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Assessment of Restored Kidney Transplantation Including the Use of Wider Criteria for Accepting Renal Donors After Cancer Excision

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Background. The transplantation of kidneys after cancer excision (restored kidney transplantation, RKT) warrants further evaluation as a source of kidneys for transplantation. We determined whether larger cancers can be safely transplanted, the risks of adverse events from RKT, and whether RKT confers a survival advantage for patients waiting for transplantation. **Methods.** In a retrospective cohort study, 23 dialysis patients awaiting transplant underwent RKT at John Hunter Hospital, Australia between 2008 and 2015. Patients were >60 years old and accepted onto the National Organ Matching Service. This RKT Group was divided into donor renal cancers ≤30 mm and >30–≤50 mm. Adverse event profiles for RKT recipients were compared with 22 standard live donor recipients using logistic regression analyses. Recipient and transplant survivals for RKT were compared with 2050 controls from Australian New Zealand Dialysis Transplant Registry using Cox regression models. To increase statistical power for survival analyses, data from 25 RKT recipients from Princess Alexandra Hospital, Brisbane were added, thus creating 48 RKT recipients. **Results.** There were no significant differences in mortality, transplant failure nor AEs between the 2 cancer Groups. RKT increased the risks of Adverse event profiles (odds ratio: 6.48 [2.92–15.44]; $P < 0.001$). RKT reduced mortality risk by 30% (hazard ratio [HR]: 0.70 [0.36–1.07]; $P = 0.299$) compared with those continuing on the transplant list who may or may not be transplanted. RKT significantly reduced mortality risk for those remaining on dialysis (HR: 2.86 [1.43–5.72]; $P = 0.003$). Transplant survival for RKT was reduced compared with control deceased donor (HR: 0.42 [0.21–0.83]; $P = 0.013$) and live donor transplants (HR: 0.33 [0.02–0.86]; $P = 0.023$). **Conclusions.** The use of larger carefully selected cancer-resected kidneys for transplantation appears safe and effective. RKT confers a possible survival advantage compared with waiting for transplantation, an increased survival compared with those remaining on dialysis but reduced transplant survival.

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Although renal transplantation is the preferred treatment for end-stage renal disease, the supply of suitable kidneys does not meet patient need in most countries.[1-3] Strategies adopted to increase supply include: national coordination of donation policy and practice[4-6]; donor identification[7]; the use of donor coordinators in organ recovery[5,6]; and improved efficiency in the use of existing renal supply including paired kidney exchange programs,[8]

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ABO incompatibility renal donors,[9] and extended criteria donors.[10]

Restored kidney transplantation (RKT) is another initiative to increase renal supply. In this procedure, a donor's localized kidney cancer is excised after total nephrectomy and the cancer-free kidney is transplanted. Two published series of RKT reported favorable recipient and transplant survivals.[11,12] The question of the relative survival of RKT recipients, however, compared with those remaining on the transplant waiting list (including those subsequently transplanted) remains unanswered. This is a fundamental issue facing the future of RKT. Comparative adverse event profiles (AEPs) for RKT have not been reported.[11-14] Furthermore, because kidney cell carcinomas grow by compressing rather than infiltrating surrounding kidney tissue and are not associated with a field change throughout the kidney,[15] it may be possible to widen the cancer criteria beyond the published limit of 30 mm diameter.

In this study, we aimed to determine whether donor kidneys with larger cancers can be safely transplanted; the risks of RKT; and whether RKT confers a survival advantage over maintenance dialysis for prospective recipients waiting for transplantation.

MATERIALS AND METHODS

Donor Selection

We selected patients with kidney cancers up to 50 mm diameter (CT scan measurement) in whom total nephrectomy was the decided cancer treatment and the amount of residual kidney was judged to be functionally sufficient if transplanted. Some nonspherical cancers exceeded 50 mm in a dimension but had volumes <50 mm sphere. Because Clinical Governance verified that these donors complied with the 50 mm criterion, we accepted them. Bias against partial nephrectomy was avoided by obtaining 2 independent urologic opinions about the optimal cancer treatment. Each patient was given information about donation and its specific risks, benefits, and alternatives. Standard donor medical assessments were made. If the patient agreed to donation and was medically suitable, then he or she was asked to sign a specific consent form for donation. Acceptance was determined by the Live Donor Acceptance Committee of the Newcastle Transplant Unit (NTU) at John Hunter Hospital (JHH). Twenty-eight patients with kidney masses were referred where total nephrectomy was planned: 2 were excluded before nephrectomy (final preference for partial nephrectomy; coincidental abdominal lymphoma). Three were excluded after nephrectomy (operative arterial injury; large central cancer with insufficient residual kidney; multiple arterial aneurysms). Hence, 23 kidneys from JHH were transplanted after mass excision (Table 1).

Recipient Selection

All NTU recipients on the National Organ Matching Service (NOMS) who were >60 old between 2008 and 2015 were considered eligible for RKT (one aged 59.2 y was also included because there was no suitable recipient >60 y old for that kidney). The nature of the RKT program and its specific risks, benefits, and alternatives were discussed with them. Interested patients were asked to specifically consent to RKT in advance emphasizing nonparticipation would not impact upon their status on the NOMS. Standard medical assessments were also done. The acceptance for RKT was determined by the Recipient Acceptance Committee of the NTU. Restored kidneys were offered to NTU recipients after ranking by the NOMS criteria.

Study Group

The Study Group consisted of 23 recipients of RKT from JHH, divided into 2 subgroups based on the size of the kidney mass: ≤30 mm diameter (n = 11) and >30 mm but ≤50 mm diameter (n = 12) on preoperative CT scan. For the patient and transplant survival studies, the published series of 25 comparable RKT recipients from Princess Alexandra Hospital (PAH), Brisbane, Australia, were included to increase the statistical power of the survival analyses. The inclusion criteria for the PAH Group were the same as those used for the JHH Group: namely the PAH recipients were on the transplant waiting list; were over 60 at the time of transplantation and had received LD transplants.

TABLE 1.

Demographics of renal donors assessed for restored kidney transplantation between 2008 and 2015

Number assessed	28
Number that underwent total nephrectomy for a cancer lesion	26[a]
Number of cancer resected kidneys transplanted (Study Group)	23[b]
Number with renal cancer size ≤30 mm (Group 1)	11
Number with renal cancer size >30 mm but ≤50 mm (Group 2)	12
Age	55.9 ± 12.9 (n = 26)[c]
Gender	M: F = 15:11
Pathology of the nephrectomy specimen (n = 26)	Renal cancer 21[d]; oncocytoma 2; benign renal cysts 3[e]
Maximum diameter of renal cancer on preoperative CT scan	38 ± 12 mm (n =26)[c]
Maximum diameter of renal cancer on preoperative ultrasound	39 ± 11 mm (n = 26)[c]
Maximum diameter of cancer at pathology	37 ± 11 mm (n = 26)[c]
Hypertension	6/26 (23%)
Diabetes mellitus	6/26 (23%)
Smoking history	6/26 (23%)

All donors underwent donor nephrectomy at John Hunter Hospital between 2008 and 2015.

[a]Two patients were rejected because of coincidental intra-abdominal lymphoma and a recommendation to change to partial nephrectomy.

[b]Three kidneys were not suitable for transplantation because of operative vascular injury combined with a renal cancer; a large central cancer with insufficient residual kidney; and multiple arterial aneurysms combined with a renal cancer.

[c]Mean ± SD.

[d]Renal cancer 21: clear cell 14, chromophobe 4, and papillary 3.

[e]Benign renal cysts 3: complex cysts 1; single cyst 1; and cystic adenoma 1.

Study Design

It was a retrospective observational cohort study. Patient survivals for the RKT Group from JHH (n = 23) and PAH (n = 25) were compared with the Control Group, which consisted of patients who otherwise would have been eligible to receive RKTs (>60 old at any time during the period January 1, 2008, to December 31, 2015, and listed on NOMS). Hence, the Control Group consisted of patients on the NOMS receiving dialysis (n = 722), recipients of transplants from deceased donors (n = 1186), live related donors (n = 102), and live nonrelated donors (n = 40). The construction of the data for the Control Group of patients (including those excluded) and the RKT Group from JHH and PAH is shown in Figure 1. Data for Controls and RKT recipients from JHH were derived from the Australian component of the Australian New Zealand Dialysis Transplant Registry (ANZDATA) and the database of the NTU. Data for RKT recipients from PAH were derived from the published series of RKTs[12] which used the Transplant Unit database and the ANZDATA Registry. Similar comparisons were done for restored kidney transplant survival. The AEPs of the Study Group from JHH were compared with a Group of 22 consecutive live donor transplant (LDT) recipients from the NTU at JHH who were >60 old when transplanted between 2008 and 2015. Data for adverse events (AEs) were derived from the NTU database. This profile consisted of delayed graft function (required postoperative dialysis at least once); blood transfusion with no return to the operating room; postoperative hemorrhage, transfusion, and return to the operating room; return to the operating room; urinary leak; urinary tract infection; and transmission of donor cancer.

Surgical Technique

The donor surgery done at JHH was initiated as a trans-peritoneal laparoscopic radical nephrectomy with hilar node dissection for staging. The artery and vein were

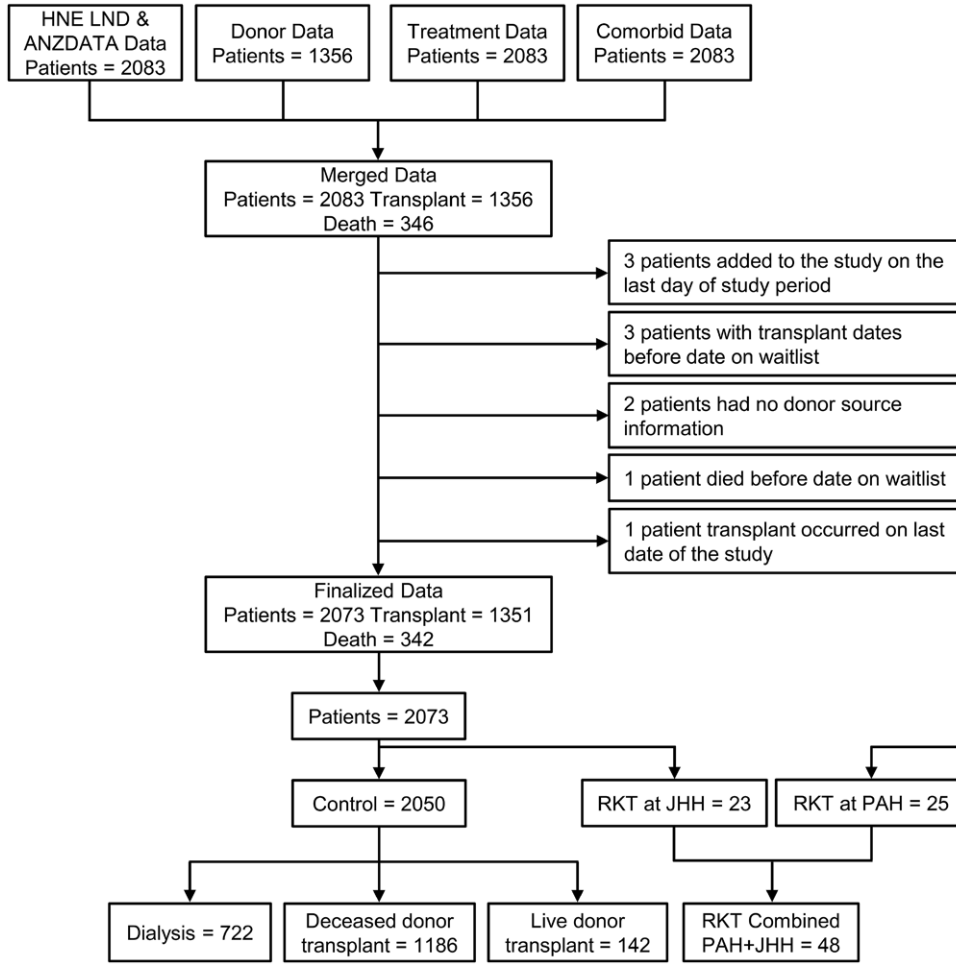

FIGURE 1. The construction of the data in the Control Group and Restored Kidney Transplant Group at JHH and PAH. Data for the both the Control Group and Restored Kidney Transplant Group at JHH were derived from Australian New Zealand Dialysis and Transplant Registry, the transplant database of the Newcastle Transplant Unit of the Hunter New England Local Health District, and the NOMS. Data from these databases were merged using a unique identifier for each patient. The original number of patients was 2083. There were 10 exclusions; the reasons are listed here. There were then 2073 patients: 2050 in the Control and 23 in the RKT Group at JHH. The Control Group consisted of patients on the NOMS who were ≥60 y at any time in the period 2008–2015 and who were eligible for transplantation: it consisted of patients receiving dialysis (n = 722); recipients of transplants from deceased donors (n = 1186), live related donors (n = 26), and live nonrelated donors (n = 116). The Restored Kidney Transplant Group at JHH then consisted of 23 recipients. For the purpose of calculating recipient and transplant survival for restored kidney transplants, published data for a Group of 25 recipients from PAH, Brisbane, selected with the same criteria, were added. The RKT Group then consisted of 48 recipients. ANZDATA, Australian New Zealand Dialysis Transplant Registry; JHH, John Hunter Hospital; NOMS, National Organ Matching Service; PAH, Princess Alexandra Hospital; RKT, restored kidney transplantation.

individually stapled (Endo TA multifire 2.5 mm Covidien, Mansfield, MA); the kidney was retrieved and immediately perfused with histidine-tryptophan-ketoglutarate solution.[16] Frozen section was used to confirm cancer clearance and hilar negativity.

Approval by Clinical Governance and Human Research Ethics Committee

Clinical Governance from the Hunter New England Local Health District and the NSW Transplant Advisory Committee gave approvals for RKT for cancers ≤30 mm as a new intervention in 2008 at JHH. Additional approval was gained for cancers up to 50 mm in 2009. The Human Research Ethics Committee (HREC) approved this study using ANZDATA Registry data in 2017 (NSW HREC Reference Number: LNR/17/HNE/210). Clinical Governance at Metro South Health Area gave approval for the PAH data to be used in this study in 2018 (HREC/18/QMS/ 45262).

Statistics

AEs With Restored Kidney Transplants and Standard LDTs From JHH

The proportion of JHH recipients with each type of AE from RKT was compared with standard LDTs from JHH. Given the small numbers, we used Bayesian analysis with noninformative uniform prior distributions and 95% credible intervals for the difference in proportions. Bayes Factors (BFs) are presented; a BF > 3.2 represents substantial evidence in favor of the null hypothesis.[17] Similar methods were used to compare AEs between the RKT subgroups. Overall AEPs were compared using mixed effect logistic regression (adjusting for length of stay, coronary artery disease, age, and diabetes) and expressed as odds ratios and 95% credible intervals.

Comparing Mortality of Restored Kidney Transplant From JHH With Those on the Transplant Waiting List

The study period was defined as January 1, 2008, to December 31, 2015; study entry date was defined as the date at which a participant >60 years old was listed on the NOMS during this period. Participants who were >60 years old and on the NOMS before January 1, 2008, had their study entry date set at January 1, 2008. Prior time on the NOMS was analyzed as a potential confounder. Kaplan-Meier survival curves were constructed comparing time from study entry to death for those receiving RKT versus those continuing on NOMS who may or may not have subsequently received a transplant of another type. Patients were censored at December 31, 2015, if not deceased beforehand. All analyses were performed with time starting when a patient was listed on the NOMS. Transplant status was treated as a time-varying covariate to avoid immortal time bias: this means that all NOMS participants contribute their pretransplant time to the control group (dialysis), their post RKT time to the test group (RKT), and their posttransplant time to other control groups (deceased, live related, live unrelated control groups) (Figure 2). Cox regressions were performed adjusting for other potential confounders: age, gender, number of comorbidities, location, and socioeconomic status. The analyses were repeated for the outcome of transplant failure, with death treated as a competing risk (using the Fine-Gray method). All patients were followed up for the study period.

Comparing Mortality of Restored Kidney Transplant From PAH With Those on the Transplant Waiting List

The control for the PAH Group was the same as the JHH Group. There were 25 participants in the PAH group who were transplanted between January 1, 2000, and December 31, 2007. The inclusion criteria were the same as those used for the JHH Group as listed above. Recipients were censored 8 years after entry if they had not deceased beforehand, thus maintaining a comparable study period with the JHH Group. The covariates (including time on the waiting list before transplantation) and analytical methods were the same as those used for the JHH Group.

RESULTS

Demographics of Kidney Donors

The demographics of kidney donors operated at JHH are listed in Table 1. Twenty-six patients underwent nephrectomy. One required conversion to open because of an intraoperative arterial injury; the remainder were completed laparoscopically. There was neither mortality nor postoperative AEs in the donor group.

Demographics of Restored Kidney Transplant Recipients

The demographics of RKT recipients at JHH are listed in Table 2. Their demographics compared with Controls are listed in Table 3. Of the 26 kidneys assessed for RKT, 3 were not suitable. Hence, the Study Group from the JHH consisted of 23 recipients of mass resected kidneys.

Outcomes of Restored Kidney Transplant Recipients With Respect to the Pathology and Size of the Donor Kidney Mass

The outcomes of the 2 subgroups from JHH in relation to the pathology of the resected mass are listed in Table 4. There were 3 nonsurgical deaths: 2 in Group 1 (≤30 mm) and 1 in Group 2 (>30 but ≤50 mm). At the end of 2015, 8 of 11 transplants in Group 1 and 11 of 12 transplants in Group 2 were functioning. One recipient in Group 1 developed recurrent cancer in the transplant 26 months after transplantation; the donated kidney had a 30-mm Fuhrman Grade 4 clear cell carcinoma with clear margins and negative nodes. There was no cancer recurrence after transplant nephrectomy.

AEPs for Restored Kidney Transplant Recipients

Compared with the Control Group consisting of standard LDTs, there were increased odds ratios of AEs for the RKT Group from JHH (odds ratio [OR]: 6.48 [95% confidence interval (CI): 2.92-15.44]); the Group with mass size ≤30 mm (OR: 7.08 [95% CI, 3.07-17.21]); and the Group with mass size >30 mm but ≤50 mm (OR: 4.81 [95% CI, 2.11-11.49]). For the JHH Group, the recipient characteristics and summaries of each AE are given in Table 5 and the results of Bayesian analyses comparing the RKT Group and the Control Group are listed in Table 6. The major contributors to the increased risk for the RKT Group from JHH compared with the Control Group were urinary leak (56% higher, 95% CI, 33%-75%, $P < 0.001$; $BF_{10} = 5007$); transfusion without return to the operating room (35% higher, 95% CI, 11%-57%, $P = 0.007$; $B_{10} = 19.48$), urinary tract infection (31%

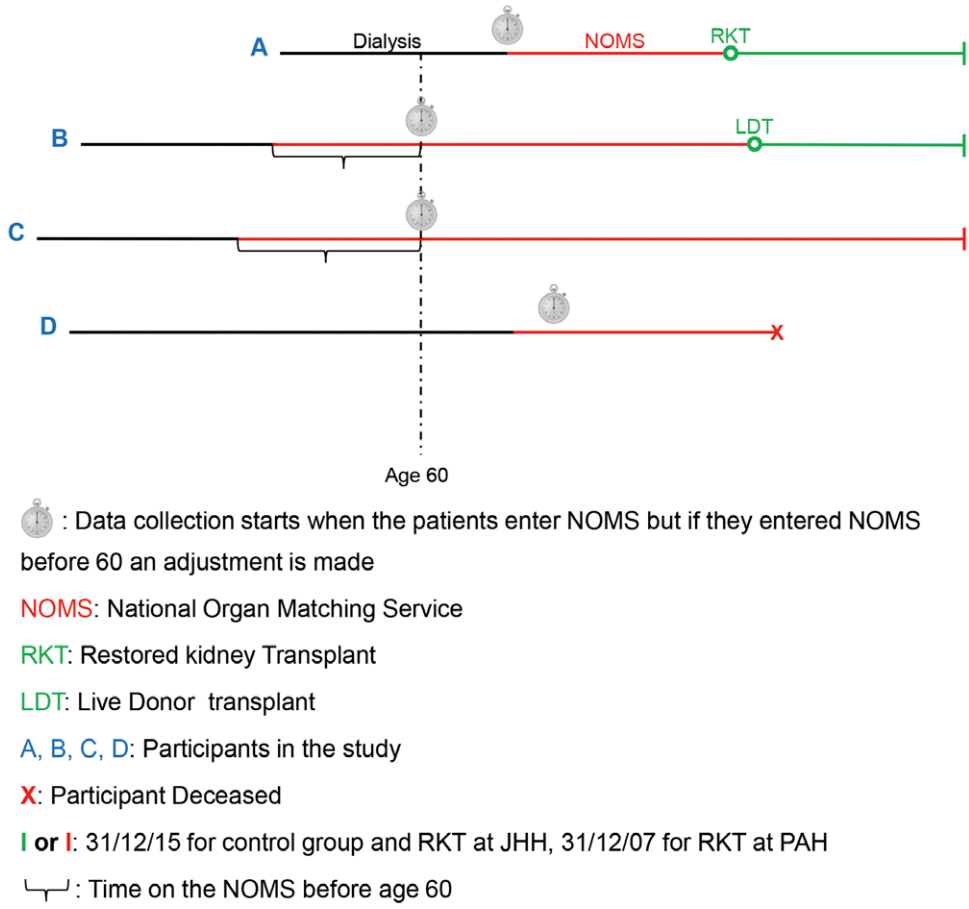

FIGURE 2. Explanation about the use of time as a covariate in the survival analyses for RKT. Basically, time in the study starts when the patient enters the NOMS; this means that they are medically fit for renal transplantation and await the allocation of a transplant. Participant A: time in the study starts when patients join the National Organ Matching System and continues until they receive an RKT at which point they contribute time to the test group. Participant B: time in the study starts at 60 y on NOMS but is adjusted for the number of y on NOMS before this. They are part of the control group used to calculate the effect of RKT because at the time of participant A's RKT they were still on the waiting list and they did not know if and when they might get a transplant. They later get an LDT and contribute the time from then on to the LDT control group (or they could have received a deceased donor or live non related transplants which are treated in the same way). Participant C: time in the study starts at 60 y on NOMS but is adjusted for the number of y on NOMS before this. They contribute their time from then on to the dialysis control group and are censored at the end of the study without ever having received a transplant. Participant D: time in the study starts when they are listed on NOMS (after 60 y) and they die on the waiting list having never received a transplant. They contribute their time as a dialysis control up until then. PAH, Princess Alexandra Hospital.

higher, 95% CI, 5%-55%, P = 0.03; B_{10} = 4.74); and return to the operating room (27% higher, 95% CI, 44%-50%, P = 0.035;B_{10} = 4.46). There was substantial evidence supporting equality in risk for the RKT compared with Control for delayed graft function (5% lower, 95% CI, –25%-15%, P = 0.665; BF_{01} = 3.85;); postoperative hemorrhage (4% higher, 95% CI, –17%-23%, P = 1.0; BF_{01} = 4.0); and donor cancer transmission (4% higher, 95% CI, –9%-18%, P = 1.0; BF = 5.08). When comparing the 2 mass Groups, there was weak but consistent evidence supporting equality for all of the 7 AE rates (Table 7).

Summary of Outcomes for Recipients of Kidneys After Excision of Cancers ≤30 mm or >30 mm but ≤50 mm in Diameter

The summary of 6 outcomes is listed in Table 8. There were no significant differences in these outcomes when the larger cancer resected Group was compared with the smaller Group; in particular there was no significant difference in the total number of AEs.

Recipient Survival of Restored Kidney Transplants Compared With Those on the Transplant Waiting List

There was a reduction in mortality from RKT for the Group of combined JHH and PAH compared with the Group on the transplant waiting list but it was not statistically significant (hazard ratio [HR]: 0.70 [95% CI, 0.36-1.37]; P = 0.299) (Table 9 and Figure 3). Similarly, the reductions in mortality risks from RKT for the JHH Group and the PAH Group separately were not statistically significant (HR: 0.65 [95% CI, 0.21-2.04]; P = 0.460; HR: 0.730 [95% CI, 0.32-1.65]; P = 0.449 respectively) when compared with the Group waiting on the transplant list. The probability, however, that the reduction in mortality risk was due to chance was reduced for the larger Group.

Patient Survival by Each Type of Treatment

The patient survival by each type of treatment is shown in Table 9 and Figure 4. Compared with RKT, remaining on dialysis significantly increased the mortality risk for the Group of combined JHH and PAH (HR: 2.86 [95% CI, 1.43-5.72];

TABLE 2.

Demographics of prospective recipients for RKT between 2008 and 2015

Number assessed for RKT	26
Number transplanted	23
Number scheduled for transplant but not transplanted	3[a]
Number transplanted with cancer resected kidney (Study Group)	23
Age at transplantation, y	65 ± 4 (n = 23)[b]
Gender	M: F = 17:6
Waiting time on transplant list, mo	22 ±18 (n = 23)[b]
Average length of stay for transplantation, d	15 ± 8 (n = 23)[b,c]
Average follow–up, mo	38 ± 20[b]
e Glomerular filtration rate at 3 mo	48 ± 14 (n = 23)[b]
Hypertension	22/23 (96%)
Diabetes mellitus	8/23 (35%)
Symptomatic coronary artery disease	6/23 (26%)

All prospective recipients were managed at John Hunter Hospital.
[a]Reasons for abandoning renal donation after nephrectomy (decisions made in the operating room): central tumor with insufficient residual renal tissue; intraoperative renal arterial injury; and multiple non reconstructible aneurysms of renal artery and branches.
[b]Mean ± SD.
[c]The average length of stay for the first 4 recipients was 26 days but it fell to 13 days for the subsequent 19 recipients.
RKT, restored kidney transplantation; SD, standard deviation.

P = 0.003), and the PAH Group (HR: 2.93 [95% CI, 1.26-6.81]; *P* = 0.012) but not the JHH Group (HR: 2.77 [95% CI, 0.88-8.75]; *P* = 0. 0.082). The mortality risks for control deceased donor and control LDT recipients were less but not significantly different when compared with the corresponding RKT Group of combined JHH and PAH, the JHH Group, and the PAH Group.

Transplant Survival of Restored Kidney Transplants

The survivals of restored kidney transplants for the 3 Groups compared with survivals of control deceased donor and control LDTs are shown in Table 9 and Figure 5. Compared with RKT, the risks of transplant failure were significantly decreased for LDTs and deceased donor transplants for the Group of combined JHH and PAH (HR: 0.33 [95% CI, 0.12-0.86]; *P* = 0.023) and (HR: 0.42 [95% CI, 0.21-0.83]; *P* = 0.013), respectively, and for the PAH Group (HR: 0.30 [95% CI, 0.10-0.89]; *P* = 0.030) and (HR: 0.40 [95% CI, 0.17-0.90]; *P* = 0.028), respectively, but not for the JHH Group (HR: 0.35 [95% CI, 0.09-1.31]; *P* = 0.119) and (HR: 0.45 [95% CI, 0.14-1.43]; *P* = 0.175), respectively.

DISCUSSION

This study suggests that RKT using kidneys with larger resected cancers (>30 mm but ≤50 mm) is safe and effective when compared with RKT using kidneys with smaller resected cancers (≤30 mm). But RKT carries a higher AE rate compared with standard LDTs. It may confer a survival advantage for prospective recipients waiting on the transplant list, although this was not significant due to the small number of RKTs to date. RKT confers a survival advantage compared with those remaining on dialysis who did not receive a transplant. Transplant survival for RKT was less than live donor or deceased donor transplant controls. To our knowledge, these findings are original in the context of transplant status as a time varying co-variate.

TABLE 3.

Demographics of control group compared with restored kidney transplant group

		Control[a]	Restored[b]	Total
		n = 2050	n = 23	n = 2073
Outcome	Failures	72 (3.5%)	3 (13%)	75 (3.6%)
	Death	339 (16.5%)	3 (13%)	342 (16.5%)
	Transplants	1328 (64.8%)	23 (100%)	1351 (65.2%)
Number of comorbidities	No conditions	906 (44.2%)	5 (21.7%)	911 (43.9%)
	1 condition	612 (29.9%)	10 (43.5%)	622 (30%)
	>2 conditions	532 (26%)	8 (34.8%)	540 (26%)
Location	Major city	1527 (74.5%)	10 (43.5%)	1537 (74.1%)
	Inner regional	359 (17.5%)	12 (52.2%)	371 (17.9%)
	Outer regional	134 (6.5%)	1 (4.3%)	135 (6.5%)
	Remote/very remote	19 (0.9%)	0 (0%)	19 (0.9%)
Gender	Female	728 (35.5%)	8 (34.8%)	736 (35.5%)
	Male	1322 (64.5%)	15 (65.2%)	1337 (64.5%)
Time on Waitlist, y	Mean (SD)	0.4 (0.9)	0.4 (1)	0.4 (1)
	Median (min, max)	0 (0, 3.8)	0 (0, 7.7)	0 (0, 7.7)
Age	Mean (SD)	65.1 (4.1)	64.3 (3.8)	64.3 (3.8)
	Median (min, max)	65 (60, 75)	64 (60, 81)	64 (60, 81)
Number of comorbidities	Mean (SD)	1.3 (1.2)	1 (1.1)	1 (1.1)
	Median (min, max)	1 (0, 4)	1 (0, 5)	1 (0, 5)
Advantage score (decile)	Mean (SD)	3.9 (1.7)	5.8 (2.9)	5.8 (2.9)
	Median (min, max)	4 (2, 9)	6 (1, 10)	6 (1, 10)
Disadvantage score (decile)	Mean (SD)	3.8 (1.6)	5.6 (2.9)	5.6 (2.9)
	Median (min, max)	4 (2, 9)	6 (1, 10)	6 (1, 10)

[a]Those patients on National Organ Matching Service awaiting transplantation who were >60 y at any time in the period January 1, 2008–December 31, 2015, and who may or may not have received a transplant.
[b]Those recipients of restored kidney transplantation performed at Newcastle Transplant Unit, John Hunter Hospital who were >60 y at any time in the period January 1, 2008–December 31, 2015.

TABLE 4.

Outcomes of restored kidney transplant recipients at JHH with respect to the pathology and size of the donor renal mass

Recipient number	Age at transplant	Preoperative maximum CT diameter	Maximum diameter at pathology	Pathology type	eGFR 3/12	Alive/dead at 31/12/2015	Transplant functioning at 31/12/2015	Cause transplant failure
Group 1: preoperative CT cancer size ≤30 mm; n = 11								
1	61	20 × 20	15	Clear cell RCC Fuhrman 2	38	Alive	Yes	
2	69	20 × 20	0	Benign cystic adenoma	26	Dead[a]	No	Recipient death
3	59	23 × 23	25	Papillary type 1 RCC	53	Alive	Yes	
4	66	25 × 25	20	Clear cell RCC Fuhrman 2	60	Alive	Yes	
5	69	26 × 22	26	Clear cell RCC Fuhrman 3	27	Alive	Yes	
6	69	28 × 24	30	Papillary RCC	26	Alive	No	BKV nephropathy[e]
7	68	28 × 32	30	Chromophobe RCC	61	Alive	Yes	
8	64	30 × 30	30	Benign cyst	50	Alive	Yes	
9	76	30 × 30	30	Clear cell RCC Fuhrman 2	46	Alive	Yes	
10	65	30 × 25	35	Clear cell RCC Fuhrman 4	37	Dead[b]	No	TX nephrectomy[f]
11	65	30 × 30	35	Clear cell RCC Fuhrman 3	87	Alive	Yes	
Mean ± SD	66 ± 5		27 ± 6.4		46 ± 15			
Group 2: preoperative CT cancer size >30 mm but ≤50 mm; n = 12								
12	71	39 × 37	45	Clear cell RCC Fuhrman 3	50	Alive	Yes	
13	65	39 × 39	45	Chromophobe RCC Fuhrman 1	41	Alive	Yes	
14	61	40 × 40	50	Oncocytoma	64	Alive	Yes	
15	60	41 × 41	30	Clear cell RCC Fuhrman 1	32	Dead[c]	No	Refractory rejection[d]
16	64	42 × 37	40	Oncocytoma	55	Alive	Yes	
17	68	48 × 47	45	Benign complex cyst	62	Alive	Yes	
18	65	50 × 48	45	Chromophobe RCC	43	Alive	Yes	
19	64	52 × 52	55	Clear cell RCC Fuhrman 2	46	Alive	Yes	
20	68	53 × 48	48	Clear RCC Fuhrman 2	40	Alive	Yes	
21	68	53 × 52	38	Clear cell RCC Fuhrman 3	40	Alive	Yes	
22	64	56 × 48	50	Papillary type 1 RCC	64	Alive	Yes	
23	66	57 × 49	44	Clear cell RCC Fuhrman 3	56	Alive	Yes	
Mean ± SD	65 ± 3		45 ± 6.4		49 ± 11			

All recipients were managed at JHH.
[a]Recipient died from acute myocardial infarction on the 1 /9/2013 with a functioning transplant.
[b]Recipient died on 6/12 /2015 from respiratory failure and insulin dependent diabetes mellitus.
[c]Recipient died on 1/9/2015 from cardiac failure and diabetes mellitus.
[d]The transplant kidney failed on the 9/7/2015 from refractory rejection.
[e]The transplant kidney failed on the 1/8/2011 from BK nephropathy.
[f]Transplant nephrectomy was done for recurrent cancer in the transplant on 11/ 12/ 2014.
JHH, John Hunter Hospital; SD, standard deviation.

Our assessment of the use of kidneys after excision of larger cancers for transplantation is relevant given the development of effective treatments for smaller kidney cancers that enable remnant kidney conservation. We have found no significant differences in the outcome measures for the 2 Groups including mortality, transplant failure, and AEs. Our study also contains the first comprehensive comparative report of the AEs from RKT; this knowledge is important in providing evidence for informed consent for the procedure. The AE rate for RKT was significantly higher than that for standard LD transplantation; the major contributors were higher rates of urinary leak; urinary tract infection; and transfusion without return to the operating room. These AEs may be expected as the excision of the mass requires transection of calyces and vasculature in the kidney. However, there was no significant change in recipient survival for the RKT Group compared with the recipient survival of other transplant types (Table 9 and Figure 4). Interestingly, there was no evidence of a difference in the AE rates between the smaller and larger mass Groups. While the evidence supported equality of AE rates between these 2 Groups, the point estimates for the smaller Group were much higher than the larger mass Group which may relate to practical experience. The donor derived cancer recurrence in one recipient may be attributed to the virulence of the donor cancer (RCC Fuhrman 4) not the cancer size (30 mm); the grade of a cancer, however, cannot be discerned from frozen section used in the operating room. Although this result is comparable with other reported series,[11,12] donor cancer transmission is a risk for all types of kidney transplantation.[18] Finally, the mortality risk for the larger mass Group was not significantly increased. Overall, these results suggest that RKT using kidneys with larger resected cancers can be done safely, but we suggest a larger study size is required to definitively answer the question. It is also important to note that the nephrectomy done for renal cancer had a discard rate of about 12% (3/26) (Table 2): this possibility should form part of the consent process.

A fundamental question addressed in this study is whether a prospective recipient on maintenance dialysis is better off waiting on the transplant list or having an RKT. We believe that this question goes to the heart of the matter: should the transplant clinician offer RKT to a dialysis patient on the list or advise waiting for an offer of a transplant kidney knowing that the offer may not occur? We answered this question by

TABLE 5.

AEs in restored kidney transplant recipients in relation to the size of the donor renal mass

Group	1	2	3	4
Cancer size	**≤30 mm**	**>30 but ≤50 mm**	**≤50 mm**	**Control**
Number of recipients	11	12	23	22
Age at transplant	66 ± 5	65 ± 3	66 ± 4	65 ± 4
Maximum pathology diameter[a]	27 ± 6.4	45 ± 6.4	36 ± 12.9	N/R
Average length of stay	17	14	15	13
Hospital days in first 30 days	19	17	18	16
eGFR at 3 mo	46 ± 15	49 ± 11	48 ± 14	44 ± 21
Delayed graft function[b]	1	1	2	3
Transfusion + no return to OR	6	5	11	2
Postoperative haemorrhage + transfusion +return to OR	2	1	3	2
Return to operating room	5[c]	4[d]	9	2[e]
Urinary leak	8	7	15	1
Urinary tract infection	7	6	13	5
Donor cancer transmission	1	0	1	0
Total AEs	30	24	54	15

All transplants were done at John Hunter Hospital between 2008 and 2015.
Group 1: RKT recipients where the masses in the donor kidneys were ≤30 mm.
Group2: RKT recipients where the masses in the donor kidneys were >30 mm but ≤50 mm.
Group 3: Group 1 plus Group 2—the Study Group.
Group 4: Control—22 consecutive live donor recipients transplanted with nonrestored kidneys in study period 2008–2015.
[a]Maximum diameter of the renal cancer at pathology ± SD.
[b]Required postoperative dialysis at least once.
[c]Percutaneous stent removal; evacuation of post biopsy hematoma and later insertion of stent and drain; laparotomy for small bowel obstruction and obstructed hernia repair; percutaneous nephrostomy then transplant pyeloneoureterostomy for extensive ureteric stricture; evacuation of transplant hematoma.
[d]Stent insertion; percutaneous drainage of a urinoma; laparoscopic internal drainage of lymphocele; evacuation of post biopsy hematoma; drainage of wound infection; and closure of urinary fistula.
[e]Transplant nephrectomy; repair of perforation of small bowel from a stitch.
AE, adverse event; OR, odds ratio; RKT, restored kidney transplantation; SD, standard deviation.

TABLE 6.

Comparison of AEs from restored kidney transplantation and standard live donor transplantation

		A	B	*P*	Bayes Factors		Uniform prior		
		Restored transplant[a]; cancer ≤50 mm; n = 23	**LD transplants[b]; n = 22**	**Fisher exact test**	B_{01}	B_{10}	**Difference[c] 95% CI**	**Probability A – B > 0**	**Probability A – B < 0.1**
Delayed graft function	Yes	2	3	0.665	3.85	0.26	–0.05	0.303	0.654
	No	21	19				–0.25-0.15		
Transfusion without	Yes	11	2	0.007	0.05	19.48	0.35	0.998	0.021
Return to OR	No	12	20				0.11-0.57		
Postop hemorrhage	Yes	3	2	1	4	0.25	0.04	0.658	0.667
Plus transfusion	No	20	20				–0.17-0.23		
Return to operating room	Yes	9	2	0.035	0.22	4.46	0.27	0.988	0.067
	No	14	20				0.04-0.50		
Urinary leak	Yes	15	1	<0.001	<0.001	5006.58	0.56	1	0
	No	8	21				0.33-0.75		
Urinary tract infection	Yes	13	5	0.033	0.21	4.74	0.31	0.99	0.054
	No	10	17				0.05-0.55		
Donor cancer transmission	Yes	1	0	1	5.88	0.17	0.04	0.74	0.825
	No	22	22				–0.09-0.18		

[a]Restored kidney transplants done at JHH between 2008 and 2015.
[b]Nonrestored live donor transplants done at JHH between 2008 and 2015.
[c]Difference: Rate A – Rate B. A negative result favors RKT as having fewer AEs whereas a positive result favors Live Donor (LD) as having fewer adverse events. There is reasonably strong evidence that LD has fewer adverse events as given by the Bayes factor B_{10} being >3.2.
AE, adverse event; CI, confidence interval; JHH, John Hunter Hospital; OR, odds ratio; RKT, restored kidney transplantation.

comparing outcomes of RKT with the outcomes of Australian controls from the ANZDATA Registry who were otherwise eligible for RKT. To increase statistical power, we combined the data from the series from two Hospitals in Australia. Our Cox regression model treated transplant status (waiting on the transplant list) as a time-varying covariate and therefore the group of patients transplanted while on the waiting list contributed their pretransplant time to the control Group, their post RKT time to the test Group (RKT), and their posttransplant time to other Control groups (deceased, live related, live unrelated control groups) (Figure 2). In essence, counting time from the moment of transplant neglects immortal time bias

TABLE 7.

Comparison of AEs from restored kidney transplantation with mass >30 to ≤50 mm vs mass ≤30 mm

		A	B	*P* Value	Bayes Factors		Uniform prior		
		Restored transplant; cancer >30 to ≤50 mm; n = 12	Restored transplant; cancer ≤30 mm; n = 11	Fisher exact test	B_{01}	B_{10}	Difference[a] 95% CI	Probability A – B > 0	Probability A – B < 0.1
Delayed graft function	Yes	1	1	1	3.33	0.3	–0.01	0.466	0.57
	No	11	10				–0.29-0.25		
Transfusion/no return to OR	Yes	5	6	0.684	1.75	0.57	–0.11	0.273	0.342
	No	7	5				–0.47-0.22		
Postop hemorrhage/ transfusion/ no return to OR	Yes	1	2	0.59	2.44	0.41	–0.09	0.272	0.461
	No	11	9				–0.38, 0.18		
Return to OR	Yes	4	5	0.68	1.82	0.55	–0.11	0.28	0.362
	No	8	6				–0.45-0.23		
Urinary leak	Yes	7	8	0.67	1.72	0.58	–0.12	0.238	0.343
	No	5	3				–0.45-0.21		
Urinary tract infection	Yes	6	7	0.68	1.72	0.58	–0.12	0.263	0.334
	No	6	4				–0.47-0.23		
Donor cancer transmission	Yes	0	1	0.478	3.13	0.32	–0.08	0.216	0.538
	No	12	10				–0.33-0.13		

[a]Difference: Rate A – Rate B. A negative result favors the RKT originally with the larger mass having fewer AEs whereas a positive result favors the RKT originally with the smaller mass having fewer AEs. There is reasonably strong evidence that the 2 treatments are not different as given by the Bayes factors $B_{01} > 3.2$.
AE, adverse event; CI, confidence interval; OR, odds ratio; RKT, restored kidney transplantation.

TABLE 8.

Summary of outcomes for recipients of kidneys after excision of cancers ≤30 mm or >30 mm but ≤50 mm in diameter

Group	1	2	3
Outcome	Cancer ≤30 mm	Cancer >30 mm but ≤50 mm	Control
Number of recipients	11	12	22
Number of AEs	30	24	15
Donor cancer transmission	1	0	0
Mortality	2	1	2
Transplant failure	3	1	2
Mean GFR at 3/12	46 ± 15	49 ± 11	44 ± 21
Average length of stay	17 ± 11	14 ± 5	13 ± 6

All transplants were done at John Hunter Hospital between 2008 and 2015.
Group 1: RKT recipients where the cancers in the donor kidneys were ≤30 mm.
Group 2: RKT recipients where the cancers in the donor kidneys were >30 mm but ≤50 mm.
Group 3: Control—22 consecutive live donor recipients transplanted with nonrestored kidneys in study period 2008–2015.
No significance difference between Group 1 and Group 2 in any outcome including AEs ($P = 0.58$) and average length of stay ($P = 0.45$).
AE, adverse event; RKT, restored kidney transplantation.

TABLE 9.

Relative risks of mortality and transplant failure for restored kidney transplant recipients compared with those remaining on the waiting list for transplantation

		JHH					PAH					JHH plus PAH				
Outcome	Model	n	HR[a] or sHR[a]	LCL	UCL	*P*	n	HR[a] or sHR[a]	LCL	UCL	*P*	n	HR[a] or sHR[a]	LCL	UCL	*P*
Mortality risk[b]	Continue on transplant waiting list	2050	1.00	0.21	2.04	0.460	2050	1.00	0.32	1.65	0.449	2050	1.00	0.36	1.37	0.299
	Restored kidney transplant	23	0.65				25	0.73				48	0.7			
Mortality risk[c]	Restored kidney transplant	23	1.00				25	1.00				48	1.00			
	Dialysis (no transplant)	722	2.77	0.88	8.75	0.082	722	2.93	1.26	6.81	0.012	722	2.86	1.43	5.72	0.003
	Living donor	142	0.86	0.25	2.95	0.807	142	0.91	0.35	2.34	0.838	142	0.89	0.39	2.02	0.779
	Deceased donor	1186	1.12	0.36	3.53	0.846	1186	1.18	0.52	2.71	0.688	1186	1.16	0.59	2.3	0.664
Transplant failure risk[d]	Restored kidney transplant	23	1.00				25	1.00				48	1.00			
	Living donor	142	0.35	0.09	1.31	0.119	142	0.30	0.10	0.89	0.030	142	0.33	0.12	0.86	0.023
	Deceased donor	1186	0.45	0.14	1.43	0.175	1186	0.40	0.17	0.90	0.028	1186	0.42	0.21	0.83	0.013

[a]Hazard ratios (HR) and sub-hazard ratios (sHR) are adjusted for time on waiting list, age at entry, number of comorbidities, gender, location, and socioeconomic status.
[b]Hazard ratios are used to estimate the mortality risk for restored kidney transplant recipients compared with those continuing on the transplant waiting list who may or may not have received a transplant.
[c]Hazard ratios are used to estimate the mortality risk for those who remained on dialysis or received a live donor or deceased donor transplant while continuing on the transplant waiting list compared with restored kidney transplant recipients.
[d]Sub-hazard ratios are used to estimate the risk of transplant failure among those transplanted while continuing on the transplant list.
JHH, John Hunter Hospital; PAH, Princess Alexandra Hospital.

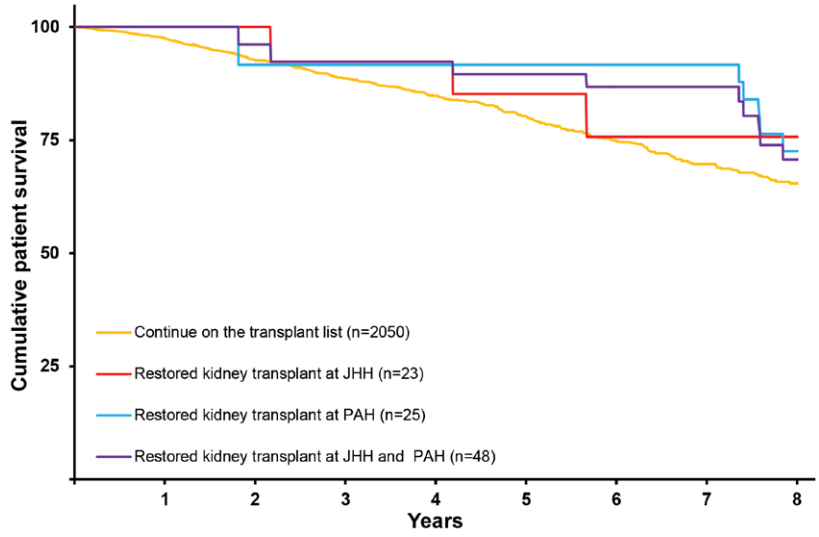

FIGURE 3. The survival of restored kidney transplant recipients compared with the survival of patients continuing on the waiting list who may or may not receive a transplant. It shows a possible survival advantage for restored kidney transplant recipients but this is not significant because of small numbers. JHH, John Hunter Hospital; PAH, Princess Alexandra Hospital.

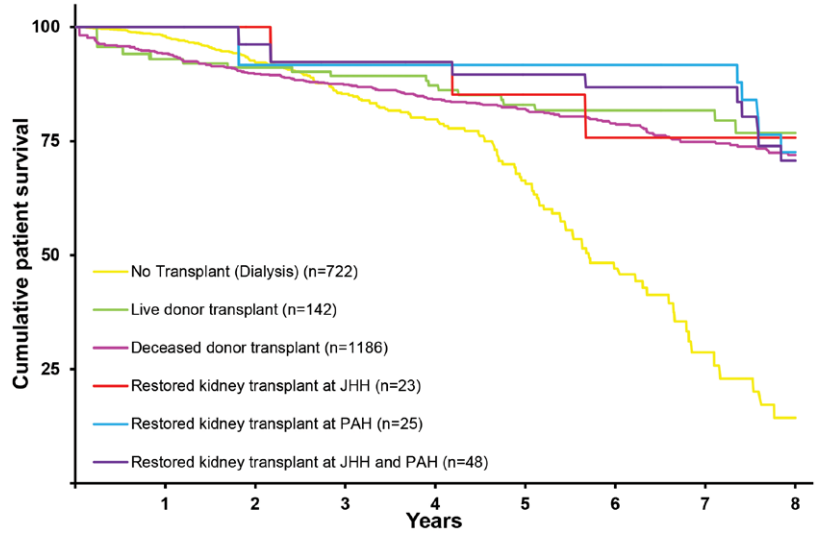

FIGURE 4. The survival of restored kidney transplant recipients compared with the survival of controls for no transplant (dialysis), deceased donor transplants, and LDTs. The survival of restored kidney transplant recipients is comparable with survival of recipients of deceased donor and LDTs. There is, however, an increased mortality risk for patients remaining on dialysis compared with recipients of restored kidney transplants for the Group of combined JHH and PAH and the PAH Group but not the JHH Group. JHH, John Hunter Hospital; LDT, live donor transplant; PAH, Princess Alexandra Hospital.

because patients must have survived long enough to receive a transplant. We argue that including this factor may improve the accuracy of estimating the relative survival of RKT recipients compared with those on the waiting list on dialysis as previously reported.[11,12] Our finding of a 30% survival advantage for RKT over patients waiting on dialysis suggests that a patient over 60 on the transplant list may have a lower mortality risk using RKT than continuing to wait on the list for another type of kidney transplant. Our results also show that a patient who waits on dialysis without ever receiving a transplant is significantly worse off compared with RKT. Given this survival advantage over dialysis, a recipient of RKT allows another prospective recipient on the list to use the kidney that would have otherwise been allocated to the RKT recipient. Effectively RKT increases kidney supply for transplantation.

These results provide strong arguments for RKT, but due to the small size of the RKT Group, we treat these results with caution and recommend larger studies. Nevertheless, our study using a combined Group of RKT recipients from 2 centers is the largest reported series. Furthermore, recipient survival of the RKT Group was not significantly different from recipient survivals for control deceased donor and control LDTs. It is also possible to extend the use of RKT to include deceased donor kidneys with renal cancers that meet accepted inclusion criteria.[12] The use of the surgical techniques for RKT could also be used for auto renal transplantation thus conserving the normal remnant nephron mass.[19,20] Both restored kidneys and extended criteria donor kidneys may be considered to be suboptimal but their relative efficacy requires another adequately powered study.

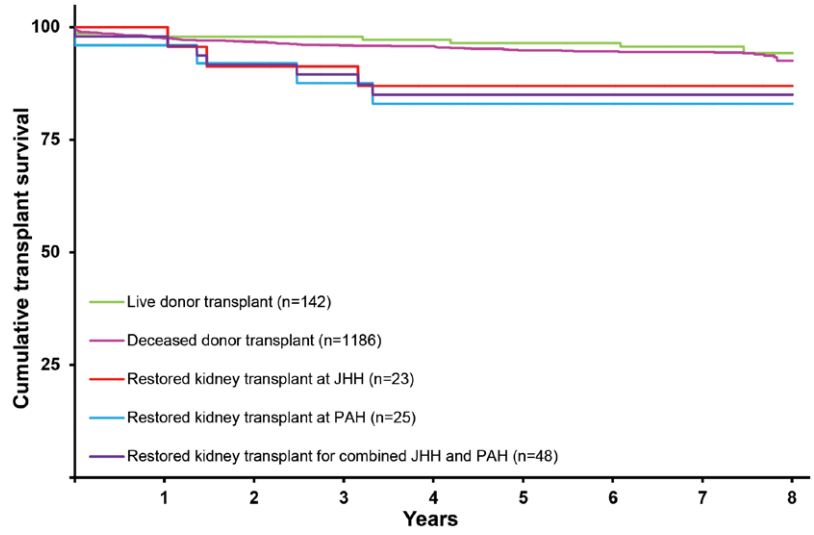

FIGURE 5. Survival of restored kidney transplants compared with survival of transplants done for patients while on the National Organ Matching Service. The latter group consists of patients who received deceased donor or live donor transplants while waiting on dialysis. The risks of transplant failure for the RKT Group compared with the control live donor and control deceased donor Groups are significantly increased for the Group of combined JHH and PAH, the PAH Group, but not the JHH Group. JHH, John Hunter Hospital; PAH, Princess Alexandra Hospital; RKT, restored kidney transplantation.

We found, however, that transplant survival for RKT was lower than control deceased donor and control LDT survivals. By contrast, one study reported similar restored kidney transplant and live unrelated transplant survivals[12] and another reported similar deceased donor transplant survival.[11] The significance of our findings are unclear but we suggest these possibilities: other studies did not treat transplant status as a time varying co variate; the survival of the controls for period 2008–2015 were better than they were for the period 2000–2007; and the nephron mass (and therefore transplant survival) of the restored kidney is reduced by excising the cancer.

Our study shows that kidneys with larger resected cancers (>30 mm but ≤ 50 mm) can be safely transplanted rendering effective results. It contains the first report of the comparative AEPs for RKT. It addresses a basic question about RKT: namely, should a patient on the transplant list be advised to accept an RKT or wait on the list where there is a chance of never receiving a transplant. It indicates that a survival advantage probably occurs but more studies are needed. Our study has other strengths: the power and generalizability gained from using national database comparisons for recipient and transplant survivals; the rigorous analysis used to avoid immortal time bias thereby improving the measurement of the survival conferred by RKT. The limitation, however, is the small size of the Group formed from 2 series of RKT and the risk of residual confounding. However, we believe that these outcomes confirm that restored kidneys can increase kidney supply for transplantation and are sufficient to encourage further clinical trials in this field.

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