Unexpected Medical Conditions Discovered During Live Donor Kidney Evaluation: Single Center Study

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ABSTRACT

OBJECTIVES: Living donor kidney transplantation (LDKT) is the preferred method of treatment for patients with end-stage kidney disease. Potential living kidney donors (PLKD) are evaluated through a thorough medical, psychological and surgical work-up to ensure successful transplantation with minimal risks to all parties involved. The transplant center at Rhode Island Hospital has noticed an increasing number of PLKDs excluded from donation due to conditions newly diagnosed during the screening process. Our objective is to understand the local trends underlying the high PLKD exclusion rates in the context of newly diagnosed conditions, age, race, and sex of the excluded donors.

STUDY DESIGN AND METHODS: Our study is a retrospective electronic medical record review of the 429 PLKDs screened at Rhode Island Hospital Kidney Transplant Center between December 2012 and April 2023. Age, race, gender, relationship to recipient, and reasons for exclusion were collected from the medical record for each PLKD.

CONCLUSION: 115 of the 429 total PLKDs screened were excluded for newly diagnosed conditions, the most common of which were renal issues (49%), diabetes mellitus (33%), and hypertension (13%), with many comorbid diagnoses. While these donors were able to receive proper treatment after their diagnosis, the earliest intervention possible yields the best prognosis. The high prevalence of treatable yet undiagnosed conditions raise many public health concerns, such as primary care gaps or discontinuous healthcare, and increases awareness about the importance of follow-up care for the excluded PLKDs.

KEYWORDS: Live kidney donor, hypertension, diabetes mellitus, kidney transplantation

BACKGROUND

Kidney transplantation is the best renal replacement therapy for patients with end-stage kidney disease.[1] Due to the severe shortage of deceased donor kidneys and the prolonged waiting time on the transplant list, living donor kidney transplantation (LDKT) remains the preferred method of treatment for these patients, with greater survival outcomes and better graft success rates than transplants from deceased kidney donors.[2] Despite the many benefits of LDKT, there are many barriers with ensuring the safety of the donor being the essential goal.[3]

Determining the suitability of donor candidates requires balancing potential risks and anticipated benefits for the donor. The evaluation of a live kidney donor is a very thorough and meticulous process. Being a kidney donor encounters the short-term risk of peri-operative complications and the long-term risk of developing chronic kidney disease, end-stage kidney disease, hypertension and possible pregnancy-related complications.[4] Therefore, minimizing these short- and long-term risks after donation should be the foundation of the donor evaluation.

The live donor candidate undergoes a thorough evaluation by having a complete medical, psychological and surgical work-up, in addition to the candidate approval by a multidisciplinary team, with an anticipated outcome of donation. The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines on the evaluation and care of living kidney donor advocates for replacing decisions based on assessments of single risk factors in isolation with a comprehensive approach to risk assessment using the best available evidence,[5] and recommends that each transplant program determine an acceptable end-stage kidney disease (ESKD) risk threshold for living donor candidates.[6] The precise evaluation protocols and decision criteria on the medical, psychological and surgical work-up still vary between countries and transplant centers, respectively.[7]

While exclusion criteria vary from center to center and are amended over time after periodic review, we have noticed an increasing number of otherwise healthy potential living kidney donors (PLKDs) who were excluded from donation due to a new medical diagnosis during the medical evaluation process at our transplant center.

Our objective is to understand the trends underlying the high PLKD exclusion rates despite the shortage of living kidney donors. This study aims to identify the most common newly diagnosed conditions precluding donation for the previous decade (December 2012–April 2023) at our center and evaluate trends in these diagnoses to achieve a better understanding on how to improve LDKT. We also aim to make meaningful comparisons between the age, race, and sex of these excluded donors.

METHODS

Study Population

We performed a retrospective electronic medical record review of PLKDs screened between December 2012 and April 2023 at the Rhode Island Hospital Kidney Transplant Center to identify which individuals were excluded from being potential donors. Our center evaluated 429 prospective donors during this time. Per our center's criteria, all PLKDs screened must be above 18 years of age, and were generally from the greater Providence region, with some exceptions from southern Massachusetts and northern Connecticut. The data collected on these excluded individuals included age, race, gender, relationship to recipient, and reasons for exclusion. For those who were excluded for conditions first discovered during the donor screening process, the method of diagnosis was also included.

Our transplant center serves the greater Providence community, which has a large Hispanic population. In the 2020 census, the Providence population was 42.9% Hispanic, compared with 19% nationally.[8,9]

Screening Criteria

The PLKD screening process is quite rigorous and involves many moving parts. It is first ensured that the donor has a comprehensive overview of the process and procedure in order to obtain proper consent. Afterwards, the PLKD undergoes extensive medical and psychosocial work-up in order to best gauge their candidacy for successful donation. While the multi-disciplinary donor team at our transplant center evaluates every PLKD and their testing and interview results, there are a few absolute contraindications that are important to note.

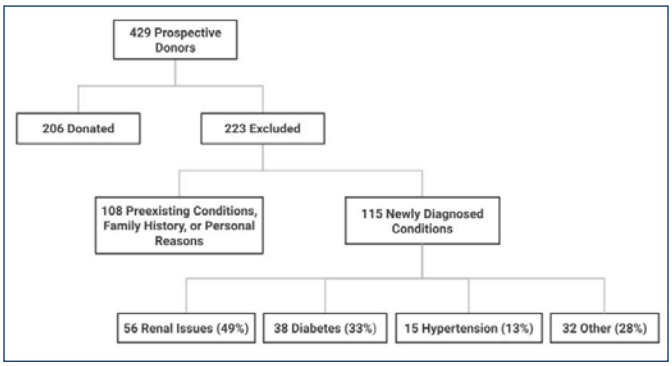
This process includes evaluating kidney function by checking creatinine-based estimated glomerular filtration rate (eGFR) by measured urinary creatinine clearance twice, as it is the cornerstone of living kidney donor screening, urinalysis with urine microscopy, quantification of proteinuria and albuminuria using urine protein/creatinine ratio, and urine culture. We follow the KDIGO guidelines: an eGFR >90 mL/min/1.73 m^2 is always compatible with LKD, and an eGFR of <60 mL/min/1.73 m^2 is always a contraindication. Cardiovascular and metabolic work-up include blood pressure readings twice in the office, hemoglobin A1c including glucose tolerance test (GTT) for high-risk patients, electrocardiogram, and fasting lipid profile. Routine laboratory testing, chest X-ray, infectious work-up, and cancer screening according to national guidelines are done on all patients. Ambulatory blood pressure monitoring is performed on patients to confirm office hypertension, and an echocardiogram is done on patients with an abnormal electrocardiogram.

RESULTS

We performed a retrospective analysis of all living kidney donor candidates who had presented for potential living kidney donation at Rhode Island Hospital Transplant Center between December 2012 and April 2023.We screened 429 PLKDs, of which 223 individuals (52%) were excluded. Of these 223 excluded PLKDs, 108 (25%) of total, (48% of excluded), were dismissed due to preexisting health conditions, significant family medical history, psychiatric concerns, opted-out voluntarily, or their intended recipient did not need a donor anymore. Meanwhile, 115 PLKDs (27%) of total, (52% of excluded), were diagnosed with new medical conditions during the screening process (**Figure 1**).

Figure 1. Outcome of the living donor evaluation process

Of the 429 overall PLKD candidates, 206 were cleared and successfully donated. Of the 223 PLKD-excluded candidates, 108 were due to pre-existing conditions, family history or personal reasons, and 115 due to newly diagnosed medical conditions discovered during the live kidney donor evaluation process. Renal issues (49%), diabetes (33%) and hypertension (13%) represent the three most common newly medical conditions. Other diagnoses represent only 28%. It is important to note that some patients were diagnosed with more than one condition.



Renal issues, diabetes mellitus marked by high hemoglobin A1c or an impaired GTT, and hypertension were the most diagnosed new medical conditions and represented 49% (56/115), 33% (38/115), and 13% (15/115) respectively. Other candidates who were excluded are due to cardiovascular issues (11%), pulmonary issues (7%), abnormal genetic testing (3%), and cancer (2%). Individuals with other health conditions such as a hepatic lesion, sexually transmitted infection, extended spectrum beta-lactamase *E coli*, lymphoproliferative disorder, or abnormal liver enzymes represented the smallest percentage of the cases. Some patients were diagnosed with more than one medical condition.

Detailed information regarding the newly diagnosed conditions of those 115 PLKDs is categorized in **Table 1**. The causes of the renal conditions discovered during the evaluation are summarized in **Table 2**.

Table 3 provides a gender and race breakdown of all the excluded donors compared to distribution in the total

patient pool. In general, females were more willing to donate than males, as 68% of excluded donors were female. This trend was echoed by the proportions in diabetes mellitus (39% male, 61% female) and renal issues (22% male, 78% female), while hypertension had a greater proportion of men (67% male, 33% female). PLKDs were also predominantly White/Caucasian (76%), followed by Hispanic/Latino (12%), Black/African American (5%), and (Asian 5%); 2% of excluded donors did not report their race. Black/African American PLKDs are overrepresented in diabetes and hypertension diagnoses, making up 11% and 13% of diagnoses respectively.

Table 1. Categorizations of Newly Diagnosed Medical Conditions

Condition	Number of Patients	Percent of Total
Renal Issues	56	49%
Diabetes Mellitus	38	33%
Hemoglobin A1C (>5.7)	37	32%
Impaired Glucose Tolerance Test	4	3%
Newly Diagnosed Hypertension	15	13%
Cardiovascular	13	11%
Left Ventricular Hypertrophy	5	4%
Coronary Artery Disease	9	8%
Fibromuscular Dysplasia	1	1%
Infrarenal Aortic Dissection	1	1%
Valvular Disease	2	2%
Pulmonary	8	7%
Lung Nodules	4	3%
Emphysema	3	3%
Ground Glass Opacities	1	1%
Genetics	3	3%
Sickle Cell Trait	1	1%
COL4A4	2	2%
Cancer	2	2%
Breast	1	1%
Anal	1	1%
Hepatic Lesion	2	2%
Sexually Transmitted Infection	1	1%
Infection (ESBL EColi)	1	1%
Lymphoproliferative Disorder	1	1%
Abnormal Liver Enzymes	1	1%

The number of patients and percentages will add up to greater than 1 because many patients had comorbid new conditions, and thus were counted for multiple disease categories.

Table 2. Renal Conditions' Breakdown

Renal Condition	Number of Patients	Percent of Total
Abnormal Creatinine Clearance	24	21%
Multiple or Bilateral Renal Cysts	7	12.5%
Hematuria	6	5%
Kidney Anatomy	4	3%
Kidney Stones	6	5%
Focal Segmental and Global Glomerulosclerosis (FSGS)	3	3%
Polycystic Kidney Disease (PCKD)	2	2%
Proteinuria	1	1%
Kidney mass	1	1%
IgA Nephropathy	1	1%
Thin Basement Membrane Nephropathy	1	1%
Horseshoe Kidney	1	1%

Table 3. Gender and Race Breakdown of Excluded Donors

Category	Gender Breakdown		Race Breakdown				
	Male	Female	White	Hispanic	Black	Asian	Not Listed
Renal	23%	77%	81%	13%	2%	4%	0%
Diabetes Mellitus	39%	61%	68%	11%	11%	8%	3%
Hyper-tension	67%	33%	80%	7%	13%	0%	0%
Total	32%	68%	76%	12%	5%	5%	2%

DISCUSSION

Living kidney donation is considered the ideal method of treatment for patients with end-stage kidney disease due to superior outcomes. However, as living kidney donation poses both short-and long-term risks for the donor, the objective of the donor evaluation process is to predict and minimize the potential for complications. Diabetes mellitus, hypertension and obesity are contraindications to kidney donation because of the postsurgical complications and the future development of renal failure and cardiovascular disorders. Thus, it is crucial to detect metabolic syndrome before living donation in order to avoid these complications in the long-term.[10]

Also, eGFR is the cornerstone in evaluating PLKDs. The 15-year risks of ESRD that have been observed among kidney donors in the United States were 3.5 to 5.3 times as high as the projected risks among non-donors, with similar patterns of risk according to race and sex in the absence of donation and in the presence of donation.[11] Long- and short-term outcomes of mortality, life expectancy, quality of life, risks

of ESRD, and hypertension for patients who have undergone living donor nephrectomy have been assessed and validated by several studies.[12,13] As a result, the evaluation of PLKDs is quite rigorous, involving a comprehensive medical, surgical and psychosocial work-up as well as a collaborative review of every PLKD by a multidisciplinary team. Our retrospective study examines excluded PLKDs from December 2012 to April 2023 and investigates the trends in the newly medical conditions discovered during the evaluation and leading to excluding these potential donors.

Our study showed that over half of excluded donors were diagnosed with new medical conditions, all of which would have severe long-term consequences on the donor's health if not discovered and properly treated. The most common newly diagnosed conditions during live kidney donor evaluation were renal issues (49%), diabetes mellitus (33%), hypertension (13%). Some patients were diagnosed with more than one medical condition.

Renal issues represented 49% of undiagnosed medical conditions. In our study, three patients underwent a diagnostic kidney biopsy in the setting of microalbuminuria and were found to have biopsy-proven secondary focal segmental glomerulosclerosis (FSGS). Due to microscopic hematuria, one patient was found to have biopsy proven IgA nephropathy, and another patient had thin basement membrane disease. Because microalbuminuria is a factor in the progression of nephropathy and increases the cardiovascular risk,[14,15] and microscopic hematuria can have long- term outcomes with a higher risk of developing ESRD in the general population,[16] these patients were excluded from donating. These patients were unaware of their kidney disease prior to the donor evaluation. Currently, they are following closely with a nephrologist and getting appropriate treatment, which will allow for favorable long-term outcomes with respect to their kidney function.

Three other patients were diagnosed with kidney stones on their CT scan, in addition to an abnormal stone panel. Given the high risk of acute kidney injury and its complication in case of a stone in single kidney,[17] these candidates were excluded from donating. They were referred to the stone clinic and are being treated accordingly.

Polycystic kidney disease (PCKD) was diagnosed in two patients with a strong family history of PCKD, but they had never been diagnosed or checked for it previously. Public education and awareness about PCKD, the most frequent genetic cause of renal failure, is pivotal. Its detection at a young age allows an early intervention for a better outcome as patients need to be educated about the complications that may include cerebral aneurysms, kidney stones, and end-stage renal disease.

Diabetes and hypertension were the next two most diagnosed conditions in our study. These conditions are particularly crucial to exclude donors for as they are two of the major risk factors for cardiovascular disease.[18-19] Additionally, studies on 10 years follow-up post-donation demonstrate that diabetes and hypertension are the leading causes of long-term risk of ESRD.[20] The increase in diagnoses of diabetes and hypertension in our study can be explained in part by the incremental trends in these conditions. There is a predicted increase in the number of cases of type 2 diabetes from 415 million to 642 million by 2040, due to an increasingly common lifestyle associated with low energy expenditure and high caloric intake.[21] Upregulation of the renin-angiotensin-aldosterone system, oxidative stress, inflammation, and activation of the immune system will likely contribute to the close relationship between diabetes and hypertension and resulting growth in hypertension prevalence.[22]

Additionally, the diagnoses and management of hypertension are a challenge for many patients more broadly. Following the Affordable Care Act, 37.3% of patients had undiagnosed hypertension and 27.0% of patients with diagnosed hypertension were without a prescribed anti-hypertensive medication.[23] Access to health insurance is a critical aspect of hypertension detection, treatment and control, and a lack of insurance can greatly exacerbate barriers to successful hypertension care and management. Therefore, the high levels of previously undiagnosed diabetes and hypertension could reflect greater public health trends of these conditions.[3]

Incidentally discovered malignancy is a major finding in the cohort of potential donors and was previously reported with rates of 0.2–0.8%.[24, 25] Malignant disease was discovered in 2% of our retrospective study. One candidate was diagnosed with breast cancer and the other candidate with anal cancer. The early detection of these asymptomatic malignancies allowed for immediate intervention with great impact on their prognosis and recovery.

In addition, genetic testing is a rapidly evolving strategy for the evaluation of potential donors that has the potential to improve risk assessment and optimize the safety of donation.[26] The growing accessibility and falling costs of genetic sequencing techniques has expanded the utilization of genetic testing in clinical practice. Although genetic testing can be a valuable tool in living kidney donor evaluation, its overall benefit in donor assessment has not been demonstrated and it can also lead to confusion, inappropriate donor exclusion, or misleading reassurance.[27] In our study, family history necessitated performing genetic testing, which resulted in three candidates being excluded. One patient was diagnosed with sickle cell trait, and two others were diagnosed with heterozygous pathogenic COL4A4. It is well known that the presence of sickle cell traits is associated with an increased risk of CKD, decline in eGFR, and albuminuria, compared with non-carriers.[28] In view of heterozygous COL4A4, there are reports of 14% to 20% of cohort of COL4A3 and COL4A4 heterozygotes with kidney failure.[29,30] Our patients in the study were excluded from donation due to these newly diagnosed genetic diseases.

Most of the new diagnoses in our study are ones frequently discovered in the primary care setting, and the high rates of new PLKD diagnoses indicates there could be issues with underutilization of primary care or discontinuous medical care in general, both of which can stem from a variety of factors. This is concerning, as many of these patients would have benefited from preventative measures or earlier treatment interventions. Furthermore, while our center takes the task of protecting PKLD's safety from organ donation seriously, we ultimately focus on the long-term health and follow-up care of the donation recipients and approved donors.

These new diagnoses could be considered a benefit of PLKD evaluation. Patients who do not have reliable access to a primary care physician can benefit from a full physical and medical work-up by agreeing to proceed with the work-up for donation. However, this presents ethical concerns regarding donor coercion and incentivized donation. We believe that this demonstrates the crucial need for greater public education regarding accessing healthcare. It is important that physicians empower patients to take control of their own healthcare and stress the importance of routine check-ups for prevention and early detection of treatable conditions.

It is important to note the gender and race breakdown in our study. Overall, we saw a marked difference in gender, as 68% of excluded donors with newly diagnosed conditions were female, a distribution that stays constant over the top three diagnosed conditions except for hypertension. This could suggest that more females are interested in being living donors overall, or that females have a higher rate of newly diagnosed conditions. In 1988, when UNOS/OPTN began to collect living donor data, the ratio of female-to-male living donors was 55%:45%, although in the past five years men now comprise less than 40% of all living kidney donors.[31] The over-representation of female living donors over the past 30 years is not unique to the US.[32] In all countries except Iran, women account for over 50% of living donors.[33]

Regarding race, White Caucasians represent most donors excluded in our center (76%). In contrast, 12% of PLKDs were Hispanic, 5% were Black, and 5% were Asian. While the lower numbers of Black and Asian candidates reflect general population demographics, the lower numbers of Hispanic candidates are significant due to the large Hispanic population of the greater Providence area. The study by Alvarado et al suggests that the lower rate of Hispanic donors in the US could be due to a lack of culturally competent care, as the Hispanic ethnicity is historically reported in different and inaccurate ways by healthcare providers.[34] Furthermore, availability of translation services also poses a challenge for accessibility of presenting as a PLKD. Barriers to LDKT specific to Hispanics are due to misconceptions about living kidney donation, fears about not being able to have children or shortening the donor's life expectancy,[35] and lack of educational materials about transplantation in Spanish.[36,37] In our study, African Americans represent only 5% of the excluded donors. Although little is known about the long-term outcomes of African American LKDs, these patients experience a substantial incidence of hypertension and modest drop in eGFR post-donation, and obesity may increase the magnitude of renal decline.[38] In addition, APOL1 genotyping may have a role in the evaluation and informed consent process of these potential donors.[39]

Limitations

Our study has some limitations. First, it is a retrospective study. Second, the data is sourced solely from one transplant center, whose donor criteria and evaluation guidelines might vary from other centers. It is important to recognize that this data does not represent all transplant centers. Importantly, because electronic health records were introduced during this time, the charts of PLKDs screened before this transition were on paper and have been scanned into the system, limiting our access to labs, imaging, and other data. Our study is restricted by the rigor and specificity of these charts, and some are not as thorough as would be ideal.

In summary, the diagnosis of new conditions during the PLKD screening process allowed patients to get proper treatment that they would not have otherwise received. Furthermore, these results also yielded information regarding the physical health and societal wellness of the population our center serves. This included the prevalence of certain conditions like diabetes and hypertension, societal barriers to healthcare, importance of empowering patients to take charge of their own personal health, and the unique challenges specific racial and gender demographic populations face.

CONCLUSION

Our study found that half of excluded donors at our center were diagnosed with new medical conditions that should have been discovered in a primary care setting. The three most common diagnosis were renal issues, diabetes mellitus and hypertension. These patients were able to receive proper treatment after their diagnosis. However, for many of these conditions, the earliest intervention possible yields to the best prognosis. The high prevalence of treatable yet undiagnosed conditions raises many public health concerns, such as primary care gaps or discontinuous healthcare, as well as the importance of follow-up care for excluded PLKDs. Overall, we believe that looking at potential living kidney donor screening could be an unconventional yet fruitful method of measuring the health of our population.

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