

ORIGINAL ARTICLE

Increasing access to renal transplantation in India through our single-center kidney paired donation program: a model for the developing world to prevent commercial transplantation

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Introduction

The majority of dialysis units (>85%) in India are in the private hospitals [1–4]. Healthcare insurance coverage is available to <15% of CKD population. It is estimated that approximately 175 000 new patients develop end-stage

Summary

Because access to transplantation with HLA-desensitization protocols and ABO incompatible transplantation is very limited due to high costs and increased risk of infections from more intense immunosuppression, kidney paired donation (KPD) promises hope to a growing number of end-stage renal disease (ESRD) patient in India. We present a government and institutional ethical review board approved study of 56 ESRD patients [25 two-way and 2 three-way pairs] who consented to participate in KPD transplantation at our center in 2013, performed to avoid blood group incompatibility ($n = 52$) or positive cross-match ($n = 4$). All patients had anatomic, functional, and immunologically comparable donors. The waiting time in KPD was short as compared to deceased donor transplantation. Laparoscopic donor nephrectomy was performed in 54 donors. Donor relationships were spousal ($n = 40$), parental ($n = 13$), others ($n = 3$), with median HLA match of 1. Graft survival was 97.5%. Three patients died with functioning graft. 16% had biopsy-proven acute rejection. Mean serum creatinine was 1.2 mg/dl at 0.73 ± 0.32 months follow-up. KPD is a viable, legal, and rapidly growing modality for facilitating LDRT for patients who are incompatible with their healthy, willing living donor. To our knowledge, this is the largest single-center report from India.

renal disease (ESRD), and >90% of patients with ESRD in South Asia die within months of diagnosis because they cannot afford treatment annually [1–4]. The charges per year of hemodialysis and chronic ambulatory peritoneal dialysis are \$9000–14 000 and \$10 000–14 000, respectively, depending on whether it is carried out in govern-

ment or private hospitals. Transplant cost, CMV prophylaxis, and immunosuppressive drugs for a year without including induction come to only \$5600 in a government hospital and \$12 000 in a private hospital. The approximate transplant expenditure for KPD renal transplantation (RT) is \$3000 in our center.

New listings of patients with ESRD that would benefit from transplantation continue to outpace the availability of organs. The crisis in organ availability has triggered innovative approaches to meet a rapidly expanding worldwide demand for donor kidneys. HLA and ABO incompatibility represents one of the most significant barriers to optimizing the utilization of living donors (LD) [5]. While LD provide 80% of kidneys for transplantation in our center and majority of donors in our country, at least one-third of these donors are incompatible with their potential recipients. RT with desensitization protocol and ABO incompatible RT are not widely available in majority of Indian transplant centers due to high costs and increased risk of infections from more intense immunosuppression.

One proposed solution to expand the organ supply has been kidney paired donation (KPD). In KPD, a potential kidney recipient who has a willing but incompatible live donor receives a kidney from the donor of another incompatible pair and vice versa. KPD allows patients with incompatible LD to receive compatible or better-matched organs by exchanging donors [5–7].

KPD benefits individuals awaiting a kidney transplant as it can make a compatible living donor transplant possible. A LDRT offers better success compared to a transplant from a deceased donor (DD). The shorter wait for LDRT also provides a substantial benefit. We believe that KPD should be preferred over desensitization as the treatment option for incompatible pairs because KPD offers the potential for lower costs and improved outcomes. Here, we present our experience of increasing access to RT in countries with limited resources like India through our single-center KPD program.

Material and methods

This is an institutional review board approved study of 56 ESRD patients who consented to participate in the KPD transplantation at our center. The written informed consent was obtained from all study participants. When two patients were from different states, RT was performed after permission of authorization committee from both states. KPD programs require a great deal of coordination, and many patients are unwilling to travel to an unfamiliar state for their permission from authorization committee.

Patients are encouraged to consider living donation and are provided with educational and counseling regarding

advantages of LDRT. Once blood group test results confirm incompatibility with the LD, the transplant team will offer to add patient name to our KPD waiting listing. This list helps find sets of donor/recipient pairs who can “swap” kidneys.

We only register those patients whose first degree immediate relatives or family members are ready to donate a kidney. Sometimes, patients approach us saying a friend is ready to donate a kidney. Such practice is not allowed. The manual data entry of a robust patient and donor database including age, sex, blood type, contact phone number, address, HLA, and anti-HLA antibodies for sensitized recipients is performed daily in our registry whenever patients came to us. The match runs are performed manually without computer software. Allocation rules are mentioned in Table 1 [6–16]. All recipients had anatomic, functional and immunological similar and suitable donors, and they were allowed to meet each other before and after RT. Simultaneous donor nephrectomies are required to assure committed donation. All recipients had complement-dependent cytotoxicity cross-matches and flow cytometry cross-match negative donor. Complement-dependent cytotoxicity cross-matches (CDC) and flow cross-match assays are performed after selection of matching pair and again after getting permission just before RT. Each donor should have glomerular filtration rate of >40 ml/min on either side by Tc99 m-DTPA (diethylene triamine pentacetic acid) renal scan. The major factors for success have been daily data entry and match reviews by the KPD team and effective communication with other team members. We performed only basic laboratory studies along with blood grouping of donors. No further donor evaluation is performed until a potential KPD match is identified. This saves cost and allows the entry of multiple donors for a given recipient. However, in case easy-to-match pairs and no alternative donor are available in family, we initiated all donor investigations. We lost two donors due to medical problems. We favored two-way exchanges over longer chains to minimize the number of discontinuations that would result if one patient becomes medically unfit for RT and minimizing the number of simultaneous transplants. Majority of the patients preferred

Table 1. Allocation rules for KPD.

1	ABO compatibility
2	Favoring 2-way vs. 3-way kidney exchange
3	Minimizing age difference between donors to less than 5–10 years
4	Bonus for pediatric, sensitized, and difficult to match patients
5	Bonus for time on deceased donor waitlist and KPD wait list
6	Favoring CMV neg/neg serology
7	Bonus for patients with geographical proximity between pairs to minimize waiting time before RT

minimal age difference between intended donor and recipient. We offered preference for sensitized, pediatric, and difficult to match patient. We considered cytomegalovirus (CMV) negative to CMV negative transplant if multiple donors are matching. HLA matches were given less importance. Participating transplant patients are not required to pay an initial entry fee, an annual membership fee, and a fee per transplanted patient. All activities have been done as part of the overall LDRT program.

How each individual rule is weighted is explained below. For instance if, within a pool, they have three 2-way chains (six transplants) one of which is O to A, with two recipient CMV+/- and two pairings with donor-recipient age difference of 30 years and the next combination is two 2-way, no O to A/B, no CMV+/- and age difference <10 years, In this scenario, we favored transplanting four patients rather than six patients. The minimal age difference between donor and recipient and next short waiting time to RT were given more importance over number of RT. We allow for maximizing the number of transplants, increasing the quality of transplants, and accommodating patients who are difficult to match. In practice, the best combination of matches is chosen from a myriad of different possibilities formed from the pool of donor/ recipient pairs. However, In an effort to increase the likelihood of a successful KPD, these donor selection decisions should be made for individual patient according to their needs. The compatible matched pairs were also included ($n = 6$). There should be balance between waiting time and better transplant quality in selection process. Patients transplanted in our KPD program at our institute are now promoting this in different dialysis centers at their native places. An open or so-called never ending chain which is initiated by a nondirected altruistic donor (who is not associated with any recipient), and the "left over" final donor in the chain, also called the "bridge" donor, was not legally allowed by our Transplant of Human Organs Act, India.

As with the donor procedures, the transplant operations are performed at the same time. This poses substantial logistical and staffing challenges. Four operating rooms must be available at once, as well as four complete surgical teams to staff those rooms. As a large academic transplant center, our center has the resources and ability to undertake such a challenge. The maximum of allowed chain length we performed was three patients and three donors. We are not encouraging long chain length in our public sector hospital as it may increase waiting time for RT. The Donor stays in the hospital for as little as 3 days. Today, our surgeons are among only a few in the world using new techniques of laparoscopic and robotic kidney RT.

We routinely perform the flow cytometry cross-match (FCM), and CDC on all allograft recipients. An anti-human globulin-enhanced lymphocytotoxicity cross-match assay

(AHG-CDC) $\leq 20\%$ and T-cell FCM median channel shift (MCS) < 50 , B-cell FCM < 100 MCS were considered cross-match negative. Panel reactive antibody (PRA) screening for anti-HLA antibodies pretransplant was also performed only in the setting of any high-risk case for presensitization. PRA was performed by the commercially available enzyme-linked immunosorbent assay technique for the detection of both HLA class I- and class II-specific antibodies. The detection of donor-specific antibodies (DSA) was performed using luminex mixed and/or single-antigen beads. DSA < 2000 MFI were acceptable for RT with negative AHG-CDC and FCXM. We are not doing ABO incompatible RT and also not doing ABO titers of the ABO incompatible pairs.

Results

Our single center has registered 100 donor/recipient pairs from across the country and has been responsible for facilitating 56 KPD transplants in 2013. Between 2000 and 2013, our transplant center has performed a total of 140 KPD transplants. In 2013, our transplant center has performed 400 RT [355 LD and 45 DD] with 56 (15.8%) transplants from the KPD program and demonstrates that KPD can provide a sustained increase in RT over time.

Recipient and donor demographics are shown in Table 2. One of the major reasons for joining a donor exchange program is ABO blood group incompatibility between the recipient and donor ($n = 46$). Another important reason is sensitization of the patient's immune system—either by previous transplants, blood transfusions, or pregnancy—to certain tissue antigens that are shared with the donor ($n = 4$). Some patients have compatible LD but choose to join a KPD program to find a better size- and age-matched RT ($n = 5$). Finally, there are some patients who join a KPD program to improve the HLA matching of the transplant, because improved matching in combination with modern immunosuppression regimens allows RT to survive for many years ($n = 1$). Two-way exchange (25 pairs) was most commonly used in our KPD program where two incompatible donor/recipient pairs matches such that the donor of the first pair gives a kidney to the recipient of the second pair and vice versa. Patient ABO type was A ($n = 24$), B ($n = 22$), AB ($n = 2$), and O ($n = 8$). Donor ABO blood group type was A ($n = 23$), B ($n = 20$), AB ($n = 2$), and O ($n = 11$). Thirty-one recipients were from our state (Gujarat), and 25 recipients were from other states of India [Rajasthan ($n = 16$), Madhya Pradesh ($n = 3$), Uttar Pradesh ($n = 3$), Haryana ($n = 1$), Bihar ($n = 1$), Chattisgarh ($n = 1$)]. The mean waiting time from KPD registration to RT was 3.1 ± 2.3 months (median 2, range 0–12) as compared to DDRT (30 months).

Table 2. Demographic data.

Recipient		N = 56
Age (year) (range)		36 ± 11.1 (10–59)
Gender (male)		83.9% (n = 47)
Original disease - ESRD		
Hypertension		41% (n = 23)
Chronic glomerulonephritis		16.5% (n = 11)
Diabetic nephropathy		7.1% (n = 4)
ADPKD		5.3% (n = 3)
Obstructive uropathy		8.9% (n = 5)
Chronic interstitial nephritis		7.1% (n = 4)
IgA nephropathy		3.5% (n = 2)
Others		7.1% (n = 4)
Dialysis duration pre-RT (months)		5.9 ± 4.2 (0–24)
ATG induction (1.5 mg/kg)		100% (n = 56)
Pre-emptive transplantation		3.5% (n = 2)
NOADT		12.5% (n = 7)
Donor		N = 56
Age (year) (range)		39.4 ± 8.7 (20–62)
Gender (male)		26.9% (n = 15)
Median HLA match		1 (0–4)
DTPA renal scan (ml/min)		
GFR (right)		52 ± 6.4 (42–67)
GFR (left)		52 ± 5.8 (40–65)
Serum creatinine (mg/dl)		0.9 ± 0.2 (0.5–1.3)

The warm ischemia time was 179 ± 60 (92–336) s, cold ischemia time (CIT) was 65 ± 35 (9–170) min, and anastomosis time was 31 ± 13 (11–74) min. The intraoperative urinary output from the time of reperfusion until surgery was completed was optimum in all patients [782 ± 445 (200–1900) ml]. Laparoscopic donor nephrectomy was performed in 96.4% (n = 54); laparoscopic RT was performed in 8.9% (n = 5); robotic RT was performed in 8.9% (n = 5); surgical complications observed were renal artery stenosis (n = 1) and bleeding (n = 1).

Graft survival was 97.5%. One graft lost due to noncompliance to immunosuppressive drugs. Three patients died with functioning graft due to sepsis (n = 2) and cardiac disease (n = 1), and 16% had biopsy-proven acute rejection. Figure 1 showed graft and patient survival in Kaplan–

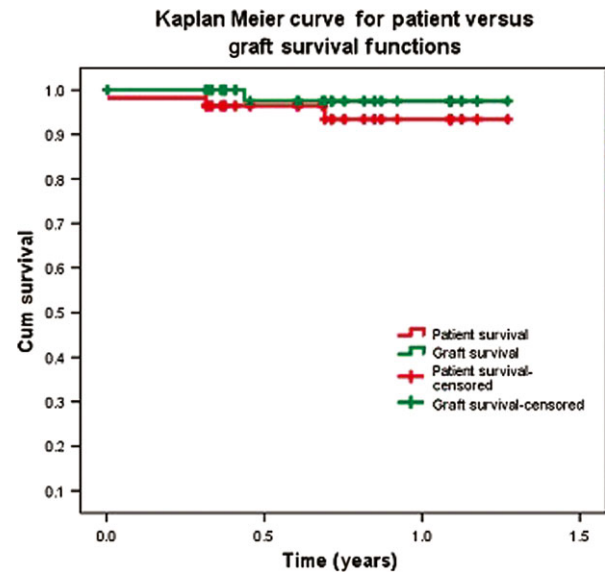


Figure 1 Graft and patient survival.

Meier curve. Mean serum creatinine was 1.2 mg/dl at mean follow-up of 0.73 ± 0.32 (median 0.72) months.

Immunosuppressive regimen included tacrolimus (n = 42), cyclosporine (n = 3), everolimus (n = 6), sirolimus (n = 5), mycophenolate (n = 54), azathioprine (n = 2). The maintenance immunosuppression with prednisolone + tacrolimus + mycophenolate was most commonly used. All donors have been followed up since donation and at 3 months and 6 months. At each visit, tests were undertaken for renal function, urine examination, complete blood count, and diabetes ± lipids. Thus far, all 56 donors were in regular follow-up without any complication due to kidney donation.

There were 44 KPD registered, not-transplanted patients. Of these, 15 patients died while on wait list, and remaining O blood group patients (n = 10) or sensitized patients (n = 10) and patients with AB donor (n = 5) were still waiting for their compatible pairs, and four patients lost follow-up due to lack of economic supports for RT. The information on PRA and HLA mismatches of KPD registered, not-transplanted would be more informative, but we

Table 3. The blood group distribution of LDRT, DDRT and KPD RT in our center.

Blood group% (N)	LDRT 74.7(299)		DDRT 11.3 (45)		KPD 14 (56)		Total 100 (400)	
	Patient	Donor	Patient	Donor	Patient	Donor	Patient	Donor
A	24 (72)	18.4 (55)	20 (9)	17.8 (8)	42.8 (24)	41 (23)	26.3 (105)	21.5 (86)
B	39.5 (118)	32.8 (98)	33.3 (15)	35.5 (16)	39.3 (22)	35.7 (20)	38.7 (155)	33.5 (134)
AB	9.7 (29)	3.3 (10)	20 (9)	17.8 (8)	3.6 (2)	3.6 (2)	10 (40)	5 (20)
O	26.8 (80)	45.5 (136)	26.7 (12)	28.9 (13)	14.3 (8)	19.7 (11)	25 (100)	40 (160)

are doing these tests before RT in case of sensitized patients and patients requiring O donors. The available data show that 20 had spouse as donor with median HLA match of 0 ($n = 10$), and 20 had parents as donor with median HLA match of three out of six [HLA, A, B, DR] ($n = 10$). The available data show that sensitized patients had median 2 HLA-DSA Luminex mean fluorescence intensity (MFI) >5000 and median PRA class 1 and 2 was 80%.

The blood group distribution of LDRT, DDRT, and KPD RT in our center is shown in Table 3. The blood group B (35%) was most prevalent in both male and female followed by group O (30%), A (21%), and AB (14%) in a retrospective study of 1000 blood donor population.

Discussion

The first interesting observation of our study is that we used 2-way loops in the majority (90%) of our KPD transplants. This is usually inefficient in identifying suitable matches, yet 56% of registered pairs were transplanted, which is an extremely high match rate. The success could be because the majority of pairs were enrolled due to ABO-incompatibility without HLA-sensitization. Furthermore, ABO-incompatibility is mainly A-to-B and B-to-A, owing to the high frequency of blood group B in northern India (30% O, 21% A, 35% B, and 14% AB) and central Asia, compared to United States/Europe (37% O, 36% A, 9% B, and 3% AB) or Australia (40% O, 31% A, 8% B, and 2% AB). Thus, in this ethnic group, finding a 2-way match between A-to-B and B-to-A pairs is a relatively easy feat that can be performed “manually without computer software”. The blood group O recipients miss out, as only 14% were transplanted, while 30% of registered patients were blood group O.

Another important finding of our study is the high mortality rate (34%) of patients who do not find a match (15 of 44). This is due to economic constraints; patients with ESRD who cannot have live donor kidney transplant cannot afford dialysis and therefore die. There were more sensitized patients among the 44 nontransplanted patients. Therefore, they will cumulate over the years. Without matching software, it will be impossible to calculate matches for highly sensitized patients, and these patients will never have a chance for a transplant. We believe that it would be valuable to understand the results of this KPD program in the context for renal replacement therapy options for ESRD in India. This is not about waiting less for a transplant; it's about life or death. Although the policy to favor transplanting 4 rather than 6 patients to facilitate age difference between donors <10 years seems unreasonable, our patients are reluctant to accept swap donors when donor age difference >10 years. We acknowledge that the lack of sophistication in managing our KPD

pool of not prospectively testing recipients for HLA antibodies and not generally allowing 3-way chains is likely to preclude an even higher match and transplant rate and thus could actually save more lives, when 1 of 3 patients die waiting for a kidney. Moreover, due to manually allocation of pairs without computer software, possible chains might be missed. This may lead to selection bias. All recipients should be tested for DSA; otherwise, a substantial proportion will have a positive CDCXM after the match run, which leads to chain breakdown. Recipients might be DSA positive even if unsensitized. Recently, we have started full donor evaluation before match runs due to high match rate of our KPD program. Inclusion of matched pairs is ethically troublesome without benefit to improve long-term transplant outcome like better HLA matching or young donor age.

Our transplant center is the India's largest transplant center performing the highest volume of RT in India. Furthermore, KPD combined with selective desensitization has provided a means for individualized assessment and management of the highly sensitized patient. This demonstrates that an effective KPD program can significantly benefit difficult patients and increase transplant access and activity in a single-center setting.

KPD was started in 2000 but was not widely adopted until recently. In the past concerns about unrelated compatibility, ethical and legal constraints were barriers to implementation. The most of the limitation is not a willingness to participate in KPD, but rather barriers to execution.

Overall, our 1-year patients and graft survival rates were comparable to those of other KPD programs and conventional living related and unrelated donor RT programs and were also similar to the national averages [8–12]. If the productivity of our KPD program was to be replicated on a national level, it will increase LDRT rate more than 15% in India and reduce the number of patients on the waiting list.

The realities of the organ shortage also motivate patients. There are more than 500 patients waiting on our DDRT wait list in our center, and time to transplant in DDRT may exceed 3 to 5 years. The waiting time in KPD is short (especially for non-O blood group recipients) as compared to DDRT. Avoidance of long waits reduces patient morbidity, improves transplant outcomes, and reduces healthcare costs all reasons to seek a route to early transplantation [8].

Single-center KPD program should keep the allocation algorithm as simple as possible without too many complicating factors like HLA matching, donor gender, donor age, and CMV/EBV serology when donor pool is small [13–18].

We need to allocate O blood group kidneys from compatible donors to overcome the barrier of HLA, non-HLA antibodies, and other donor-related factors to improve

transplant quality and long-term outcomes. This will increase transplantation of O blood group patients [17]. Acceptance of blood group-incompatible donors for patients with low to moderate antiblood group antibody significantly increases transplant rates for highly sensitized recipients.

Regional issues in KPD in India

The women not only donate kidneys more often, but are also less likely to receive a live kidney than men. Complex social and economic factors are responsible for the overall gender imbalance in direct kidney donation and also in KPD. KPD could place female donors under even greater pressure to donate because it eliminates incompatibility as an excuse to avoid donation. It is important to understand that ethical concerns including coercion, privacy, confidentiality, exploitation, and commercialization should be carefully addressed. There is no religious bar for organ donation. There were five pairs of inter-religion swapping in our study. As long-term hemodialysis is not widely available, LDRT soon after the diagnosis is the only viable form of long-term renal replacement therapy (RRT) for most patients. KPD is first opportunity to substantially increase donor pool by utilizing high-quality organs, rather than merely accepting more organs of uncertain caliber (expanded criteria donation, donation after cardiac death). A large majority of patients were not aware of KPD; however, after counseling, we identify strong support for KPD for patients with a healthy willing living donor who is not compatible. CIT ≤ 8 h did not have negative impact for the LDRT outcome. In India, a compact country which is densely populated donor travel to the transplant center where their paired recipients are being transplanted and care which is similar to transplant centers in Canada. However, we are less comfortable with transporting living donor kidneys which is routine practice in United States.

Our single-center registry represents the beginning of a national KPD program in India to maximize pool size that promises hope to the growing number of patients suffering from ESRD. The lack of coordination required between transplant centers, developing consensus on allocation, and determining the best approach for funding is some of the challenges currently preventing a national program in the India. There is need of national KPD registry and computer software for allocation algorithm to increase donor pool. Although the logistics of doing so will no doubt remain challenging. Attitudinal changes must take place to truly increase donation of high-quality organs through KPD to make an impact on those dying on the waiting list.

In the future, we would like to employ additional separate staff to fasten the legal permission for KPD to further

decrease waiting time, storage of blood sample for lymphocyte cross-match in case of sensitized patient, list exchanges, use of social networking site for participation in KPD [19], and increasing participation of compatible pairs to improve long-term outcome through regulated incentives like donor insurance policy free of cost. We should develop, evaluate, and implement best allocation algorithm to achieve optimal outcome.

Conclusion

We believe that all transplantation centers should consider the development of an effective KPD program. KPD is viable, legal, and rapidly growing modality for facilitating LDRT for patients who are incompatible with their healthy, willing living donor. To our knowledge, it is largest single-center report from developing country.

Authorship

All authors have equal contribution in designed study, performed study, collected data, analyzed data, and wrote the paper.

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