosed in 1/74 and 2/74 cases in the 1st year of follow-up, respectively. The rate of post-transplant complication was 35/74 (47.3%, 95%CI= 36.4-59.6%) with the most frequent complication being infection in 29/58 and mortality rate was 1/74 (1.4%). The rate of complication didn't show a statistically significant difference based on any of the studied patient characteristics.

Conclusion: The post-transplant outcome of live donor kidney transplant recipients abroad who were followed for an average of 24.7 ± 13.2 months showed that kidney function can remain stable for most patients and only few progressed to stage 2 and 3 CKD, a considerable proportion has developed one or more complication(s) and mortality rate was very low.

Recommendation: The findings of the study provide an insight to clinicians to understand the post-transplant complications of patients who travel for transplantation, what to expect and be prepared accordingly and also serves as a baseline for further studies.

Key words: Kidney Transplant, Post-transplant complications, post-transplant mortality, Retrospective chart review, Ethiopia

1. INTRODUCTION

1.1. Background

Kidney transplantation is the treatment of choice for patients with ESRD, providing better patient survival, quality of life and cost saving compared to dialysis (1). Since the first successful kidney transplant performed by Dr. Joseph Murray in 1954, one year kidney allograft outcomes have significantly improved over the years along with advancement in surgical immunosuppressive and monitoring protocol (2,3).

In the US, Death-censored allograft survival rates among transplant recipients from living donors are 99%, 94%, and 84% at 1, 5, and 10 years, respectively (4). Similarly, Live donor kidney transplant survival rates in Australia are 98% and 91%, at one year and five years respectively. Additionally, the patient survival rate is excellent, which is 100% and 96%, after one year and five years respectively (5).

Kidney transplantation is difficult in Sub-Saharan Africa (SSA) due to a lack of resources, extreme poverty, and restricted access to immunosuppressive and tissue typing. Despite these limitations, in South Africa, Graft survival for transplants from living donors at 1-, 2-, and 5 years was 90.3%, 85.8%, and 82.6%. Living donor patient survival at 1-, 2-, and 5 years was 93.3%, 88.2%, and 85.0%. (6).

In Ethiopia since the establishment of the first kidney transplant center at SPHMMC in Addis Ababa, the first kidney transplant center in 2015, an estimated 137 patients have received the service until September 2020 (7, 8). A study conducted on the outcomes of the first 52 patients showed graft survival of 97.5 % (9).

Currently because of the long waiting list and limited transplant center in Ethiopia, Patients travel for transplantation after getting board approval by the local transplant team. According to the 2008 declaration of Istanbul, Travel for transplantation is the movement of persons across borders for transplantation purpose and it becomes transplant tourism if it entails organ trafficking and/or transplant commercialism (10). Although many studies have shown the poor clinical outcomes of kidney transplant tourism, there is limited study which exclusively studied clinical outcomes of patients who travel for transplantation along with their donors (11, 12). Therefore the current study aims to address this gap by assessing graft and patient survival rate and post-transplant complications.

1.2. Statement of the problem

Kidney transplantation is a safe procedure and best treatment options for patient with ESRD which improves patient's quality of life and life expectancy as compared to dialysis (13)

Once the patients have undergone the surgery, the transplanted organ is vulnerable to a variety of acute insults including immunologic injury, ischemia-reperfusion injury, drug toxicity, and surgical complications (14). However, because of advancement in surgical, immunosuppressive, and monitoring technique, patient and graft survival rate have greatly improved. Despite all these advancements, post-transplant complications still remain a big challenge. Some of these complications are side effects of immunosuppression, vascular and urologic complications, peri transplant fluid collection, graft rejection, infection and Acute tubular necrosis (15,16)

A study from North western Nigeria which enrolled 16 patients tried to highlight the challenges in the management of Nigerian patient who sought kidney transplant outside their country. All of the subjects had a living donor and 87.5% of them were related to the recipient. India was their transplant destination for most of the patients. Although there was no statistically significant relationship between the country where the procedure was performed. The commonest complications in this study were, graft rejection which accounted for 71% and the diagnosis was made on clinical ground while only one patient had graft biopsy. All of the patient with graft rejection died 7(44%). The other challenge in this study was most of the subjects had no serum tacrolimus level test throughout the follow up period. One year graft and patient survival rate were 81.25% (17)

A single-centered retrospective cohort study from Saudi Arabia, compared patients who underwent transplant tourism to patients who were transplanted locally and followed up in their hospital from January 2015 to December 2018. A total of 254 local transplants and 60 patients from the transplant tourism group were included. Transplant tourism recipients were younger otherwise both groups were similar in gender, body mass index, diabetes, and hypertension. Recipients in the transplant tourism group had a significantly higher rate of delayed graft function (18.3% vs. 6.3%, $p = 0.005$), acute rejection (40% vs. 7.9%, $p < 0.001$), and higher posttransplant infection in

general. With more urological complications and higher graft failure at 3-years' follow-up (11.7% vs. 0.8%, $p < 0.001$)(10)

A study from Egypt assessed the surgical complications following living related kidney transplants and determined their impact on long term recipient and graft survival. In this study 104 patients were included. There were 41 surgical complications reported in 37 recipients, prevalence of 35.5%. Nineteen vascular complications developed in 17 (16.3%) recipients while 13 urologic complications developed in 11 (10.5%) recipients. Lymphocele was post-operatively diagnosed in 9 (8.7%) recipients. Recipient survival at 1 year and 5-year were 100% and 97% respectively. Graft survival at 1 year and at 5 years was 96% and 85.5% respectively. Surgical complications Mentioned, other than renal artery thrombosis, had no statistically significant impact on the graft and recipient survival (18)

According to a review of 52 patients who received renal allografts at SPHMMC between September 2015 and August 2017, there was no biopsy-proven rejection episode but there was one report of early graft loss from an unknown cause. 19 patients had at least one episode of infection requiring antibiotic use. Three patients were treated for CMV infection, while one was for BKV nephropathy. Only one recipient developed tuberculosis after the transplant. New onset diabetes after transplant developed in 7.69%, while 36.5% developed post-transplant erythrocytosis. Death-censored graft survival at one year is 97.5% while mean GFR at one week, three months, six months and one year was 73.1, 93.6, 95.6, and 96 ml/min, respectively. (9).

The same 52 kidney transplant recipients participated in a second study that examined surgical complications and kidney transplant outcomes. In this study, Post-surgical complications occurred in eight (15.3%) of the patients, and most (9.6%) of the complications were related to a surgical wound. There was one (1.9%) urologic complication due to ureteric kink. Lymphocele occurred in one (1.9%) of the patients (19).

Currently, increasing demand for kidney transplantation and the long waiting list of the local transplant center has enticed some patients with end-stage renal disease (ESRD) to venture kidney transplant outside their country and made their follow-up at the local transplant center..

As the transplant tourism is growing, we are also having patient who made their follow up at our transplant center after getting kidney transplant abroad. During their follow-up, we have observed some surgical and medical complications in this group of patients. Therefore, we wanted to assess their transplant outcomes by measuring the graft and patient survival rates and also by identifying the post-transplant complications.

1.3. Significance of study

For most patients with end-stage renal disease (ESRD), the only treatment strategy is renal transplantation. The rising prevalence of chronic kidney disease (CKD) mandates increased focus on strategies to expand kidney transplantation activities and improve the management of kidney transplant patients.

The data obtained from this research will provide evidence-based findings to clinicians to optimize the follow-up care of patients who travel abroad for transplantation. It will increase awareness regarding the major challenges of following patients who sought a transplant abroad and made their follow-up at the local transplant center and the way forward. The finding could also provide information for informing strategies that support clinicians and patients when making decision about travel for transplantation.

2. LITERATURE REVIEW

Effects of donor and recipient demographics on kidney transplant outcome.

A Swiss study which included 2,366 kidney transplant recipients analyzed the relationship between age at time of kidney transplantation with mortality, graft loss and self-rated health status in adult kidney transplant recipients. The average recipient age was 52.9 years (SD 13.6, range:18–82) at the time of transplantation, 35.8% (n =848) of the recipients were female. In 58.8% (n =1392) of cases grafts were received from deceased donors, and the average donor Age was 52.4 years (SD 16.1, range: 0–88). In this study Age at the time of transplantation predicted mortality in a linear fashion [HR (Hazard Ratio) =1.07; 95% CI: 1.06–1.08; $p < 0.0001$]. The relationship remained intact when adjusting for covariates (HR =1.07; 95% CI: 1.05–1.08; $p < 0.0001$), of which current smoking ($p = 0.0060$), diabetes mellitus ($p = 0.0056$) and donor type ($p = 0.0002$, better survival for living donor grafts) were significant. Concurrently, age at time of transplantation predicted graft loss, though in a non-linear way ($p = 0.0224$). This non-linear relationship remained significant ($p = 0.0224$) after controlling for covariates. Recipients who received a transplant from a living donor ($p = 0.0008$) and preemptive KT ($p = 0.0184$) recipients experienced lower graft loss rates.(20)

According to one systematic review and meta-analysis that included 5129 studies, there was no discernible difference in recipient 1-year survival between recipients of donors aged 50 and recipients of donors aged > 50 and recipients of donors aged 60 and recipients of donors aged > 60. But in patients who received grafts from donors younger than 60, the risk of AR and DGF was significantly reduced. This meta-analysis revealed that receivers of grafts from male donors had lower 1-year serum creatinine and greater eGFR than recipients of grafts from female donors (21). In a study from Korea that looked at the temporal trend, Pretransplant dialysis >6 months increased graft failure risk than preemptive KT (22).

Post kidney transplant complications and kidney transplant outcome

According to the 2019 Australian Data Registry Report, the 1- and 5-year kidney transplant survival rates in Australia for living donors are 98% and 91%, respectively. Similarly, patient survival rates at 1 year and 5 years are 100% and 96%, respectively. The survey also revealed that,

in the first year following transplantation, vascular complications, and technical problems accounted for 41% of graft losses, followed by acute rejection (17%) and glomerulonephritis (3%). After one-year, chronic rejection (63%) and glomerulonephritis (6%), respectively, were the main causes of graft losses. Cardiovascular disease (which accounted for 31% of fatalities with a working graft in the first year), infections (31%), and cancer (7%), were the main causes of death after the first year (23).

Among the 399 kidney transplant recipients in a Swiss study between January 2006 and December 2015, 191 (48%) were living donors. Out of 399 patients, 134 surgical complications were experienced by 24% of the patients. Nine grafts were lost as a result of vascular problems, which made up 39% of all complications. While urological and parietal problems accounted for 46 and 15% of all complications respectively. However, graft loss was not linked to any parietal or urinary problems. Five patients died in the first year, although none of these deaths were associated with graft loss. At one year, the graft survival rate was 96%, including patients who were still alive (12%) (24).

In one Dutch study, 3329 kidney transplant recipients were evaluated for the prevalence of major urological complications (MUCs), which are defined as urine leakage and ureteral blockage. The findings indicated that 208 (6.2%) patients experienced urological problems. Between recipients of living donors and recipients of deceased donors, there were no appreciable variations in the rates of complications. Urinary leakage and urethral blockage together accounted for 83 (2.5%) and 142 (4.3%) of the 208 MUCs. Early MUCs had little impact on the survival of the graft or the patient(25).

In a clinical data study of 253 kidney recipients from Kazakhstan, where the majority of transplants came from living donors, 83 (33%) were women and 170 (67%) were men with a female-to-male ratio of 1:2. In both groups, the median age of the receivers and donors were 39. 107 (42%) individuals experienced some post-operative problems following transplantation. Graft loss and acute postoperative rejection had a strong correlation. Acute rejection affected 18 (7% of the sample), and 13 (72%) of those affected were women, these post-operative issues significantly influenced graft loss. The 5-year graft survival rate for individuals who did not experience problems after transplantation was 94.7%, compared to 84.8% for the second group. (26).

A Study from Nepal that included 250 patients who underwent living donor kidney transplants from 8/8/2008 to 16/7/2014 showed that Infections were the most common complication after kidney transplants involving 94.2% of the patients. In 33.04 percent of patients, post-transplant diabetes mellitus (PTDM) developed. 43.3% of patients underwent indication biopsies; 131 indication biopsies were performed; of these, 29.01% revealed acute cellular rejection, 17.56% glomerulonephritis, and 12.21% antibody-mediated damage. In 9 individuals, acute tubular necrosis was observed (biopsy proven-7, clinical-2). Five patients developed stenosis of the graft renal artery. (27).

A prospective observational study from India included 122 kidney transplants which were followed for 9 months. Forty patients (30.1%) underwent biopsy for graft dysfunction, and 32 (26.2%) had graft rejection: 18 (14.8%) with antibody-mediated rejection, 5 (4.1%) with T-cell-mediated rejection, and 9 (7.4%) had mixed rejection. One patient lost their life soon following a transplant due to medical issues. Opportunistic infections were detected in 24.5% of the patients in this investigation, with the most common ones being CMV (10.7%), TB (5.7%), and aspergillosis (3.3%). 29 patients (about 24%) developed diabetes after the transplant. 93 patients (76.2%) had normal graft function (serum creatinine ≤ 1.2 mg/dL) at the end of the 9-month follow-up, 21 patients (17.2%) had chronic graft dysfunction (serum creatinine > 1.2 mg/dL for more than 3 mo), and 3 patients suffered graft loss (became dialysis dependent). In two patients who did not respond to treatment, graft loss was caused by ABMR, and in one patient, the primary illness (C3 glomerulonephritis) returned. Five patients (4.1%) died, 4 due to infection (2 fungal, 1 disseminated tuberculosis, 1 bacterial pyelonephritis), and 1 due to surgical complications (28).

A study from Nigeria evaluated the management of 47 KTR patients and reported that the majority of them were Males; 76.6% (36), and the mean age was 45.4 ± 13.6 years. Chronic glomerulonephritis, hypertension, diabetes mellitus, and kidney disease linked to HIV were the most frequent causes of CKD. All of the donors were alive, although only 25.5% of them were connected biologically, 4.3% were emotionally related (spouse), and 70.2% were neither. 90% of the transplants took place in India, while 4% each occurred in Nigeria and the United Kingdom. Good was the immediate result in 68.1% of cases, Fair in 29.8%, and Poor in 2.2%. During the trial, 29.8% of the patients passed away. In this research 95.3% of grafts survived for one year, and 2 years. (29).

A Sudanese study from a single center examined the initial 150 transplants carried out between November 2011 and 2015. In this study, 51% of the donors were females with a mean donor age of 30 ± 9.1 years. 77% of the recipients were males and the mean recipient age was 34.3 ± 10.7 years. 10% of participants experienced postoperative surgical problems. The most frequent side effects were urine incontinence and postoperative hematoma. DGF occurred in 4% of the patients, and AR occurred in 10.4% of the patients. In two individuals, graft loss as a result of renal vein thrombosis happened. According to the study, patient and graft survival rates were 87% and 88%, respectively, at four years. Major causes of mortality were linked to infections, especially tuberculosis (30)

According to a review of 52 patients who received renal allografts at Saint Paul's Hospital Millennium Medical College between September 2015 and August 2017, 41 (70.8%) of the patients were male. All kidneys were obtained from living donors, the majority of whom (89%) had a blood connection to the recipients, with 46% being siblings. 75% of donors were under the age of 45, and 23% were under the age of 25. 32.6% of native kidney disorders had unknown causes, whereas 30% had chronic glomerulonephritis, 7.7% had hypertensive nephrosclerosis, and 2% had ADPKD. 5.8% of patients (5%) underwent a preventive

There was no biopsy-proven rejection episode but there was one report of early graft loss from an unknown cause. 19 patients had at least one episode of infection requiring antibiotic use. Three patients were treated for CMV infection, while one was for BKV nephropathy. Only one recipient developed tuberculosis after the transplant. New onset diabetes after transplant developed in 7.69%, while 36.5% developed post-transplant erythrocytosis. Death-censored graft survival at one year is 97.5% while mean GFR at one week, three months, six months and one year was 73.1, 93.6, 95.6, and 96 ml/min, respectively. After a successful kidney transplant, pre-transplant hypertension subsided in 46.5% of patients (9).

The same 52 kidney transplant recipients participated in a second SPHMMC study that examined surgical complications and kidney transplant outcomes. In this study, Post-surgical complications occurred in eight (15.3%) of the patients, and most (9.6%) of the complications were related to a surgical wound. There was one (1.9%) urologic complication due to ureteric kink. Lymphocele occurred in one (1.9%) of the patients (19).

Conceptual framework

In this subsection, a conceptual framework of the characteristics and outcome of live donor kidney transplant recipients with procedure performed abroad and the relationship between these factors is presented.

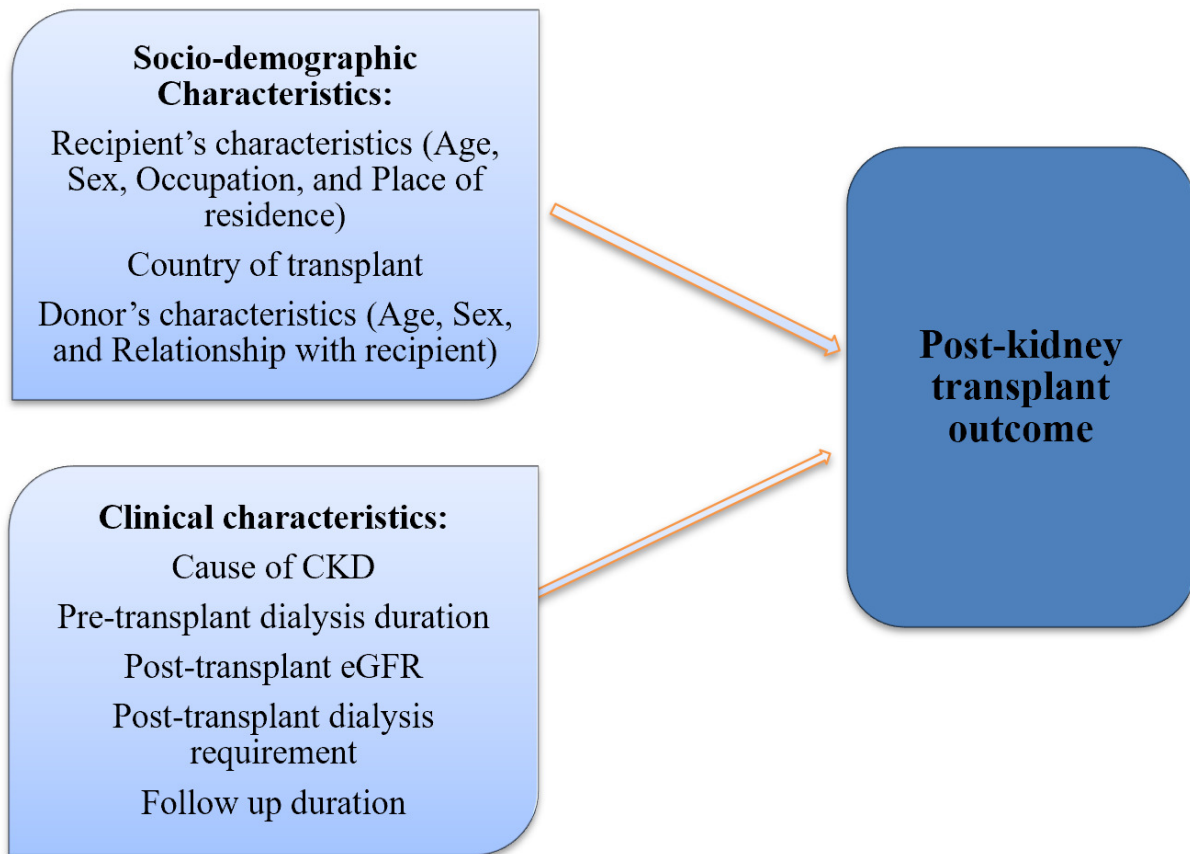


Figure 1: Conceptual framework of characteristics and outcome live donor kidney transplant recipients with procedure performed abroad, SPHMMC, Ethiopia, 2023.

3. OBJECTIVES

3.1. General objective

- To assess the outcomes of patients returning after receiving live donor kidney transplantation abroad at Saint Paul Hospital Millennium Medical College (SPHMMC), Addis Ababa, Ethiopia, from September 1st 2015 to December 31st 2022.

3.2. Specific objectives

- To determine post-transplant outcomes of patients returning after receiving live donor kidney transplantation abroad at SPHMMC
- To compare socio-demographic and clinical characteristics of patients who developed one or more post-transplant complication(s) and those who did not after receiving live donor kidney transplantation abroad at SPHMMC

4. METHODS AND MATERIALS

4.1. Study Setting and Period

The study was conducted at St. Paul's Hospital Millennium Medical College (SPHMMC), is a referral and teaching hospital established in 2007 and located in Addis Ababa, the capital city of Ethiopia. It has a catchment population of more than 5 million (31). In September 2015 the first and only national kidney transplantation center was opened at the hospital in collaboration between the ministry of health and the medical faculty at the University of Michigan. According to the data registered on the transplant OPD registry, since its establishment, an estimated total of 137 patients have received kidney transplant and a total of 168 patients are on follow up at the hospital after undergoing the kidney transplant abroad (32).

The study was conducted from February 1st to April 30th, 2023.

4.2. Study Design

An institutional based retrospective chart review was conducted with the duration of review from September 1st 2015 to December 31st 2022.

4.3. Source and Study Population

The source population was all kidney transplant recipients who were/are on follow up at SPHMMC after getting kidney transplant abroad from September 1st 2015 to December 31st 2022. Among these, all who fulfill the eligibility criteria of the study will be included as a study population.

4.4. Eligibility Criteria

All kidney transplant recipients who were/are on follow up at SPHMMC after getting kidney transplant abroad from September 1st 2015 to December 31st 2022 and who fulfill the following criteria will be included.

- Adult kidney transplant recipients
- Those who were/are on follow up for at least 1 year
- Those whose board approval for the kidney transplant was obtained from SPHMMC

4.5. Sample Size and Sampling Procedure

The study included all eligible patients who were on follow up from September 1st 2015 to December 31st 2022. During this period, there were a total of 168 kidney transplant recipients who were on follow up at SPHMMC after getting a kidney transplant abroad. From these, 74 fulfilled the eligibility criteria and were included in the final analysis. The remaining 94 were on follow up for less than a year and didn't get board approval from SPHMMC.

4.6. Study Variables

Dependent variable

- Post-kidney transplant outcome
 - o Complication status (Complication vs No-complication)
 - o Final outcome (Alive vs Death)

Independent variable

- Socio-demographic characteristics
 - o Recipient's characteristics
 - Age
 - Sex
 - Occupation
 - Place of residence
 - o Country of transplant
 - o Donor's characteristics
 - Age
 - Sex
 - Relationship with recipient
- Clinical characteristics
 - o Cause of CKD
 - o Pre-transplant dialysis duration
 - o Post-transplant eGFR (1 week, 3 months, 6 months, 1 year, 2 years, and 3 years)

- Post-transplant dialysis requirement
- Follow up duration

4.7. Operational Definitions

The following operational definitions will be used in the study.

- **End Stage Renal Disease:** irreversible decline in a person's own kidney function, which is severe enough to be fatal in the absence of dialysis or transplantation.
- **Chronic Kidney Disease:** a condition characterized by a gradual loss of kidney function over time.
- **Kidney Transplantation:** the organ transplant of a kidney into a patient with end stage renal disease.
- **Living Donor kidney Transplantation:** the removal of a kidney from a living donor and placement into a recipient whose kidneys no longer function properly.
- **Delayed graft Function:** is acute kidney injury that occurs in the first week of kidney transplantation, which necessitates dialysis intervention
- **Graft rejection:** is a process in which a transplant recipient's immune system attacks the transplanted organ or tissue.
 - ABMR.is a B cell-mediated process characterized by production of IgG antibodies against the transplanted kidney.
 - TCMR. Is type of rejection in kidney transplantation, Characterized by T cells and macrophages infiltration.
- **Graft failure:** A return to long term dialysis or re-transplantation.
- **Graft survival:** time from transplant to graft failure, censoring for death with a functioning graft and grafts still functioning at time of analysis.
- **Patient survival:** defined as time from transplant to patient death, censoring for patients who are lost to follow up or are still alive at time of analysis.

4.8. Data Collection Tool and Quality Assurance

A pre-tested data abstraction tool containing questions on all the study variables was used to collect data from medical follow up charts of kidney transplant recipients and donors obtained from routine clinic visits which followed the best clinical practice guidelines set out by KDIGO. This

was further supplemented with review of medical records obtained from abroad and by interviewing the recipients on information not obtained on the medical records.

Data was abstracted by two nephrology fellows who were trained on the tool. Data cleaning was made through checking for inconsistencies, numerical errors, and missing parameters, and appropriate measures were taken. Whenever a discrepancy in patient information was encountered, data was double-checked by referring to the main record and cross-referencing with another database whenever possible. SPSS version 25.0 software was used for all data management and analysis.

4.9. Data Analysis

The data was entered into SPSS version 25.0 statistical software package for analysis. Data for categorical variables was summarized using frequency with percentages. Numerical variables were summarized using mean with standard deviation (for normal data) or median with interquartile range (for skewed data) as required after testing the assumption of normal data distribution by using Shapiro-Wilk test of normality where $p\text{-value} > 0.05$ shows normal distribution.

Follow-up eGFR was presented using the Error Bar graph by using the mean with 95 CI of eGFR values collected at 1st week, 3rd month, 6th month, 1st year, 2nd year, and 3rd year of follow up. Furthermore, follow-up graft function with stage of CKD was presented using Bar graph for all the same follow up times.

To compare the socio-demographic and clinical characteristics of the participants between those who developed one or more complication(s) and those who did not, the following statistical tests were used. To compare the groups based on a categorical independent variable, a chi-square test was run. When the assumption of a chi-square test where no cell should have expected count of <5 failed, Fisher's exact test was used. To compare the groups based on a numeric independent variable, independent t-test was used. When the assumptions of t-test, normality and homogeneity of variance, failed then the parallel non-parametric test, Mann-Whitney U test was used. For all tests, $p\text{-value}$ of <0.05 indicates a statistically significant difference in the characteristics between those who developed one or more complication(s) and those who did not.

4.10. Ethical considerations

The study was carried out after securing ethical clearance from SPHMMC institutional review board (IRB). Since the study uses a secondary data, consent was waived by the IRB on behalf of the patients to be included in the study. Medical record number was used for the data collection and personal identifiers of the patient are not used in the research report. Access to the collected information is limited to the research team and confidentiality was maintained throughout the project.

4.13. Dissemination of results

The thesis report will be shared to SPHMMC IRB and the department of internal medicine. Further attempts to disseminate will be made through publication at nationally or internationally reputable journals and presentation at conferences, seminars and scientific forums targeting clinical care providers and policy makers so that the results can be used as an input to plan targeted clinical therapies and public health interventions both nationally and internationally.

5. RESULT

5.1. Baseline characteristics

The mean age of the participants was 34.9 ± 11.3 years and 54/74 were males. The majority were employed either in the government (35/74), private (23/74) or other (7/74) sectors and were from Addis Ababa, the capital city of Ethiopia (51/74).

The cause of CKD was identified in only 34 participants among which diabetes mellitus and hypertension constituted the largest proportion diagnosed in 14/34 and 12/34 of them. The majority of the participants (68/74) were on dialysis before the transplantation; 25/68 were on dialysis for less than a year, 31/68 for one to two years, 11/68 for two to five years, and 1/68 for more than 5 years. The transplant was done in India for 50/74 and in Turkey for 24/74.

The donor characteristics show that their mean age was 35.7 ± 8.8 years and most were females (40/74). The majority of the donors (47/74) were siblings and parents (11/74) of the recipients. (Table 1)

Table 1: Socio-demographic and baseline clinical characteristics of live donor kidney transplant recipients with procedure performed abroad, SPHMMC, Ethiopia, September 1st, 2015, and December 31st, 2022 (n=74)

Variable	Frequency / Mean $\pm$ SD	Variable	Frequency/ Mean $\pm$ SD
Age in years (Mean $\pm$ SD)	34.9 $\pm$ 11.3	Pre-transplant dialysis duration	
Sex		< 1 year	25
Male	54	1-2 year	31
Female	20	>2 year	12
Occupation		Not on dialysis	6
Government employee	35	Country of transplant	
Personal business	23	Turkey	24

Jobless	9	India	50
Others	7	Donor characteristics	
Place of residence		Age in years	35.7 ± 8.8
Addis Ababa	51	Sex	
Outside Addis Ababa	23	Male	34
Causes of CKD		Female	40
Diabetes Mellitus	14	Relationship with recipient	
Hypertension	12	Sibling	47
Glomerulonephritis	4	Parent	11
ADPCKD	3	Spouse	9
Nephrocalcinosis	1	Cousin/Nephew/Aunt	5
Unspecified	22	Child	2

5.2. Post-transplantation clinical characteristics and outcome

The 74 cases were followed for an average of 24.7 ± 13.2 months, the minimum being 1 year and the maximum 3 years. Follow-up eGFR was measured for 46/74 at the 1st week, for all 74 at the 3rd month, 6th month and 1st year, 23 (out of 23) at the 2nd year, and 5 (out of 13) at the 3rd year. The mean eGFR during the follow-up periods of 1 week, 3 months, 6 months, 1 year, 2 years, and 3 years was 100.9 ± 27.5 , 90.9 ± 22.2 , 91.7 ± 21.6 , 93.2 ± 24.7 , and 93.9 ± 23.9 ml/min/1.73 m², respectively. In the 3rd year, the median eGFR was 109.6 (IQR, 82.5-129.4) ml/min/1.73 m². **(Figure 2a)**

With regard to the progression of the CKD status, stage 3a CKD was diagnosed in 4/74, 1/23, and 1/5 cases on the 1st, 2nd, and 3rd year of follow up. Stage 3b CKD and stage 2 CKD were diagnosed in 1/74 and 2/74 cases in the 1st year of follow-up, respectively and in none in the subsequent years. During the entire post-transplant follow-up period, none progressed to stage 5 CKD and hence none required dialysis. **(Figure 2b)**

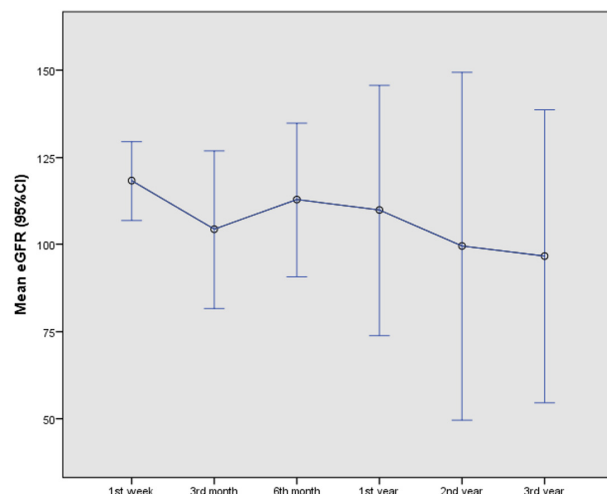


Figure 2a: Follow-up mean eGFR of live donor kidney transplant recipients, Ethiopia, 2023

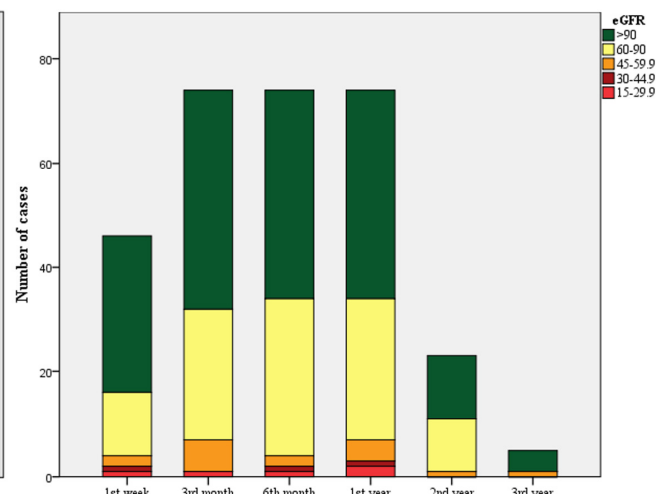


Figure 2b: Follow-up graft function of live donor kidney transplant recipients, Ethiopia, 2023

Of the 74 live donor kidney transplant recipients, 35/74 cases developed one or more post-transplantation complication(s) making the rate of complication 47.3% (95% CI= 36.4-59.6%). A total of 58 complications was observed among these 35 cases; 25/35 had only one complication and the rest 10/35 had up to four different complications. Among the 58 complications, the most frequent was infection in 29/58, mainly secondary to bacteremia (14/29) and UTI (12/29). In addition, 1 patient with BK viremia, 1 patient with fungal infection and 1 patient with CMV viremia and gastrointestinal tuberculosis were recorded. This was followed by acute rejection in 8/58 (antibody mediated in 5/8 and cellular in 3/8), NODAT in 8/58, hematoma or urinoma collection in 4/58, urethral injury in 3/58, and CVD in 3/58.

At the end of the follow-up period, 71/74 were alive, 2/74 died and 1/74 was lost to follow-up. The first death is a 39 years old male patient who died on the 13.5 month of his follow up. He was on warfarin for post double valve replacement and the cause of death was suspected to be warfarin associated bleeding resulting in diffuse alveolar hemorrhage and upper GI bleeding, and also a possible massive PE. The other death was a 23 years old male who died on 24.8 month of his follow up due to a car accident, he didn't have any complications. Both transplants were done in Turkey. This makes the patient mortality rate (considering only the death associated with warfarin

associated bleeding)1/74 (1.4%). The lost to follow-up case is a 27 years old male patient who was operated in India and had no remarkable complication during the 46.8 months follow-up time. (Table 2)

Table 2: Post-transplantation clinical characteristics and outcome of live donor kidney transplant recipients with procedure performed abroad, SPHMMC, Ethiopia, September 1st, 2015, and December 31st, 2022 (n=74)

Variable	Frequency / Mean $\pm$ SD	Variable	Frequency/ Mean $\pm$ SD
Follow-up duration in months (Mean $\pm$ SD)	24.7 $\pm$ 13.2	No. of complications	
Post-transplant eGFR in ml/min/1.73 m² (Mean $\pm$ SD)		Single	25/35
1 st week (n=46)	100.9 $\pm$ 27.5	Multiple	10/35
3 rd month (n=74)	90.9 $\pm$ 22.2	Type of complication	
6 th month (n=74)	91.7 $\pm$ 21.6	Infection	29
1 st year (n=74)	93.2 $\pm$ 24.7	Acute rejection	8
2 nd year (n=23)	93.9 $\pm$ 23.9	NODAT	8
3 rd year (n=5) (Median, IQR)	109.6 (82.5-129.4)	Collection	4
Post-transplant dialysis requirement		Urethral injury	3
3 rd month	0	CVD	3
1 st year	0	Others ^a	4
3 rd year	0	Final outcome	
Complications		Alive	71
No	39	Died due to medical cause	1
Yes	35	Died due to other cause	1
		Lost to follow up	1

^a Acute limb ischemia which required below knee amputation, chronic diarrhea and pancytopenia secondary to MMF, uretero-cutaneous fistula and lymphocele.

5.3. Comparison of characteristics of the participants based on complication status

A comparison of the socio-demographic, baseline and post-transplant characteristics of the participants was made between those who developed complications and those who didn't and it shows that the development of complication didn't show a statistically significant difference based on any of the characteristics, including country where transplant was done.

Table 3: Comparison of complication status based on characteristics of live donor kidney transplant recipients with procedure performed abroad, SPHMMC, Ethiopia, September 1st, 2015, and December 31st, 2022 (n=74)

Variable	Complications		p-value
	No	Yes	
Age in years (Mean $\pm$ SD)	35.4 $\pm$ 12.2	34.4 $\pm$ 10.5	0.720
Sex			
Male	29	25	0.777
Female	10	10	
Place of residence			
Addis Ababa	27	24	0.951
Outside Addis Ababa	12	11	
Causes of CKD			
Glomerulonephritis	4	0	0.101
Hypertension	3	9	
DM	7	7	
ADPCKD	2	1	
Nephrocalcinosis	1	0	
Unspecified	22	18	
Pre-transplant dialysis duration			
< 1 year	10	15	0.492
1-2 year	18	13	
>2 year	7	5	

Not on dialysis	4	2	
Country of transplant			
Turkey	12	12	0.747
India	27	23	
Post-transplant eGFR in ml/min/1.73 m² (Mean ± SD)			
1 st week (n=46)	103.3 ± 25.8	98.7 ± 29.5	0.574
3 rd month (n=74)	94.6 ± 19.3	86.9 ± 24.8	0.140
6 th month (n=74)	93.2 ± 18.8	90.1 ± 24.5	0.541
1 st year (n=74)	98.4 ± 21.2	87.4 ± 27.3	0.055
2 nd year (n=23)	99.1 ± 17.7	87.1 ± 29.9	0.280
3 rd year (n=5)	122.3 ± 21.5	83.3 ± 37.2	0.221
Follow-up duration in months (Mean ± SD)	25.6 ± 13.4	23.7 ± 13.2	0.538

6. DISCUSSION

In this study we assessed the outcomes of 74 patients returning after receiving live donor kidney transplantation abroad and were on follow-up at SPHMMC in Ethiopia from September 1st 2015 to December 31st 2022. The transplant was done in India for 50/74 and in Turkey for 24/74. The average age of the patients was mid-30s (34.9 ± 11.3 years) and the majority were male (54/74). Diabetes mellitus and hypertension were identified as the leading causes of CKD in over two-thirds of the cases. The majority of the patients were on dialysis before the transplantation for up to five years.

The mean eGFR during the average follow-up duration of 24.7 ± 13.2 months showed that kidney function remained stable for most patients after kidney transplantation. However, a small proportion of patients did develop stage 2, 3a and 3b CKD. However, none of these patients progressed to stage 5 CKD or required dialysis. This finding is similar with the previous study at SPHMMC. This could be attributed to proper selection of donor and recipient candidates by the local transplant team for those who travel abroad, and early detection of graft dysfunction along with proper management during post-transplant care. However, stage 3 CKD is lower in our study. This could be due to the lower rate of complicated infections in our study groups as compared to the study population of the previous research (9).

The results of the study show that almost half (35 out of 74) developed one or more post-transplantation complications. The most common complication was infection, which occurred in 29 out of 58 total complications. The most common type of infection was bacteremia (14/29). Infection is similarly reported to constitute the largest proportion of post-transplant complication in other studies as well (23,27). Acute rejection and NODAT were recorded each in 8/58 complications. The rate of these complications in this study is lower than findings from other studies where as high as 29.0% acute rejection rate and 33.0% NODAT were reported (23,26-28,30). In addition, CMV viremia and TB were recorded each in 1/74 patient in our study, which is lower than a study conducted in India where CMV infection rate of 10.7% and TB infection rate of 5.7% were reported (28).

At the end of the follow-up period, 71/74 were alive, 2/74 died (1 due to medical cause and 1 due to car accident) and 1/74 was lost to follow-up. This makes the patient mortality rate (considering

only medical related death)1/74 (1.4%). This is a lower Mortality rate compared to a previous report at SPHMMC which might be attributable to better focus on primary prophylaxis, screening for emerging infection before causing serious complications allowing for preemptive therapy, better infection prevention strategies, and it could also be transplant center effect (9).Furthermore, this is a relatively lower rate as compared to reported mortality rates of 4.0 % up to as high as 11.0% in studies conducted in Australia and South Africa and a rate of 29.8% in a study conducted in Nigeria (5, 6, 29).

The comparison of complication development based on the country of transplant showed that there is no statistically significant difference in the rate of complication between those who were operated in India and those who were operated in Turkey. This means that the country where the transplant was performed does not seem to be a factor in the development of complications. In addition, the rate of complication didn't show a statistically significant difference based on other socio-demographic and clinical characteristics. Our report on recipient age,sex,place of residence and dialysis vintage is similar as compared to the previous study at SPHMMC (9).In addition to this the incidence of DM Nephropathy is higher in our study. However there is no statistically significant difference in the diabetic patients between those who develop complications or not. This is in contrast to a report from istanbul which showed an increased morbidity and mortality in patients with DM (33). This may be attributed to meticulous pre transplant evaluation in diabetic patients and close follow up during post op care.

The results of this study have to be interpreted in consideration of the following strengths and limitations. Its strength is that it is the first study to assess the characteristics and outcome of live donor kidney transplant recipients who were operated abroad and hence will serve as a baseline to support the clinical decision and to do further research. On the contrary, the study has its own limitations due to the following reasons. The first is, due to the retrospective nature of the study data on a number of additional relevant clinical factors were not accessible and hence cannot be studied. The second is, due to the small sample size of the study adequate number of potential outcomes was not observed and hence patient and graft survival could not be assessed and also further confirmation of the relationship of rate of complication with country of transplant and other variables could be confirmed with regression analysis. Lastly, due to the lack of a comparator

group of patients who were operated in the country, it is difficult to pinpoint if the outcomes of patients who were operated abroad is actually comparable, worse or better as compared with those operated in the country and thus make a clinical decision accordingly.

7. CONCLUSIONS

The post-transplant outcome of live donor kidney transplant recipients abroad who were followed for an average of 24.7 ± 13.2 months showed that kidney function can remain stable for most patients and only few progressed to stage 2 and 3 CKD, a considerable proportion has developed one or more complication(s) and mortality rate was very low. The rate of complication didn't show a significant difference in terms of country of transplant.

8. RECOMMENDATIONS

The findings of the study provide an insight to clinicians to understand the post-transplant complication pattern, what to expect and be prepared accordingly. It also serves as a baseline for further studies. For better conclusion, we recommend further large-scale prospective study by including cases operated in Ethiopia as comparator and by considering all relevant sociodemographic, behavioral, and clinical characteristics.

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ANNEXES

Annex I. Patient's information document & Informed Consent Form

Dear participant,

My name is Tigist Fikre. I am collecting data for a research study intended to determine the Outcomes of patients returning after receiving live donor kidney transplantation abroad at Saint Paul Hospital Millennium Medical College (SPHMMC), which is expected to assess post-transplant complications in patients who undergone the kidney transplant abroad. You are selected to participate in this study. Your participation in this study is based on your will. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you are willing to participate or refuse or decide to withdraw later, you will not be subjected to any ill-treatment. If you are willing to participate in this research, you need to sign the agreement form. After then you will be interviewed by the data collector. You do not need to write your name or tell your name to the data collector and all your response and the results obtained will be kept confidential by using a coding system

Person to contact

This research is approved by the SPHMMC School of Public Health Institutional Review Board (IRB). If you have any questions, you can contact any of the following individuals and you may ask any time you want

Investigator: -

Mobile:

E-mail:

Informed consent Form

I am told that this study aims to determine the Outcomes of patients returning after receiving live donor kidney transplantation abroad at Saint Paul Hospital Millennium Medical College (SPHMMC), which is expected to assess post-transplant complications who undergone kidney transplant abroad and the information document has been given to me. I understood the purpose of the study. I have agreed to participate in this study voluntarily. I have understood that I have every right to refuse participation in this study at any time and I will not be denied any benefit and services I am getting as a result.

I have understood that I will not be provided any incentives or payment to take part in this project. I have understood the information taken from me will serve only for this study, not for any other purpose, and will be kept confidential also no personal information or name will be published

Agreement of participation

Signature of participant

Signature of witness

Signature of Investigator

Annex 2: Questionnaire

Code:

Date:

Part 1: Background information on Socio-Demographic Factors

Recipient Data	
1. Gender	1. Male 2. Female
2. Age	_____ years old
3. Occupation	1, Governmental employee 2, Personal business 3, Jobless 4, Others
4. Address	1. Addis Ababa 2. Outside Addis Ababa
5. Relationship with donor	_____
Donor Data	
6. Age	_____ years old
7. Gender	1. Male 2. Female

Part 2. Pre transplantation information

8. Causes of ckd	1. Glomerulonephritis----- 2. Hypertension----- 3. Diabetes Mellitus----- 4. Unknown-----
9. How long was the patient on dialysis before transplant.....?	1. <1 year---- 2. 1-2 year---- 3. 2-5 year-----

	4. >5 year----- 5. Not on dialysis
--	---------------------------------------

Part three: Information on post transplant

10.Where did the patient have the kidney transplant(Country)?.....	1, Turkey 2, India 3, Thailand 4, Other
11. When did the patient have the kidney transplant?	DD/MM/YY.....
12. What was the Creatinine(mg/dl) at the following post transplant time period.	
12.1 . 1 st week	
12.2. three months	
12.3. six months	
12.4 . one year	
12.5. two years	
12.6. Three years	

Part 4: Was there documented complications post-transplant?

Complications	Yes	No
13.Delayed graft function		
14.Acute rejection		
15.If the answer is yes and if biopsy was done ,then which type of rejection was it? 1,Cellular rejection----- 2,Anti body mediated rejection..... 3,Mixed----- 4,other		
16. Wound infection		
17. Urethral injury		
18,Collection		
19. If the answer is yes,What was the collection 19.1,Hematoma----- 19.2,Lymphocele----- 19.3,Urinoma-----		

20,Vascular complication(Renal vein thrombosis or Renal artery thrombosis)		
21,UTI		
22,Post TransplantDiabetic mellitus		
23. Was there documentedInfection? If yes what was the infection		
A,Bacteremia		
B,Fungal		
C,CMV Viremia		
D,BkViremia		
E,Tuberculosis		
F, Covid 19		
24. ,CVD(cardiovascular disease)		
Others		

25,. Patient status at 3month and one year

Patient status at	At 3month	At 1 year
1. Alive		
- Off dialysis		
- Dialysis dependent		
2, Dead		

DECLARATION

I the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide a timely progress report to my advisors and seek the necessary advice and approval from my primary advisors in the course of the research. I will communicate timely to my advisors all stakeholders involved in the study including any source of funding for this research

Name of the student: _____

Signature: _____

Date: _____

Approval of the Primary Advisor

Name of the primary advisor: _____

Signature: _____

Date: _____

Approval of the Co-Advisor

Name of the Co-advisor: _____

Signature: _____

Date: _____