

ORIGINAL ARTICLE

Outcomes of shipped live donor kidney transplants compared with traditional living donor kidney transplants

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Introduction

There are a disproportionate number of kidney transplant candidates who are currently in need of safe transplantation from a healthy donor [1,2]. Some creative solutions have included utilizing organs from extended criteria deceased donors, adopting strategies for transplanting ABO-incompatible or highly sensitized recipients, and kidney paired donation (KPD), which utilize exchanges or chains for incompatible pairs [3–5]. Until recently, a living donor in KPD traveled to their matched recipient's hospital, so that the donor nephrectomy and kidney transplant were performed at the same institution in an effort to minimize cold

Summary

The disparity between kidney transplant candidates and donors necessitates innovations to increase organ availability. Transporting kidneys allows for living donors and recipients to undergo surgery with a familiar transplant team, city, friends, and family. The effect of shipping kidneys and prolonged cold ischemia time (CIT) with living donor transplantation outcomes is not clearly known. This retrospective matched (age, gender, race, and year of procedure) cohort study compared allograft outcomes for shipped live donor kidney transplants and non-shipped living donor kidney transplants. Fifty-seven shipped live donor kidneys were transplanted from 31 institutions in 26 cities. The mean shipping distance was 1634 miles (range 123–2811) with mean CIT of 12.1 ± 2.8 h. The incidence of delayed graft function in the shipped cohort was 1.8% (1/57) compared to 0% (0/57) in the nonshipped cohort. The 1-year allograft survival was 98% in both cohorts. There were no significant differences between the mean serum creatinine values or the rates of serum creatinine decline in the immediate postoperative period even after adjusted for gender and differences in recipient and donor BMI. Despite prolonged CITs, outcomes for shipped live donor kidney transplants were similar when compared to matched nonshipped living donor kidney transplants.

ischemia time (CIT). In 2007, a live donor kidney flew with the surgeon across the United States on a private jet following nephrectomy as part of an exchange. The CIT was 8 h, and the graft underwent successful transplantation without any adverse events [6]. Despite this success, many institutions and national KPD programmes forbid and restrict shipping kidneys.

The concept of shipping live donor kidneys is not new. Over 40 years ago, Terasaki and Collins shipped live mammalian (canine) kidneys from Los Angeles to Sydney, London, and Tel Aviv, and demonstrated allograft functionality even with CITs approaching 50 h [7]. In human living donor transplants, Simpkins *et al.* [8] reviewed 38 467

cases from the UNOS/OPTN database and found 393 cases that had unintended delays as a result of technical complications during the donor nephrectomy or recipient operation. These 393 live donor organs with 6–8 h of CIT had equivalent 10-year graft survival when compared to the remainder of the group. In a multicenter review, shipped live donor kidneys with a median CIT of 7.2 h and a mean transported distance of 792 miles demonstrated no delayed graft function, as defined by a need for dialysis in the first week [9]. Despite the recent advent of shipping live donor kidneys, there is a paucity of good studies describing the incidence of delayed graft function and outcomes.

The purpose of this study was to compare a matched cohort of shipped live donor kidney transplants to traditional (nonshipped) living donor transplants performed at a single institution to report any differences in delayed graft function (DGF) as well as immediate and intermediate graft and patient outcomes.

Patients and methods

Matched study cohorts and preoperative evaluation

The study population included kidney transplant recipients who underwent living donor kidney transplantation at a single tertiary referral academic center (University of California Los Angeles Ronald Reagan Medical Center) between July 2008 and May 2013. The shipped kidney cohort comprised all recipients participating in KPD through the National Kidney Registry (NKR) exchange programme whose paired living donor had their nephrectomy performed at an outside institution during the study period. The identification of donor/recipient pairs was made through the NKR using their established protocols and matching algorithm. Blood group, HLA typing, PRA, and other routine laboratory testing were performed at the donor/recipient respective institutions using the established clinically approved laboratory assays. The final cross-match using the potential donor blood was shipped to and performed at the recipient center. The donor preoperative evaluation, workup, and surgery were performed at the donor institution with all pertinent medical information reviewed by the participating donor and recipient surgeons prior to proceeding with the transplantation procedures and shipping of the donor organ. The matched nonshipped kidney cohort comprised recipients undergoing compatible donor-directed transplantation or internal KPD exchange where the living donor organ was removed and immediately transplanted at the recipient institution. For this cohort, donor and recipient workup was performed within the single institution. One-to-one matching with simple random sampling without replacement was performed in SAS 9.4 (Cary, NC, USA) using the PROC SURVEYSELECT

procedure to match on recipient age, gender, race, and year of procedure. Gender and race were exact matches, age was matched within ± 7 years, and year of procedure within ± 2 years.

Organ procurement and transportation of kidneys

For this shipped kidney cohort, donor nephrectomies were performed at the donor institution per their preferred surgical approach. No significant operative or postoperative complications occurred. Once the organ was removed from the donor, it was immediately flushed with Belzer University of Wisconsin cold storage solution. The organs were packaged and labeled using established Organ Procurement Organization (OPO) deceased procurement procedures and then transported using their established protocols. The donor kidneys were transported to and from the airport utilizing couriers with ‘chain-of-custody’ detailed documentation (including name and phone number). One organ was transported by private jet at the recipient’s personal expense, while all others were transported using commercial airlines. ‘Lifeguard status’ prioritized all commercial flights to expedite takeoff and landing. The first 20 shipped kidneys did not utilize a tracking device. Flight plans and backup flights were verified between the transplant centers. The donor and recipient surgeons communicated before and after the nephrectomy to review anatomy and coordinate operating room times. The distances from the donor institution to the recipient center were determined using Google Maps. For the matched control group, donor nephrectomies were performed at the recipient institution. A laparoscopic approach was used with a low transverse incision made just prior to organ extirpation. Once removed, the kidney was flushed using heparinized lactated Ringer’s solution on ice and carried immediately into the adjacent operating room for transplantation.

Data and statistical analysis

Recipient and donor demographic and clinical data were abstracted from the electronic medical records. For the shipped kidney group, CIT was calculated from the exact time and time zone the organ was cross-clamped and the exact time and time zone in which warm reperfusion occurred; for the nonshipped group, we imputed a CIT of 1.0 h to allow for the time incurred while the organ was back tabled and prepared for transplantation. Patient and transplant characteristics were compared with a McNemar’s test for paired samples for the 2×2 categorical variables (or Bowker’s test of symmetry for higher order variables) and a paired *t*-test for the continuous variables. Serum creatinine was measured daily post-transplant at 1–7 days, 14 days, 28 days, 3 months, 6 months, and 1 year.

Paired-sample *t*-tests were conducted on the serum creatinine at each time point. Adjusted means were also calculated from a matched pair, mixed model analysis, controlling for two variables (recipient gender and difference in recipient and donor BMI) that we chose *a priori* which have been previously associated with allograft success. The rate of serum creatinine decline was calculated for each subject from day 1 to day 7 post-transplant using least squares regression, and a paired-sample *t*-test tested the mean rates between the groups. Allograft survival was compared between groups using Cox regression analysis (SAS PROC PHREG), accounting for paired samples (STRATA statement) to calculate the hazards ratio. All tests were two-sided, and a *P*-value of 0.05 or less was considered statistically significant. Statistical analysis and graphing were performed using SAS 9.4 (Cary, NC). Appropriate institutional review board approval (IRB#11-000406) and patient research protocols were obtained prior to initiating this study in accordance with the Declaration of Helsinki.

Results

The first shipped live donor kidney was transplanted in July 2008, and at the time of this study analysis, 57 transplants from shipped live donors had been performed. The donor kidneys originated from 31 different institutions in 26 cities across the United States (Fig. 1). Overall recipient and donor patient characteristics divided by cohort are described in Table 1. The oldest shipped kidney donor was a 70-year-old female. Shipped kidney recipients were more likely than nonshipped recipients to have had a prior

transplant (23% vs. 9%, $P = 0.06$), but less likely to have an Asian donor (2% vs. 21%, $P < 0.01$). An expected significant difference was also seen in the donor/recipient relationship with all the shipped recipients being unrelated (100% vs. 23%, $P < 0.01$).

Transplant procedure and outcomes are reported in Table 2. Notably, the maximum CIT was 18 h and 35 min. All except for one kidney were shipped using existing Organ Procurement Organization (OPO) networks on commercial airlines with an estimated average cost of \$550/kidney. One kidney was shipped via private jet at an estimated cost of \$30 000 per the recipient's request and expense. The mean peak PRA was significantly higher for the shipped group when compared with the nonshipped group (44.2% vs. 7.6%, $P < 0.01$). Patients are typically referred into the exchange programme for incompatibility and therefore are likely to be more sensitized. Despite this, there were no significant differences between the mean serum creatinine values of the shipped and nonshipped kidney transplant cohorts except at 4 weeks postoperative (all *P*'s > 0.10) (Table 2), even after adjustment for gender and differences in BMI (Fig. 2). One subject in the shipped kidney cohort underwent dialysis within a week of transplantation (discussed below) for a DGF rate of 1.8%, which was not significantly different from 0% in the nonshipped group ($P = 1.00$). The rate of serum creatinine decline from day 1 to 7 for the shipped kidney cohort was 0.38 mg/dl per day, which was not significantly greater than the rate of 0.30 mg/dl per day in the nonshipped cohort ($P = 0.11$) (Table 2). There was no significant correlation between the rate of serum creatinine decrease

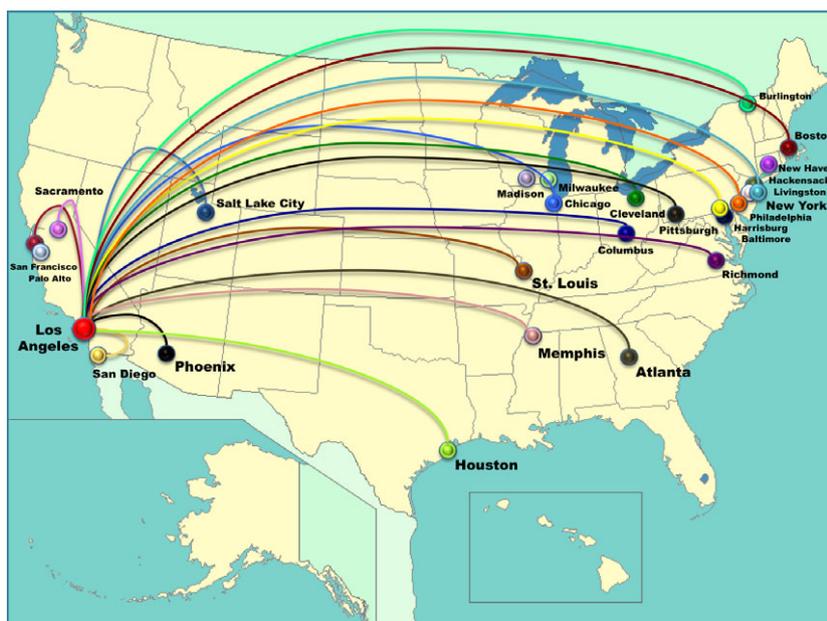


Figure 1 Shipped kidney donor cities.

Table 1. Paired tests for patient and donor characteristics by shipped kidney status ($n = 114$).

	Total		Shipped		Nonshipped		P-value*
	$n = 114$		$n = 57$		$n = 57$		
	%	n	%	n	%	n	
Year of transplant							
2008	2%	2	2%	1	2%	1	0.96
2009	11%	12	9%	5	12%	7	
2010	22%	25	21%	12	23%	13	
2011	25%	28	23%	13	26%	15	
2012	25%	29	26%	15	25%	14	
2013	16%	18	19%	11	12%	7	
Recipient							
Age at transplant, mean \pm SD	48.9 \pm 13.9		48.9 \pm 14.1		48.9 \pm 13.8		0.99
Gender							NA
Male	46%	52	46%	26	46%	26	
Female	54%	62	54%	31	54%	31	
Race							0.99
White	32%	37	41%	19	32%	18	
Hispanic	16%	18	20%	9	16%	9	
African American	5%	6	7%	3	5%	3	
Asian	25%	28	30%	14	25%	14	
Other	22%	25	21%	12	23%	13	
Marital status							0.40*
Married	68%	77	72%	41	63%	36	
Not married	26%	37	29%	16	37%	21	
BMI, mean \pm SD	25.1 \pm 4.7		25.3 \pm 4.2		24.8 \pm 5.2		0.64
Normal/Overweight (BMI \leq 30)	85%	97	88%	50	82%	47	0.58*
Obese (BMI > 30)	15%	17	12%	7	18%	10	
Cause of ESRD							0.99
Diabetes	23%	26	19%	11	26%	15	
Hypertension	17%	19	16%	9	18%	10	
Glomeruloephritis	27%	31	26%	15	28%	16	
Cystic kidney disease	12%	14	14%	8	11%	6	
Other urologic	3%	3	4%	2	2%	1	
Other	18%	21	21%	12	16%	9	
History of prior kidney transplant							0.06*
Yes	16%	18	23%	13	9%	5	
No	84%	96	77%	44	91%	52	
On dialysis prior to transplant							0.80*
Yes	74%	84	75%	43	72%	41	
No	26%	30	25%	14	28%	16	
Donor							
Age at transplant, mean \pm SD	42.3 \pm 11.8		41.6 \pm 12.3		43.1 \pm 11.4		0.45
Gender							0.17*
Male	33%	38	40%	23	26%	15	
Female	67%	76	60%	34	74%	42	
Race							0.01
White	54%	61	54%	31	53%	30	
Hispanic	16%	18	12%	7	19%	11	
African American	11%	12	16%	9	5%	3	
Asian	11%	13	2%	1	21%	12	
Other	9%	10	16%	9	2%	1	
BMI, mean \pm SD	26.1 \pm 4.4		26.7 \pm 4.9		25.2 \pm 3.7		0.16
Normal/Overweight (BMI \leq 30)	86%	98	81%	46	92%	52	0.18*
Obese (BMI > 30)	14%	16	19%	11	9%	5	

Table 1. continued

	Total		Shipped		Nonshipped		P-value*
	n = 114		n = 57		n = 57		
	%	n	%	n	%	n	
Relationship to recipient							
Child	9%	10	0%	0	17%	10	NA
Parent	3%	3	0%	0	5%	3	
Sibling	15%	17	0%	0	30%	17	
Other related	5%	6	0%	0	11%	6	
Spouse	6%	7	0%	0	12%	7	
Unrelated	61%	70	100%	57	23%	13	

*P-values for McNemar tests for 2 × 2 categorical variables (McNemar's exact if denoted with an asterisk), Bowker's test of symmetry for higher order categorical variables, and paired t-tests for continuous variables.

Table 2. Paired tests for transplant characteristics by shipped kidney status (n = 114).

	Shipped n = 57 % (n)	Nonshipped n = 57 % (n)	P-values*
Cold ischemia time, hours			
Mean ± SD	12.1 ± 2.8	1.0 ± 0.0†	<0.01
Median [Range]	12.5 [5.7–18.6]	–	
Distance travelled, miles			
Mean ± SD	1634 ± 899	–	NA
Median [Range]	1882 [123–2811]	–	
Follow-up time, years			
Mean ± SD	2.5 ± 1.3	2.7 ± 1.3	0.12
Median [Range]	2.2 [0.6–5.8]	2.7 [0.1–5.7]	
Delayed graft function	2% (1/57)	0% (0/57)	1.00*
1 – Year allograft survival (n = 46)	98% (45)	98% (45)	1.00*
2 – Year allograft survival (n = 28)	93% (26)	93% (26)	1.00*
3 – Year allograft survival (n = 18)	89% (16)	89% (16)	1.00*
4 – Year allograft survival (n = 7)	86% (6)	71% (5)	1.00*
5 – Year allograft survival (n = 2)	50% (1)	100% (2)	NA
Allograft Failure	7% (4)	7% (4)	1.00*
Peak PRA (%), mean ± SD	44.2 ± 39.3	7.6 ± 20.1	<0.01
Serum creatinine, mg/dl (mean ± SD)			
Time since transplant			
1 day (n = 56)	3.80 ± 2.14	3.54 ± 1.90	0.46
2 days (n = 56)	2.29 ± 1.54	1.93 ± 1.15	0.14
3 days (n = 53)	1.70 ± 1.27	1.55 ± 0.97	0.47
4 days (n = 56)	1.53 ± 1.08	1.39 ± 0.70	0.42
5 days (n = 37)	1.34 ± 0.94	1.29 ± 0.77	0.80
6 days (n = 27)	1.32 ± 0.66	1.32 ± 0.65	1.00
7 days (n = 38)	1.36 ± 0.81	1.28 ± 0.65	0.64
2 weeks (n = 56)	1.22 ± 0.41	1.25 ± 0.40	0.64
4 weeks (n = 56)	1.16 ± 0.34	1.32 ± 0.51	0.04
3 months (n = 56)	1.19 ± 0.38	1.30 ± 0.55	0.18
6 months (n = 41)	1.39 ± 0.94	1.28 ± 0.46	0.47
1 year (n = 29)	1.18 ± 0.56	1.39 ± 0.67	0.13
Change from day 1 to 7, mg/dl/day (mean ± SD)	–0.38 ± 0.35	–0.30 ± 0.26	0.11

*P-values for McNemar tests for categorical variables (McNemar's exact if denoted with an asterisk) and paired t-tests for continuous variables.

†One hour imputed for all nonshipped kidneys.

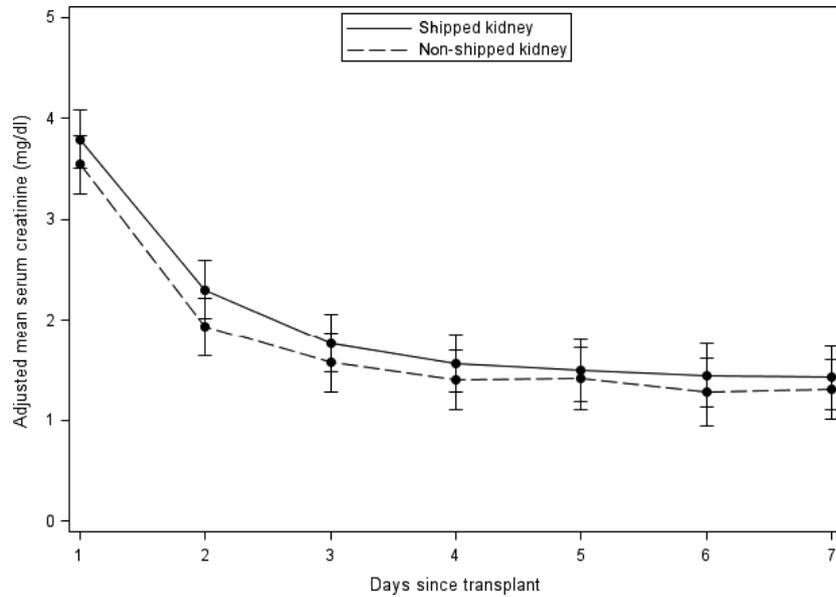


Figure 2 Mean serum creatinine values (mg/dL) post-transplant by shipped kidney status adjusted for recipient gender and difference between recipient and donor BMI.

and CIT among the shipped group ($\rho = -0.15, P = 0.28$). There was also no difference in allograft failure between the two groups either by frequency of failures (7% vs. 7%, $P = 1.000$) (Table 2) or by Cox regression analysis of allograft survival (HR = 1.33, 95% CI = 0.30–5.96) (Fig. 3).

The single case of DGF among the shipped kidney cohort had 15 h of CIT. The patient developed severe hypotension at the time of surgery from a medication reaction, which subsequently required treatment with multiple vasopressors for several perioperative hours. A single hemodialysis treatment was administered on postoperative day 4, and an

allograft biopsy showed acute tubular necrosis. At 1 month, the recipient remained dialysis-free with a serum creatinine of 1.1 mg/dl, reaching a nadir of 1.0 mg/dl at the 2-year follow-up.

Discussion

This matched cohort study demonstrates shipped live donor kidneys having similar short-term outcomes to traditional live donor transplantations. Despite the mean CIT of 12 h (nearly double the mean CIT from other reports), the 1-year

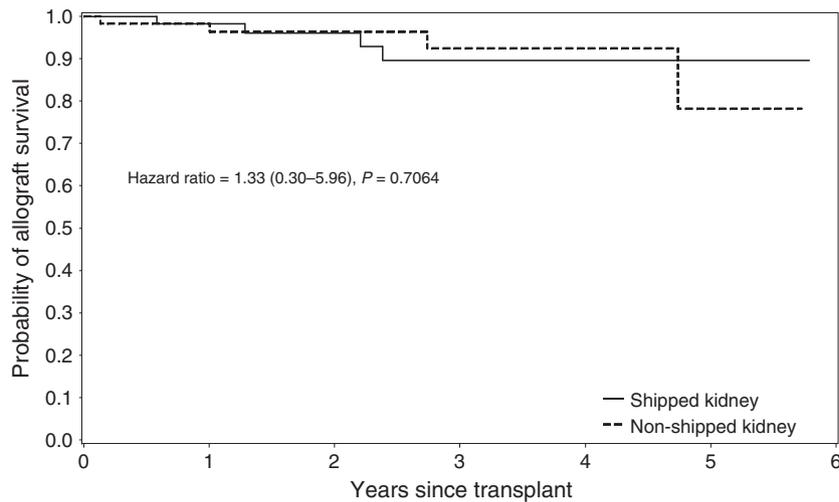


Figure 3 Probability of allograft survival by shipped status.

graft survival rates were the same in this study [8,9]. The 1.8% DGF rate among our shipped group is below the reported national rate for all living donor transplants of 2.8% reported for 2011 [10]. When considering the severe perioperative hypotension experienced, we cannot definitively conclude that the prolonged CIT led to DGF; however, the CIT may have made the graft more susceptible.

Some clinicians remain hesitant about shipping live donor kidneys, as there is a perceived benefit of avoiding extended CITs that arise from deceased donor transplantation. Live donor allografts likely have superior function to deceased donor allografts as these donors are in a better state of health and avoid hypotension, cytokine, and inflammatory protein release that are associated with death. This superior function is not necessarily due to shorter CITs. In fact, some of the longest functioning deceased donor allografts in the United States have incurred long CITs as a result of six antigen-match programs [11]. There was no difference in outcomes or mean serum creatinine values between the shipped and nonshipped groups at all time intervals suggesting prolonged CIT minimally impacts overall kidney allograft and outcome. This finding was further supported when considering recipients in the shipped group were more immunologically and technically complex as they had a significantly higher mean peak PRA and often received multiple kidney transplants when compared to their matched cohort. Furthermore, we reported the shipment of a live donor kidney from a 70-year-old female with approximately 13 h of CIT. The kidney was transplanted into a 65-year-old diabetic male, whose BMI was 35.1. The 2-week follow-up serum creatinine of this recipient was 1.4 mg/dl. Recipient centers in exchange programmes often deny potential offers based on donor age and size, and the early success highlighted by this transplant may encourage more clinicians to broaden their acceptance criteria in seeking ideal matches for their patients and fear prolonged CIT less.

Shipping kidneys requires cooperation between a multitude of centers, physicians, coordinators, operating room personnel, OPOs, and the exchange programme or registry. In our experience, couriers and commercial airlines often went above and beyond to ensure no travel delays. On one occasion flight control delayed the departure of a commercial aircraft on the tarmac to ensure the safe and timely arrival of a live donor kidney that was late being transported to the airport. Applying this strategy to more remote transplant programmes may prove complicated by requiring connector flights and/or extended ground transportation. Recently, for added security, GPS tracking devices were packaged with the donor kidneys to allow for real-time monitoring of the movement and transport progress of the organs. Hypothetical risks of losing or damaging an organ in route exist; however, with careful

coordination and effort, these risks become minimal and outweigh the benefits of this option to patients.

Benefit of transporting organs arises from the recent initiation and growth of kidney transplant exchanges to augment the growing disparity between transplant candidates and donor organs. The donor in an exchange often lives a great distance apart from the recipient. Transporting the recovered organs allows for donors and recipients to undergo surgery and recover with their loved ones and friends in a familiar setting, thus encouraging living donation. There is great potential to expand the living donor pool by an estimated 35% through KPD [11].

This study shipped live donor allografts with CITs up to 18 h, which supports expanding exchanges internationally [12] and follows in the footsteps developed to expand living donor bone marrow registries to meet organ demand [13,14]. However, bureaucracy involved in international exchanges may prove more of a barrier than the concerns about increased CITs. For example, UNOS must approve international exchange protocols; the current policy prohibits international exchanges of living donor organs in the United States [15]. The obstacles are not insurmountable, as demonstrated by a successful exchange between Canada and the United States in 2010 [9]. The high cost of dialysis should motivate the governing bodies to pursue this option, particularly when a donor kidney from another country could be easily transported and be matched to a highly sensitized recipient. The Netherlands, United Kingdom, and Spain have established exchange programmes within Europe, which follow international standards for organ recovery, as articulated by the Amsterdam Forum and in the Istanbul Declaration.

Our results need to be considered in the context of the study. Participants were matched according to age, gender, race, and year of procedure; however, matching for more factors such as cause of renal disease could not be included despite the large pool of patients from our database. Medical practices likely vary between the two groups, and the shipped kidney cohort may have access to more aggressive treatments for immunosuppression and desensitization leading to better graft survival considering they had higher mean PRAs. The trends in creatinine, DGF, and allograft survival would likely be slightly affected by these advancements. Lastly, this is a single-center experience from a tertiary, high-volume transplant center. Replicating these results may prove difficult in different center/programme where practices vary. Despite these limitations, the two groups show strong similarities and do provide a deeper analysis of CIT in a broader context. Further studies and carefully monitoring of CIT should be performed in any study or programme involved in shipping living donor kidneys to continue to validate and confirm these findings.

Conclusion

Despite prolonged CITs, outcomes for shipped live donor kidney transplants appear to be similar when compared with age, gender, race, year of procedure, and institution matched traditional (nonshipped) living donor kidney transplants.

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Authorship

EGT and ETM: Manuscript authorship, data collection, editing, and statistical analysis. LK: Manuscript authorship, data collection, editing, and statistical analysis. SEC, SLM, EMH, KCW, LAW and HAG: editing and data interpretation. SMM: editing, data collection, and coordination of shipping kidneys. TDM: editing, and coordination of shipping kidneys. JLV: study conception, editing, data collection, data interpretation, Manuscript authorship.

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