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Living related donor nephrectomy in transfusion refusing donors

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Summary

Many transplant programs are averse to evaluate potential kidney donors with preferences against accepting human blood products. We examined the donor and graft outcomes between our transfusion-consenting (TC) and transfusion-refusing (TR) live kidney donors to determine whether a functional or survival disadvantage resulted from the disallowance of blood product transfusion during live donor (LD) nephrectomy. From July, 1999 to August, 2005, 82 live donor nephrectomies were performed, eight of who were TR donors (10%). Blood conservation techniques were utilized in TR donors. Demographics, surgical and functional outcomes, admission and discharge hematocrit, and creatinine were compared between TC and TR donors. No donor mortalities occurred. Two TC donors received blood transfusions (2.7%), and each study group experienced a single, <1-year graft loss. Intra-operative blood losses were significantly less in TR donors (298 ± 412 vs. 121 ± 91 ml, $P < 0.03$). No differences were noted between donor demographics, intra-operative events, and graft and patient survival. Successful donor nephrectomy from TR patients has the potential to expand the kidney allograft pool to include the TR donor population. Precautionary blood conservation methods allow the informed and consenting TR individual to donate a kidney with acceptable risk and without compromise to donor or graft outcomes.

Introduction

Kidneys procured from live donors (LD) have become an increasing source of renal allografts for transplantation. This increase in live donation is partially attributable to improved donor outcomes due to less invasive surgical approaches such as laparoscopic nephrectomy or open mini-laparotomy incision nephrectomy. Despite the improved techniques, complications remain which may require blood or blood product transfusion. Personal or religious preferences prevent some potential donors from accepting human blood products, and many transplant programs are averse to accepting these transfusion ineligible patients for kidney donation. We modified our peri-operative approach to these patients to include them as living kidney donors. To determine whether a functional or survival disadvantage resulted from the disallowance of blood product transfusion during LD nephrectomy, we examined the peri-operative management and compared donor and graft outcomes between our transfusion-consenting (TC) and transfusion-refusing (TR) live kidney donors.

Materials and methods

From July, 1999 to August, 2005, approximately 450 patients were screened as potential candidates for LD nephrectomy. LD nephrectomies were performed in 82 (18%) of accepted candidates using both laparoscopic and open approaches. Noncompleted work-ups were mostly because of medical and/or psych-social evaluation failures, although ABO blood group incompatibility and medical insurance noncoverage were also contributory. Records document 2 TR potential donors who did not undergo surgery for these reasons. No potential donors were otherwise refused surgery based on blood transfusion preferences. The TR study group consisted of eight of these donors (10%) who refused consent for blood transfusion (six were Jehovah's Witnesses (JW) and two cited personal beliefs regarding blood borne infections). All donors obtained cardiopulmonary clearance prior to undergoing surgery. The majority of donors were evaluated with helical CT angiography with 3D reconstructions to determine kidney volumes and vascular anatomy. These parameters were used to select which kidney to procure.

In addition to our standard screen and work-up for live kidney donors, TR donors met preoperatively with a representative from our Transfusion-Free Surgery Program to discuss options for transfusion. Each donor was required to demonstrate a full understanding of the potential complications of refusing blood or blood product transfusion during surgery.

Peri-operative management of TR donors included preoperative blood augmentation, intraoperative cell scavenging techniques, acute normovolemic hemodilution (ANH) [1], hand-assisted laparoscopy, and postoperative blood conservation (e.g. avoidance of protocol blood tests, minimization of blood draw volumes) [2].

Demographics between donor study groups were compared. Donor hospital records were examined prospectively to obtain data for donor operating room time (ORT), estimated blood loss (EBL), intra-operative urine output (UO), warm ischemia time (WIT), length of hospitalization (LOH), donor complications, donor preoperative serum creatinine, donor and recipient discharge creatinine, as well as allograft (recipient) follow-up creatinine. Procured allografts having renal arteries with multiple origins from the aorta or having renal veins with multiple tributaries to the inferior vena cava were categorized as aberrant vascular anatomy. Renal arteries bifurcating early or renal veins displaying multiple tributaries draining into a single renal vein were considered normal variants. LOS spanned from the time of admission to the time of discharge from the hospital. WIT is defined as the time from renal artery clamping to cold perfusion in the backtable. Delayed graft function is determined by the need for dialysis within the first postoperative week due to poor allograft function. Graft loss is defined as the loss of function requiring a return to dialysis and/or removal of the allograft. The prevalence of hypertension and/or diabetes (HTN/DM) as the primary cause of renal disease in the recipient was examined as a potential risk factor for postoperative complications. All donor and recipient procedures were done in tandem, and thus incurred a uniform cold ischemia time, which was not analyzed further.

Laparoscopic techniques used for nephrectomy included both standard and hand-assisted methods; the open technique utilized an anterior, retroperitoneal approach through a 'mini-laparotomy' incision. A summary of our protocol is described [3]. Musculoskeletal complications were defined as either self-limited arthralgias or myalgias that were not incision related. Incisional cellulitis or infections comprised the majority of wound complications.

Immunosuppression used for recipients consisted of a steroid induction (Solumedrol 500–1000 mg i.v.) with an anti-interleukin-2 receptor antibody or thymoglobulin induction. Subsequent administration of a calcineurin inhibitor, mycophenolate mofetil, and a steroid taper were used as maintenance therapy.

Operative management

Donors underwent a bowel prep on the evening prior to surgery. Heparin 5000 units s.c. and i.v. furosemide and mannitol are admininistered preoperatively. The donor is placed in the lateral decubitus position. For left nephrectomy, a 10/12-mm and a 5-mm trocar are used as working ports, with a 10–12 mm trocar for use as the camera port. Trocar sites for right nephrectomy mirror those for left nephrectomy with an additional 5-mm sub-xiphoid trocar used to retract the liver.

After pneumoperitoneum (10–13 mmHg) is achieved, a harmonic scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) or using cautery is used for dissection. The abdominal incision made is midline or pfannenstiel for the left nephrectomy, and midline or right lower quadrant for the right. The ureter is divided, as are the hilar vessels, with a vascular stapler (Ethicon Endo-Surgery, Inc.). The allograft is then extracted out of the abdomen. The kidney is taken to the backtable and perfused with and stored in a 4 °C U. Wisconsin (Viaspan; Dupont, DE, USA) or HTK (Custodiol; Odyssey, NJ, USA) solution.

Similarly, the abdominal incision for hand assisted laparoscopic donor nephrectomy (the length approximates the operating surgeon's glove size) is midline/peri-umbilical for a left nephrectomy, and midline or

transverse right lower quadrant for a right nephrectomy. An intra-abdominal access device is positioned through the abdominal incision, and the abdomen is insufflated to a pressure of 10–13 mmHg.

The method used for the anterior, retroperitoneal ('mini-incision') procedure is modified from the technique described by Jones *et al.* [4]. All dissection is performed using electrocautery. A 7–9 cm lateral, subcostal incision is made and with placement based on the preoperative CT scan. The hilum is dissected to identify, ligate, and divide the adrenal vein branch(es), the gonadal vein, and any lumber branches from the renal vein. The renal vein is divided using a vascular staple, and the renal artery is clipped and oversewn. Upon completion of the nephrectomy, the dissection bed and stapled or clipped vascular closures are re-examined for hemostasis. Wounds are infiltrated with 0.25% bupivacaine and closed using a 1-0 absorbable monofilament for the fascial layer, and staples or a 4-0 absorbable subcuticular suture to approximate the skin. NSAIDS were avoided and i.v. and p.o. narcotics were used for postoperative analgesia in TR donors.

Modifications for TR donors begin peri-operatively. TR donors with a hematocrit of <35% were administered erythropoietin (40 000 units SQ q week) with oral iron supplementation at least 2 weeks prior to the scheduled operative date until a 35% hematocrit (40% for patients over 50 years old) was achieved [5]. Additionally, consumption of aspirin products was discontinued 1 week prior to nephrectomy. Intraoperative ANH is performed when needed, and involves the preoperative removal and temporary storage of 10–20% of the patient's blood, which is then augmented with a colloid solution and reinfused during indications for transfusion or upon completion of the procedure. This procedure is performed under scrutiny to ensure continuity between the collected blood and the donor, in accordance with religious practice if the donor is a JW patient [6]. Hand assistance was utilized during laparoscopic nephrectomy, and potentially difficult or higher risk donors required the availability of red blood cell scavenging in the OR. Collected RBC's are washed and filtered prior to re-infusion back to the donor.

Data from both groups were analyzed by utilizing Fisher's-exact test (two-sided) for categorical variables and a Mann–Whitney rank-sum test for means.

Results

Table 1 summarizes donor demographics in each group. No donors were declined solely on the basis of refusal to consent for blood product transfusion. In the TR group, peri-operative erythropoietin was administered to one donor, while ANH was utilized in two other donors. No TC donor required either of these interventions. Hand-assisted laparoscopic nephrectomy was performed on three TR donors and on 15 TC donors. The use of cell scavenging techniques was not required for either group. Postoperative blood conservation practices were done for all TR donors. Two TC donors (2.7%) received blood transfusions intra-operatively (EBL 2100 and 2500 ml, both cases secondary to vascular complications), while no TR donors needed any blood product. Blood losses were significantly less in TR donors (298 ± 412 vs. 121 ± 91 ml, $P < 0.03$). No statistical difference was noted between study groups with respect to incidence of vascular abnormalities in the allograft (22% vs. 12%, $P = 1.00$), ORT (273 ± 68 vs. 259 ± 73 min, $P = 0.938$), WIT (198 ± 85 vs. 160 ± 77 s, $P = 0.411$), intraoperative UO per body weight (3.3 ± 2.5 vs. 3.0 ± 1.6 ml/kg, $P = 0.919$), change from preoperative to discharge creatinine (0.32 ± 0.20 vs. 0.35 ± 0.19, $P = 0.622$), difference between pre- and postoperative hematocrit (-4.46 ± 4.05 vs. -5.44 ± 2.40, $P = 0.517$), LOH (101 ± 33 vs.

Table 1. Donor demographics.

Parameter	Subgroup	Transfusion consenting ($N = 74$)	Transfusion refusing ($N = 8$)	*P*-value
Demographics, % (*n*)				
Gender	Male	47 (35)	50 (4)	1.000
	Female	53 (39)	50 (4)	
Anatomical abnormalities	Yes	22 (16)	12 (1)	1.000
	No	78 (58)	88 (7)	
Side of kidney used	Left	73 (54)	88 (7)	0.673
	Right	27 (20)	12 (1)	
HTN/DM in recipient	Yes	39 (29)	38 (3)	1.000
	No	61 (45)	62 (5)	
Age (years), Mean ± SD		37 ± 12	43 ± 14	0.339
Body mass index, Mean ± SD		27.3 ± 3.9	27.0 ± 2.6	0.926
Pre-op creatinine (mg/dl), Mean ± SD		0.85 ± 0.24	0.81 ± 0.17	0.887

Fisher's-exact test (two-sided) for categorical variables; Mann–Whitney rank-sum test for means.

Table 2. Analysis of Peri-operative variables between transfusion consenting and transfusion refusing groups.

Parameter	Subgroup	Transfusion consenting ($N = 74$)	Transfusion refusing ($N = 8$)	*P*-value
Procedure, % (*n*)	Lap	62 (46)	62 (5)	1.000
	Open	38 (28)	38 (3)	
Conversion to standard procedure, % (*n*)	Yes	7 (5)	12 (1)	0.471
	No	93 (69)	88 (7)	
Warm ischemia time (sec), Mean ± SD		198 ± 85 ($n = 61$)	160 ± 77 ($n = 5$)	0.411
Operative time (min), Mean ± SD		273 ± 68	259 ± 73	0.938
Estimated blood loss (ml), Mean ± SD		298 ± 412	121 ± 91	0.024
Urine output (ml), Mean ± SD		1119 ± 761	931 ± 638	0.508
Urine output per body weight (ml/kg), Mean ± SD		3.3 ± 2.5	3.0 ± 1.6	0.919
Pre-op hematocrit (%), Mean ± SD		39.76 ± 5.10 ($n = 73$)	42.66 ± 3.05	0.075
Post-op hematocrit (following A.M.), Mean ± SD		35.45 ± 4.76 ($n = 69$)	37.23 ± 2.04	0.172
Change in hematocrit, Mean ± SD		−4.46 ± 4.05 ($n = 69$)	−5.44 ± 2.40	0.517

Fisher's-exact test (two-sided) for categorical variables; Mann–Whitney rank-sum test for means.

Table 3. Analysis of postnephrectomy variables between transfusion consenting and transfusion refusing groups.

Parameter	Subgroup	Transfusion consenting ($N = 74$)	Transfusion refusing ($N = 8$)	*P*-value
Complications, % (*n*)	Wound	8% (6)	12% (1)	0.527
	Musculoskeletal	14% (10)	0% (0)	0.587
	Other	4% (3)	12% (1)	0.342
Creatinine at discharge (mg/dl), Mean ± SD		1.16 ± 0.24	1.16 ± 0.30	0.919
Change in creatinine, Mean ± SD		0.32 ± 0.20	0.35 ± 0.19	0.622
Hospital stay (hours), Mean ± SD		101 ± 33	104 ± 23	0.539
Recipient creatinine (mg/dl), Mean ± SD	Pre-op	8.62 ± 3.85 ($n = 73$)	7.34 ± 2.63 ($n = 8$)	0.365
	At 7 days	1.42 ± 1.14 ($n = 72$)	1.85 ± 2.03 ($n = 8$)	0.798
	At 1 month	1.14 ± 0.46 ($n = 72$)	1.21 ± 0.32 ($n = 7$)	0.413
	At 3 months	1.15 ± 0.35 ($n = 69$)	1.39 ± 0.47 ($n = 7$)	0.213
	At 6 months	1.21 ± 0.34 ($n = 65$)	1.44 ± 0.29 ($n = 7$)	0.070
	At 1 year	1.21 ± 0.38 ($n = 50$)	1.50 ± 0.32 ($n = 6$)	0.072
Change of recipient creatinine from Pre-op, Mean ± SD	At 7 days	−7.14 ± 3.95 ($n = 72$)	−5.49 ± 1.61 ($n = 8$)	0.268
	At 1 month	−7.42 ± 3.81 ($n = 72$)	−5.37 ± 1.73 ($n = 7$)	0.111
	At 3 months	−7.48 ± 3.83 ($n = 69$)	−5.20 ± 1.67 ($n = 7$)	0.076
	At 6 months	−7.26 ± 3.85 ($n = 65$)	−5.14 ± 1.76 ($n = 7$)	0.115
	HematocritAt 1 year	−7.30 ± 3.95 ($n = 50$)	−4.82 ± 1.77 ($n = 6$)	0.091

Fisher's-exact test (two-sided) for categorical variables; Mann–Whitney rank-sum test for means.

104 ± 23 h, $P = 0.539$), nor interval allograft creatinine up to 1 year post-transplant (Tables 2 and 3; distribution of hypertension and/or diabetes as the primary diagnosis was proportional between both study groups, $P = 1.00$). The rate of operative conversion to a standard, open nephrectomy was not significantly different between groups (7% vs. 12%, $P = 0.471$); conversion was uniformly performed to control bleeding. Donor creatinine and hematocrit levels at 1 week follow-up were not significantly different from post-op values (data not shown), and none required clinical intervention. Donor survival was 100% in both groups. Delayed graft function was observed in two (2.7%) TC donors and was not observed in any of the TR donors. Each group experienced a single, <1-year graft loss, neither of which were related to the donor procedure.

Complications occurred in 3/8 TR donors (one conversion, one wound cellulitis, and one narcotic related respiratory depression), while complications occurred in 24/74 TC donors (10 complaints of musculoskeletal pain, six minor wound problems, five conversions, one temporary shortness of breath, one urinary retention, and one pancreatitis) (P = NS). Neither donor group incurred incisional hernias or complications requiring re-operation or re-admission. Mean follow-up time was 1188 ± 551 days and 1206 ± 384 days in TC and TR donors, respectively.

Discussion

Laparoscopic and open approach LD nephrectomies each report transfusion requirements in 0–10% and 0–5% of

patients respectively, with transfusions most frequently occurring early in the operative experience of reporting groups [7,8]. Transfusion rates for postoperative bleeding are similar [9]. Intraoperative blood transfusions have been required during challenging cases or after complications arising from vascular mishaps or unexpected equipment failure e.g. stapler misfires [10]. To protect against these potential complications, blood-sparing techniques already established in practice within our Transfusion-Free Surgery Program during liver transplantation have been similarly applied to our TR donor population for LD kidneys. Preoperative work-up and intervention in these patients increase the physiological margin of safety based on expected cardiovascular tolerance to blood loss, acute intravascular fluid shift, and risk factors for a prolonged operative time. The work-up also facilitates an informed surgical approach based on anatomy and clinical history with a predetermined situational or quantitative threshold (based on physiological tolerance) to open conversion.

Preoperative consultation with a liaison from the Transfusion-Free Surgery Program is mandatory to establish medico-legal allowances in the context of personal beliefs, religion, and available modalities for blood conservation. In addition to designating a power of attorney, the consult obtains consent for permissible blood products (e.g. albumin, cryoprecipitate) and contingency plans. These agreements are subsequently conveyed to the surgeon and anesthesiologist.

Although the majority of our kidney donors were performed with one attending staff member, two senior surgeons were present during the nephrectomy for TR donors [11]. Safety over cosmesis is emphasized; all kidney extraction incisions during laparoscopic approaches were vertical, midline peri-umbilical or epigastric (versus a suprapubic or lateral incision) due to its proximity to the renal hilum and ease for a rapid celiotomy exposure. A lower tolerance for blood loss favors the use of a hand assisted over a standard laparoscopic approach, as it affords the capability for manual pressure during hemostasis. With limited time available to control potentially lethal hemorrhage, our conservative EBL during open conversion cases reflects a policy towards minimizing unnecessary blood loss. Although the collective difference in EBL between study groups appears clinically modest ($\sim$170 ml), the blood sparing techniques are intended to provide a safety net during unexpected and significant blood loss. The techniques offer alternative red blood cell mass augmentation methods in lieu of a traditional (and unacceptable) allotransfusion, as complications requiring transfusion in TC donors can similarly occur in TR donors.

The procurement would be aborted in the event of uncontrolled bleeding, and an understanding must be established that the graft may need to be forfeited to preserve the donor's life. The exposure would be converted to the standard open incision (or extended during laparoscopic cases), while albumin and crystalloids are used as volume expanders with salvaged blood re-infused and clotting factors supplemented. Postoperative erythropoietin would be administered. Despite successful resuscitation, however, the potential remains for cardiac and neurologic sequelae from prolonged hemodynamic instability [12].

Other practices are implemented to reduce the potential for further blood loss. Systemic anticoagulation prior to hilar cross-clamping has not been proven beneficial [13,14], and is avoided. ANH and epidural anesthesia may have similar anti-thrombotic effects [15,16]. As critical hemorrhage occurs most frequently during the renal artery and vein dissection, hilar vessels are transfixed for vascular control [12]. A 'sentinel' drain may be placed within the dissection bed; the drain is usually removed within 48 h. Additional methods to minimize blood loss in the setting of coagulopathy include supplementation with co-factors (factor VIIA or cryoprecipitate), pro-coagulants (aprotinin), or platelet-enhancing agents (desmopressin). These agents do not breach religious allowances on blood products among JW donors, in contrast to fresh-frozen plasma and platelets. Furthermore, pediatric sized blood tubes are used to circumvent the limitations on blood draws. It is critical to avoid hematopoietic insults, such as those caused by severe hypophosphatemia leading to hemolysis or those caused by administration of medications leading to bone marrow suppression.

Many of a hospital's pre-existing resources can be channeled, under collective supervision, to minimize additional capital expenditures to implement a service to support TR donors. Disposables for the cell salvage unit and synthetic coagulation factors (if needed) and calcium–phosphate–dextrose bags for ANH are material costs incurred intra-operatively.

Consideration of a TR LD appears more acceptable during liver transplantation, where its utility occurs in a situation with limited options [17]. Although alternate renal replacement therapies are available in ESRD, renal transplantation is acutely life saving in the setting of significant intolerance to dialysis or rapidly progressive loss of hemodialysis access. The majority of candidates infrequently encounter these difficulties; however, which possibly undermines the role of a TR live kidney donor.

The program liaison assists in addressing not only the question of whether transfusion-free nephrectomy can be done, but also whether it should be done. The former inquiry is relatively straightforward, and includes a discussion on complications and mortality and transfusion rates, although data on mortalities as a result of

nontransfusion are unavailable. Alternative therapies and nonsurgical options are explained. The process is reviewed and the methods and techniques used are described, with the understanding that while these measures do not necessarily prevent a bleeding event, their purpose and utilization are to decrease the likelihood of a serious complication or mortality resulting from the event.

The relationship between a matched pair is explored to complement the intentions of the donor with the wishes of the recipient, and to rule out coercion, conflict of interests, or direct monetary involvement. For JW patients, the tenets of the faith with regard to organ donation and blood transfusion are reviewed, and shared 'medico-religious' responsibilities between donor and recipient, in the event of a need for rescue transfusion, are identified and outlined [18].

Upon validation of a sincere and altruistic intention, the central issue shifts from acknowledging potential death from the act of donation, to acceptance of a preventable death secondary to operative blood loss. The argument for avoiding the latter situation by readily performing a transfusion can be applied similarly to the donation process itself, with avoidance of preventable death by simply not performing the nephrectomy altogether. Whether personal or programmatic, however, such a policy would be risk-averse at best and religious bigotry at its worst. Thus, assuming sufficient intellect, judgment, and cognitive competence, comprehension (after 'full disclosure') and acceptance (after adequate time allowed for reflection and discussion) of the medical, legal, religious, and personal ramifications of their actions should not discriminate TR donors and candidates from participating in live organ donation, especially in the setting of a survival benefit demonstrated for transplantation over chronic dialysis [19,20], and where an emotional attachment between parties has been clearly established. Accurate information on probabilities and outcomes need to be conveyed, but qualifying or delimiting a donor's altruistic intent appears inappropriate and outside the realm of the surgeon's or transplant committee's counsel.

From a surgical perspective, once the donation process is agreed upon, peri-operative scenarios (and thus, the critical questions faced) can be arranged as a 2×2 table:

	Donor lives	Donor dies
Transfused	A	B
Not transfused	C	D

Situation B is presumed to be not possible if the rescue transfusion is performed to avoid a mortality, (assuming other complications, e.g. fatal blood transfusion reaction, do not occur) and situation C is the usual and intended outcome in the majority of cases. If prior instructions prohibiting blood transfusion were accepted from a donor, then allowing situation A to occur without subsequent approval from that (conscious, competent, and communicating) donor would constitute a violation of the patient's right to bodily self-determination and informed consent. Conversely, a donor's decision to refuse transfusion under any circumstance may result in situation D. Independent of the action taken and/or the resultant outcome, the key objectives are to maintain and uphold the decisions made on a patient's right to personal privacy and self-determination by completely and explicitly documenting the wishes of the donor regarding rescue transfusion, and to follow through on his/her directives [21].

Conclusion

Successful donation from transfusion ineligible patients demonstrates the applicability of transfusion sparing surgical techniques to the TR live kidney donor population, thus expanding the pool of potential kidney donors. Programs and surgeons have the process and techniques available to perform LD kidney transplant for TR participants, and a transfusion free awareness and practice has applicability and advantages in all fields of surgery [2]. Precautionary blood conservation methods allow the TR individual to donate a kidney without compromise to donor or graft outcomes, and if informed candidates and their intended donors are willing, able, and ready, transfusion-free donor nephrectomy and renal transplantation can be proffered under acceptable risk.

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