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Living donor evaluation and exclusion: the Stanford experience

Jessica B. Lapasia^a, Soo-yea Kong^a, Stephan Busque^b, John D. Scandling^a, Glenn M. Chertow^a, and Jane C. Tan^a

^aDepartment of Medicine, Stanford University School of Medicine, Stanford, CA, USA

^bDepartment of Surgery, Stanford University School of Medicine, Stanford, CA, USA

Abstract

Background—The proportion of prospective living donors dis-qualified for medical reasons is unknown. The objective of this study is to delineate and quantify specific reasons for exclusion of prospective living donors from kidney donation.

Methods—All adult prospective kidney donors who contacted our transplant program between October 1, 2007 and April 1, 2009 were included in our analysis (n = 484). Data were collected by review of an electronic transplant database.

Results—Of the 484 prospective donors, 39 (8%) successfully donated, 229 (47%) were excluded, 104 (22%) were actively undergoing evaluation, and 112 (23%) were withdrawn before evaluation was complete. Criteria for exclusion were medical (n = 150), psychosocial (n = 22), or histocompatibility (n = 57) reasons. Of the 150 prospective donors excluded for medical reasons, 79% were excluded because of obesity, hypertension, nephrolithiasis, and/or abnormal glucose tolerance. One hundred and forty-seven (61%) intended recipients had only one prospective living donor, of whom 63 (42%) were excluded.

Conclusions—A significant proportion of prospective living kidney donors were excluded for medical reasons such as obesity (body mass index >30), hypertension, nephrolithiasis, and abnormal glucose tolerance. Longer-term studies are needed to characterize the risks to medically complex kidney donors and the potential risks and benefits afforded to recipients.

Keywords

donor evaluation; donor exclusion; kidney transplant; living donor

Despite advances in dialysis and transplantation, the burden of morbidity and mortality in patients with end-stage renal disease (ESRD) continues to be high. The survival benefit and improvement in quality of life with transplantation has been well documented (1–5). Severe organ shortage and long wait-times on the deceased donor list have increased pressure to accept non-traditional donors for organ transplantation. Owing to shorter wait-times and superior allograft performance, living donor transplantation has become the preferred mode of transplantation in recent years. Identifying ways of safely increasing the living donor pool should be an essential component of any multi-faceted strategy aimed to address the widening gap between donor organ supply and potential recipient demand.

Survey-based studies have highlighted the wide variability in the living kidney donor evaluation process across the United States (6–8). Specifically, these studies have demonstrated considerable regional and transplant center-specific variation in the acceptance of donors with obesity, hypertension, nephrolithiasis, and histoincompatibility. Additionally, an analysis of the Organ Procurement and Transplantation Network (OPTN) database reported that 24.2% of living kidney donors in the United States between July 2004 and December 2005 had obesity, hypertension, and/or estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m² (9). However, the proportion of prospective donors excluded for these reasons remains unclear. Although there are some international reports of the donor evaluation process and specifics regarding donor exclusion (10–12), we were unable to find published studies in the United States that characterized the candidate living donor population and reasons for exclusion.

The goal of this study was to examine the living donor evaluation process at a single center, to determine the proportion of prospective donors that actually donate, and to identify the key reasons for exclusion. Clearer delineation of the process by which prospective living donors are accepted as donors or excluded is a first step toward determining strategies for better evaluation and utilization of living donors. We hypothesized that a substantial portion of prospective donors were excluded for medical reasons that have yet to be consistently associated with increased morbidity for either donors or recipients.

Methods

Study population

All prospective living kidney donors, 18 yr of age, who contacted our transplant program between October 1, 2007 and April 1, 2009 were included (n = 484). Follow-up was ascertained through April 1, 2010. No specific exclusion criteria were applied. The percent of subjects with missing data in each category did not exceed 5%.

Data were collected by review of an electronic clinical transplant database (TransChart, Dublin, OH, USA). Characteristics collected for prospective donors included age, sex, height, weight, relation to intended recipient, referral date (date of first contact with transplant coordinator), donation status (donated, excluded, undergoing evaluation, or evaluation withdrawn), date of transplantation (if successful donation), and reasons for donor exclusion (if applicable). Characteristics collected for intended recipients included age, sex, height, weight, and status (transplanted, remain on waiting list, removed from waiting list or on hold, or death).

Of the single-organ kidney transplants at our center over the study period, 49% were living donor transplants. Of the deceased donor transplants, 8% were expanded criteria donor transplants. The average wait-time for deceased donor kidney transplantation in our region is 6–8 yr, depending on blood type and degree of sensitization.

This study was approved by the Stanford University Institutional Review Board.

Data analysis

Continuous variables were expressed as mean $\pm$ SD. Categorical variables were expressed as proportions. We performed no inference tests.

Results

Of the 484 prospective donors, 39 (8%) successfully donated, 229 (47%) were excluded, 104 (22%) were actively undergoing evaluation, and 112 (23%) were withdrawn before

evaluation was complete (Fig. 1). Of the successful donors, 27 were first-degree relatives, eight were spouses, and four were unrelated to the recipient. Of the prospective donors who were excluded, 205 (90%) were excluded prior to a clinic visit.

The mean age of prospective donors was 43 ± 11 yr (range 25–66 yr), 59% was women and mean body mass index (BMI) was 26 ± 4 kg/m² (range 23–32 kg/m²) (Table 1). There was a total of 242 intended recipients. Mean intended recipient age was 47 ± 14 yr (range 20–84 yr), 45% were women and mean BMI was 27 ± 6 kg/m² (range 16–47 kg/m²) (Table 1).

Two hundred and twenty-nine prospective donors (47%) were excluded for medical (n = 150), psychosocial (n = 22), or histocompatibility (n = 57) reasons (Table 2). The number of prospective donors evaluated per recipient varied from 1 to 14. One hundred and forty-seven (61%) intended recipients had only one prospective living donor, of whom 63 (42%) were excluded. Of these recipients, six underwent deceased donor transplantation (including one expanded criteria donor), 38 are still active on the waitlist, two transferred care to an alternate transplant center, and 14 are inactive or no longer on the waitlist (of whom three died).

Of the 147 intended recipients with only one prospective donor, 39 (26.5%) were transplanted (living donor or deceased donor). Of the 45 with two prospective donors and the 19 with three prospective donors, 16 (35.6%) and 6 (32%) were transplanted, respectively. Of the 31 with four or more prospective donors, 19 (61%) were transplanted (Fig. 2).

Discussion

One of the key steps in determining ways of safely expanding the living donor pool is to better understand current practices in living donor evaluation and exclusion. In our study, nearly half of all prospective donors were excluded. Of the 150 prospective donors excluded for medical reasons, 79% were excluded for obesity (BMI > 30), hypertension, nephrolithiasis, and/or abnormal oral glucose tolerance. At the time of study analysis, 22% of prospective donors were still actively being evaluated and nearly 23% were withdrawn before the evaluation process was complete, most often because the intended recipient was transplanted from a deceased donor or an alternate living donor.

Historically, prospective donors with obesity and hypertension have not been allowed to donate. However, severe organ shortages and long wait-times have increased pressure to consider acceptance of these medically complex donors. In 2005, the median wait-time for kidney transplantation (living donor or deceased donor) in the United States was 3.5 yr (13). In some regions, however, the wait-times for deceased donor transplantation are as high as 6–8 yr, based on blood type and degree of sensitization. Many patients remain on dialysis during this time, suffering high mortality rates and experiencing significant morbidity. In this study, our objective was to characterize the prospective donor population at a single transplant center and to determine the prevalence of, and reasons for, donor exclusion.

A flowchart of the current living donor evaluation process at our center is presented in Figs. 3 and 4. Although the specifics may differ somewhat among centers across the country, most follow a similar stepwise approach. In cases where the intended recipient has several prospective donors, the most compatible donor (based on histocompatibility, age, and other known comorbidities) is typically evaluated first. The evaluation process begins with prospective donor-initiated contact with the transplant center. Living donor coordinators then complete a phone screening interview sheet that details basic demographics, relation to intended recipient, and key medical and surgical history. Prospective donors with preexisting kidney disease, diabetes mellitus, cancer, cardiovascular disease, or recent

history of nephrolithiasis are considered unacceptable and are routinely excluded at this point. Whenever possible, an alternate living donor is then evaluated. Donors with a BMI > 30 kg/m² are counseled to lose weight and encouraged to contact the center when they reach their target weight. Similarly, donors with an abnormal two-h glucose tolerance test are reevaluated after successful weight loss. Although donors with hypertension requiring antihypertensive medications have been routinely excluded in the past, more recently, we have allowed them to proceed with a clinical visit if the potential donor is (i) strongly motivated to proceed in a setting where no alternative living donor is available, (ii) a first-degree relative or spouse to the intended recipient, and (iii) able to achieve normal blood pressure with a single agent.

If the phone screening does not reveal a clear contraindication to donation, a transplant clinic visit is scheduled. Prospective donors undergo evaluation by a transplant nephrologist and social worker. In cases where the blood pressure at the visit is >140/90 mmHg, ambulatory blood pressure monitoring is routinely ordered. Prospective donors with a history of nephrolithiasis within the past 10 yr or history of intervention for stones are excluded. Those with asymptomatic stones or calcification found on imaging studies are considered on a case-by-case basis, based on the extent of the stones and comprehensive metabolic evaluation.

Most centers in the United States, including ours, follow the 2007 UNOS guidelines for absolute contraindications (Table 3). The evaluation in prospective living donors with one or more relative contraindications, however, can be much more variable. Included in these relative contraindications are grade 1 obesity (BMI 30–35 kg/m²), kidney stones, and hypertension well controlled on fewer than three medications and without evidence of end-organ damage (14).

Although the 2007 UNOS guidelines have set BMI > 35 kg/m² and evidence of impaired kidney function or proteinuria as absolute contraindications to donation (14), there is no clear consensus for candidates with BMI in the range of 30–35 kg/m² without evidence of impaired kidney function. At our center, general practice has been to exclude prospective donors with a BMI > 30 kg/m²; 56 (12% of all donors, and nearly 40% of excluded donors) donors were excluded on the basis of obesity. The mean BMI in those excluded was 37 ± 5 kg/m² (range 31–50 kg/m²). Given the high prevalence of obesity nationwide (and the exceptionally high prevalence in selected regions), prospective donors with grade 1 obesity will likely account for the largest fraction of excluded willing donors in the coming decades. Few studies have explored the long-term effects of donor nephrectomy on kidney function in obese donors. A higher incidence of proteinuria at 13.6 ± 8.6 yr post-transplantation in patients with obesity at the time of donor nephrectomy has been shown (15). Among the 14 patients with a BMI > 30 kg/m², 13 (92%) developed proteinuria/renal insufficiency, compared with only seven (12%) of the 59 patients with a BMI < 30 kg/m². A retrospective analysis of patients undergoing donor nephrectomy 5–40 yr earlier did not demonstrate this difference when compared to BMI and age-matched two-kidney controls from the National Health and Nutrition Evaluation Survey (NHANES) dataset (16). Donors with BMI > 30 kg/m² were found to have a higher incidence of hypertension and dyslipidemia compared with donors with BMI < 30 kg/m². Recent studies have highlighted the association between obesity and chronic kidney disease in the general population (17, 18). Yet unknown is whether the higher incidence of hypertension and/or dyslipidemia will translate to higher long-term cardiovascular mortality and morbidity in this donor population.

Although most centers routinely exclude prospective donors with poorly controlled hypertension and/or evidence of end-organ damage, the decision of whether to exclude donors with well-controlled hypertension, without proteinuria or diminished kidney

function, remains controversial. The long-term risks of donor hypertension on the donor and recipient remain unclear. A survey of transplant centers published in 2007 showed that 47% and 41% of centers excluded patients taking any antihypertensive medication or taking more than one medication, respectively (7). A meta-analysis of living kidney donors examining blood pressure changes post-donation showed that kidney donors may have a 5-mmHg increase in blood pressure within 5–10 yr (19). However, several of these studies were limited in sample size and duration of follow-up. At our center, prospective donors older than 50 yr of age with a history of hypertension controlled with one to two medications and with normal renal parameters (absence of proteinuria, measured creatinine clearance >80 mL/min/1.73 m²) are assessed on a case-by-case basis. The decision of whether to proceed with evaluation is based on donor and recipient characteristics (including age, relationship, comorbidities) and the availability of alternate living donors. Of the 484 prospective donors analyzed in this study, 37 (8%) were excluded for hypertension. Additionally, 7/56 (13%) prospective donors excluded for obesity reported coexisting hypertension. Of the 37 prospective donors excluded for hypertension, 24 (65%) were above the age of 50 yr.

Practices in evaluating and excluding prospective donors with a history of nephrolithiasis vary considerably across the United States (6). Although many centers proceed with transplantation if metabolic evaluation is normal and in the absence of a current stone, approximately 20% exclude all patients with a history of nephrolithiasis. At our center, prospective donors with a history of nephrolithiasis within the past 10 yr, history of intervention for stones, and/or abnormal metabolic evaluation are excluded. In the present study, 10 (2%) prospective donors met at least one of these criteria.

Although centers in the United States routinely exclude prospective donors with diabetes, the evaluation of donors with an impaired fasting glucose, or abnormal two-h oral glucose tolerance test (OGTT), is more variable. Prospective donors with obesity, a family history of diabetes, or a history of gestational diabetes often undergo a two-h OGTT. Most centers exclude patients with a confirmed result >140 mg/dL. Although studies in the general population show that impaired glucose tolerance correlates with an increased risk of diabetes and cardiovascular disease, corresponding data in the living donor pool are not available. In the present study, 15 (3%) prospective donors were excluded because of abnormal glucose tolerance. In the case of glucose intolerance, as with hypertension and obesity, a reluctance to accept a prospective donor relates not only to concerns regarding donor safety but toward recipient survival and allograft function as well.

Prospective donors with dyslipidemia are not excluded from kidney donation. Those with borderline hypertension and not on antihypertensive agents or those with family history of diabetes but normal glucose tolerance tests are also not routinely excluded from donation. Long-term follow-up of such donors remain elusive and questions of whether donation may accentuate metabolic syndrome is unknown. Inclusion of donors with known hypertension, obesity, or impaired glucose tolerance raises the concern of accelerating the clinical sequelae of a metabolic syndrome in these potentially higher risk living donors, leading to a conservative approach to living donor selection in many centers.

Historically, cross-match positivity and ABO-incompatibility have been considered absolute contraindications to donation. More recently, desensitization and kidney-exchange programs have led to the successful expansion of the living donor pool. Roodnat et al. (12) described a significant increase in the number of living donor transplants in the Netherlands with the initiation of alternative living donation programs. US centers have been participating in paired donor exchange with promising early results (20). Of the 484 prospective donors analyzed in this study, 35 were excluded based on ABO-incompatibility and 22 were excluded based on positive cross-match results. All prospective donors excluded for these

reasons were routinely given information and literature about paired donor network exchange.

There are several limitations to this report. This is a single-center study. Larger multicenter prospective studies are needed to further examine the living donor evaluation process at centers with different size and donor and recipient characteristics. The data for this study were obtained by chart review of our electronic transplant database. Basic demographic information is easily available for all subjects. However, detailed information such as an extensive past medical history was not consistently available. While we could assess the presence or absence of a specific medical condition, we could not necessarily assess its severity. More detailed information is likely available to clinicians and could influence decision-making.

In this study, the majority of prospective living donor candidates were excluded for medical reasons such as obesity (BMI > 30), hypertension, nephrolithiasis, and abnormal oral glucose tolerance test. While these perceived risk factors for long-term morbidity in donors have been applied to protect the donor, definitive evidence of increased long-term risk is still lacking. Recent long-term outcomes studies in healthy uneephric cohorts are reassuring for donors selected using the traditional guidelines for living donor evaluations (21, 22), and hence, strict adherence to these guidelines better assures the long-term well-being of living kidney donors. However, an overly conservative approach will also prevent a realistic opportunity for kidney transplantation, especially in those ESRD patients who are older, have multiple comorbidities, and only one potential living donor. At our center, we routinely provide follow-up clinical examination in living donors up to two yr after donation that includes measurement of comprehensive metabolic panel, complete blood count, and urine analysis. As many recipients on the waiting list have waiting times far in excess of their life expectancy, the complexity lies in balancing the risks to donors with the potential benefits to recipients. Additional longer-term studies are needed to determine risks in medically complex donors and to better define this balance. Challenges to such analyses include limited access to living donors beyond the first year of transplantation and lack of medical insurance reimbursement for such follow-up. In the meantime, we favor a careful stepwise personalized approach that incorporates characteristics of both the prospective donors and intended recipients.

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Fig. 1.
Outcomes in all prospective donors.

Fig. 2.
Outcomes in intended recipients per number of prospective donors referred.

Fig. 3.
Flowchart of living donor evaluation process prior to transplant clinic visit.

Fig. 4.

Flowchart of living donor evaluation process at transplant clinic visit. *Further evaluation necessary. #Laboratory studies: complete blood count, comprehensive metabolic panel, ABO and Rh typing, lipid panel, uric acid, phosphorus, PT/PTT, bilirubin, quantiferon TB test, urinalysis, urine protein/creatinine ratio, 24-h timed urine creatinine clearance, protein, and albumin, hepatitis B (sAg, sAb, core total Ab, core IgM), RPR, CMV Ab, EBV panel, HTLV I & II Ab, HIV I & II Ab. Imaging studies: chest X-ray and electrocardiogram.

Table 1**Baseline characteristics**

<i>Prospective donors (n = 484)</i>
Gender: 59% female, 41% male
Mean age: 43 ± 11 yr (range 25–66 yr)
Mean BMI: 26 ± 4 kg/m ² (range 23–32 kg/m ²)
<i>Intended recipients (n = 242)</i>
Gender: 45% female, 55% male
Mean age: 47 ± 14 yr (range 20–84 yr)
Mean BMI: 27 ± 6 kg/m ² (range 16–47 kg/m ²)
Cause of end-stage renal disease
Unknown (n = 76)
Diabetes mellitus (n = 47)
Glomerulonephritis (n = 45)
IgA nephropathy (n = 18)
Systemic lupus erythematosus (n = 13)
Focal segmental glomerulosclerosis (n = 8)
Other (n = 6)
Hypertensive nephrosclerosis (n = 25)
Polycystic kidney disease (n = 25)
Retransplant/graft failure (n = 13)
Obstructive uropathy (n = 4)
Chronic pyelonephritis/reflux nephropathy (n = 3)
Scleroderma (n = 2)
Sarcoidosis (n = 1)
Cirrhosis (n = 1)

BMI, body mass index.

Table 2

Outcomes in prospective donors

All prospective donors (n = 484)
<i>Donated (n = 39)</i>
<i>Excluded (n = 229)</i>
Medical reasons (n = 150)
Body mass index >30 (n = 56)
Hypertension (n = 37)
Known diabetes or abnormal GTT (n = 15)
Kidney stones (n = 10)
Renal structural abnormalities (n = 7)
GFR < 80 mL/min/1.73 m ² (n = 2)
Hematuria and/or proteinuria (n = 2)
Heart disease/hepatitis/malignancy/other (n = 18)
Unknown (n = 3)
Psychosocial reasons (n = 22)
Donor unsure about donation (n = 13)
Lack of meaningful relationship (n = 7)
Recipient refused transplant from donor (n = 2)
Active mental illness (n = 0)
Histocompatibility reasons (n = 57)
ABO incompatible (n = 35)
Cross match positive (n = 22)
<i>Evaluation ongoing (n = 104)</i>
<i>Evaluation withdrawn (n = 112)</i>
Intended recipient died prior to transplantation or no longer a transplant candidate (n = 28)
Intended recipient transplanted from an alternate donor (n = 53)
Intended recipient transferred care to an alternate transplant center (n = 11)
Intended recipient listed for SPK (n = 7)
Intended recipient GFR > 15 mL/min/1.73 m ² BSA (n = 7)
Donor died (n = 1)

Table 3

2007 United Network of Organ Sharing (UNOS) guidelines for living donor evaluation (adapted from http://optn.transplant.hrsa.gov/CommitteeReports/board_main_LivingDonorCommittee_2_26_2008_12_19.pdf)

Absolute contraindications	Relative contraindications
Age < 18 yr Hypertension BP > 130/90 in someone younger than 50 yr old, evidence of end-organ damage, non-Caucasian, on three or more anti-hypertensive medications Diabetes (diagnosis of diabetes) Abnormal glucose tolerance test: 2 h OGTT > 140 History of thrombosis or embolism Psychiatric contraindications Obesity (BMI > 35 kg/m ²) Coronary artery disease Symptomatic valvular disease Chronic lung disease with impairment of oxygenation or ventilation Recent malignancy or cancers with long times to recurrence Urologic abnormalities of donor kidney Creatinine clearance < 80 mL/min/1.73 m ² , or projected GFR with removal of one kidney at 80 yr old of <40 mL/min/1.73m ² Peripheral vascular disease Proteinuria > 300 mg/24 h HIV infection Hepatitis B or hepatitis C virus infection	Age 18–21 yr Obesity (BMI 30–35 kg/m ²) Kidney stones Distant history of malignancy Past history of psychiatric disorder Renovascular disease Thin basement membrane disease Prior valve surgery Moderate cardiac valvular disease with otherwise normal echocardiographic findings and Mild sleep apnea without pulmonary hypertension

BMI, body mass index.