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Personal Viewpoint

The Use of Kidneys with Small Renal Tumors for Transplantation: Who Is Taking the Risk?

S. M. Flechner* and S. C. Campbell

The Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH
**Corresponding author: Stuart M. Flechner, flechns@ccf.org*

The ever-increasing disparity between the number of organs available for transplant and the need for organs drives further exploration into the use of compromised or marginal donors. There is now an emerging advocacy for the use of kidneys with existing tumors, which may be rendered tumor free after surgical excision and reconstruction. This practice is based on reliable data that renal cancers <3 cm in diameter behave with minimal malignant potential and likelihood of transmission to the immunosuppressed recipient. However, in the case of live donors this creates a potential ethical conflict between those treating patients with renal masses and those with an interest in renal donation. The best available treatment for patients with a small renal tumor is a form of nephron-sparing tumor excision or ablation, as this approach provides for the maximum amount of residual kidney function and enhances survival. Thus, patients newly diagnosed with small renal tumors should be referred to centers with expertise in nephron sparing techniques, not transplant centers. In the case of an individual undergoing a live donor evaluation in which a small renal tumor is detected, a careful analysis of risk and benefit for the potential donor and the recipient is indicated.

Key words: Deceased donor, kidney cancer, living kidney donor, renal mass

Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; GFR, glomerular filtration rate; RCC, renal cell carcinoma.

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The Problem

The excellent survival rates enjoyed by recipients of renal transplants today have created a demand for both deceased donor and live donor organs well past the available supply. There have been a steadily increasing number of patients waiting for a transplant each year, now rising to over 90 000 in the United States. This has been coupled with a flat total number of kidney transplants performed each of the last five years, at about 16 500–17 000 (1). The progressive imbalance in these numbers has intensified efforts to find more kidneys to transplant, which usually results in finding ways to utilize organs considered marginal. Examples include kidneys from donors at age extremes, those anatomically, physiologically or metabolically damaged, or those with some potentially transmissible infection. More recently, we have seen advocacy for using kidneys with small renal cancers, in which the malignancy is excised, the kidney reconstructed *ex vivo* and subsequently transplanted. Two transplant centers have reported organized programs to identify such patients, and specifically refer them to transplant centers for subsequent renal donation (2,3). A recent abstract has proffered that there are as many as 3000 kidneys with tumors going "untransplanted" in the United States each year. In essence, suggesting there is a new pool of donors from which to find kidneys for transplant (4). The purpose of this report is to review the current knowledge regarding renal cancer, the possibility of using such organs, what has been learned about this practice, and the ethical implications for both the recipient and the donor.

Epidemiology of Kidney Cancer and Likelihood of Metastases

Renal cell carcinoma (RCC) currently accounts for about 52 000 new cancer diagnoses and 13 000 cancer-related deaths each year in the United States, representing about 2–3% of all malignant diseases in adults. RCC is a male-predominant (2:1 ratio) disease with a typical presentation in the sixth and seventh decades of life (median age about 60 years). Known risk factors for RCC include cigarette smoking, obesity, hypertension, end-stage renal disease, acquired renal cystic disease and tuberous sclerosis, and 2–3% are familial (5). However, there is great variance in biological aggressiveness, and most small, solid, contrast-enhancing renal tumors (<3.0 cm) are manifestly on the less hostile end of the spectrum. Overall, 20% of small renal tumors are benign, 60% are relatively indolent RCC and only about 20% are RCC with potentially aggressive features such as high tumor grade or locally invasive phenotype (6,7). Smaller tumors, such as those <2.0 cm, are a notable extreme (8). In many series approximately 30–40% of such tumors are benign (oncocytoma, fat-poor

angiomyolipoma) and benign histology is also particularly common in young (<45 years old) women with small renal tumors (9). Studies of active surveillance also support reduced biological aggressiveness for most small renal tumors. This literature now includes over 15 studies of select patients with small, solid, homogeneous appearing renal tumors managed expectantly, mostly in the elderly or infirm. In these series the average growth rate is only about 0.31 cm per year, and the incidence of metastatic progression within 2–3 years remains relatively low, approximately 1–2% (10,11). Ideally, percutaneous renal mass biopsy would define histology and tumor aggressiveness, but difficulty differentiating oncocytoma from eosinophilic variants of RCC remains an ongoing challenge (12). In the future molecular profiling will be required to resolve this dilemma allowing more intelligent counseling and management.

Nephron-Sparing Surgery

Given our understanding of the limited aggressiveness of most small renal masses and the current limitations of renal mass biopsy, it is clear that there is great potential for overtreatment of this patient population, particularly because radical nephrectomy (removing the entire kidney) has traditionally be considered the standard of care for the management of localized RCC. However, over the past 2 decades partial nephrectomy, so-called nephron-sparing surgery, has been shown to provide equivalent oncologic outcomes when compared to radical nephrectomy in removing the pathological stage pT1 renal cancers (13,14). More importantly partial nephrectomy provides for optimal preservation of renal function after definitive cancer treatment. In a landmark study of 662 patients, the incidence of stage 3 (GFR 30–59 cc/min/1.73 m2) or higher chronic kidney disease (CKD) after radical nephrectomy in patients with an apparently normal contralateral kidney was 65% compared to 20% after partial nephrectomy, confirming a distinct functional advantage to the nephron sparing approach (15).

The surgical management of kidney cancer has also undergone a transition in the United States during the past 10–15 years. Whereas 10-years ago virtually all patients with small renal cancers undergoing partial nephrectomy were treated with an open transabdominal or flank surgical incision, today the trend is for small <3 cm peripheral tumors to be removed via minimally invasive laparoscopic techniques. In large comparative trials the oncologic outcomes for small tumors treated by laparoscopic partial nephrectomy are reported to be similar to open surgery with less immediate surgical morbidity (16). In addition, the utilization of minimally invasive robotic techniques has recently increased substantially for these cases (17). Lastly, in patients with other medical co-morbidities, the treatment of small renal tumors with nonsurgical approaches such as radiofrequency ablation and cryotherapy is under intense investigation as an alternate nephron-sparing approach (18,19). Therefore, the data are compelling that patients with small renal tumors should not be treated by total removal of the kidney (Figure 1). However, it is just these kidneys with small peripherally located tumors that are being advocated as a new source of organs for transplant.

Chronic Kidney Disease After Nephrectomy for Renal Tumors

The level of renal function has been well established as an independent risk factor for both cardiovascular and noncardiovascular mortality and subsequent hospitalization (20–22). Therefore, maximizing renal function in kidney tumor patients is clearly advantageous. In reality, the "normal" contralateral kidney in kidney tumor patients is often compromised – this patient population is distinctly different when compared to potential renal donors who are carefully prescreened for good health and other favorable cardiovascular characteristics. Renal tumor patients tend to be older, typically have multiple co-morbidities such as hypertension, diabetes and dyslipidemia, and the incidence of CKD prior to intervention is approximately 20–30% (15). In the elderly with localized renal tumors the stakes are even higher, as the incidence of stage three or higher CKD prior to intervention is 45%, and increases to 86% if the patients are managed with radical nephrectomy. Several studies have demonstrated that the excess loss of renal function after total versus partial nephrectomy exceeds 25%, and appears to be associated with increased cardiovascular specific mortality (23–25). Based on these data, the American Urologic Association Guidelines panel has come out strongly in favor of nephron sparing approaches for the management of small renal tumors, with partial nephrectomy now classified as the reference standard in this field (26). For these reasons there has been a paradigm shift in the management of SRM in the United States, and over the past 15 years the annual rate of partial nephrectomy and ablative therapy has risen fourfold. By 2007 the majority of renal masses <3 cm in the United States are managed without total nephrectomy; and 75% of the smallest lesions were treated by other than total nephrectomy (27).

Results of Transplanting Kidneys with Small Renal Tumors

Using donors with existing or past cancers for transplant has generally been considered a contraindication due to the chance that cancer cells will be transferred with the allograft, and the host who is immunosuppressed will be susceptible to tumor implantation and metastases. However, the risk for these events has been stratified by the source, stage and grade of the cancer. Localized and excised squamous cell skin cancer, superficial bladder tumors and low-grade CNS tumors (WHO grade I or II)

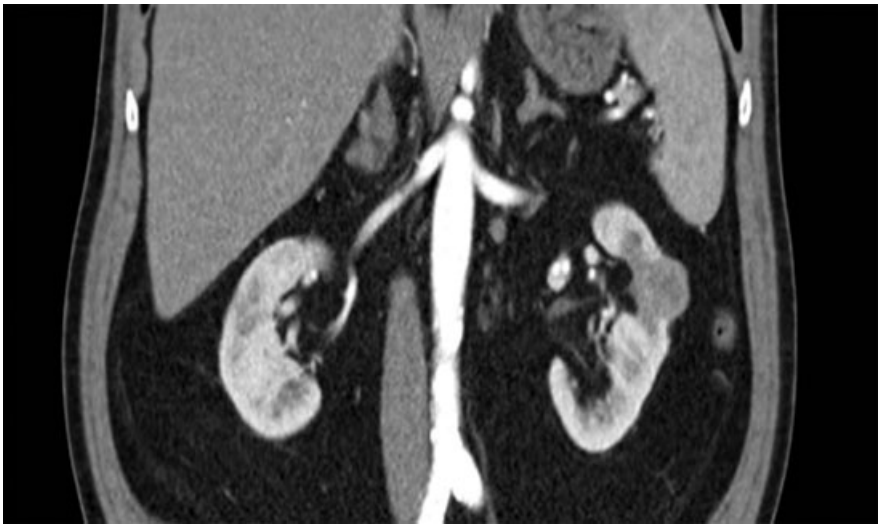

Figure 1: CT scan of kidneys with i.v. contrast demonstrating an enhancing (solid) 2.8 cm mass in the mid to upper third of the left kidney. The tumor was treated by partial nephrectomy with preservation of 90% of renal function. The final pathology was a fat-poor angiomyolipoma (benign).

do not result in a significant risk of tumor transference; whereas melanoma or metastatic lung cancer are a prohibitive risk (28,29). As described, small volume low-stage renal cancers (pT1a) have a favorable natural history, and if completely excised from a kidney would be expected to have a low risk of recurrence or progression in the recipient. In reports to the Penn Tumor Registry in 2005, Buell et al. reported that of 14 known cases of intentional transplant of kidneys with excised tumors (mean diameter 2.0 cm) there were no cancers detected in the recipients at a mean of 69 (14–200) months (30). These included 11 from live donors and three from deceased donors, thus supporting the presumed favorable biology of these cancers in the transplant setting (Table 1). However, these cases were voluntarily reported, and may under-represent the actual numbers of index cases and subsequent instances of tumor transmission. Using kidneys with an SRM for subsequent transplant also creates logistical problem that include the need for rapid histological preparation and interpretation (invasiveness and Fuhrman grade) by a skilled pathologist; best judgment regarding completeness of resection and anatomic suitability for transplant; and further discussions of risk and benefit with the potential recipient.

Ethical Considerations Are Based on Circumstances of Tumor Detection

The presentation of an individual as a potential kidney donor is altogether different from that of a patient undergoing evaluation of a solid renal mass who is seeking the best advice for the diagnosis and treatment of that lesion. The thought process that goes into the decision to donate a kidney is complex and unique, and requires specialists from several disciplines to evaluate and inform the potential donor of their current medical status, the implications of donation on their future health, their psychosocial circumstances and their right to proceed or decline the donor surgery absent coercion. In fact, since 2007 the Centers for Medicare and Medicaid Services (CMS) rules and regulations for transplant programs, final rule has mandated an independent donor advocate to assure proper donor evaluation and consent (31). Each transplant center must identify a unique donor advocate charged with being the independent caregiver responsible for educating and seeing the individual through the donation process. It would be awkward if the donor advocate were also required to become a go-between for decision-making regarding the best treatment of a kidney cancer.

Patients with Small Renal Masses Present in Three Different Clinical Scenarios

Patients who have a symptomatic or an asymptomatic SRM detected during radiologic imaging of their kidneys

Patients with SRM should not be counseled to have their kidney removed for the purpose of transplantation to another individual. It is not reasonable for a treating urologist to have any other motivation or concern when caring for a patient with a renal mass, other than providing the best therapy to cure that patient of the potential renal cancer. It is troubling to consider that screening for kidney donors could be a new avocation of treating urologists, oncologists or radiologists when evaluating renal masses. The evidence-based data are compelling that such patients with small renal masses should be treated with a partial nephrectomy, ruling out donation. While it may be true that some patients with a small solid renal mass still undergo a total nephrectomy in the United States, those in the Transplant Community should not enter this debate. Patients with small renal masses should be referred to centers with the necessary expertise to perform nephron sparing surgery, not to transplant centers. For example,

Table 1: Cases of small renal tumors excised from kidneys subsequently transplanted

Study	Year	No. cases	Donor source	Tumor size (cm), mean range	Tumor histology	Donor age (years), mean range	Recipient age (years), mean range	FU (months), mean range	Development of RCC in the recipient
Buell et al. (29)	2005	14	LD 11 DD 3	2.0 0.5–4.0	RCC all Fuhrman I = 6 II = 8	NA	40.8	69 14–200	0/14
Nichol et al. (2)	2008	43	LD 38 DD 3	< 3.0	KC 31 ONC 4 AML 3 CC 3	NA	> 60 years in 93%	32	1/43
Mannami et al. (3)	2008	8	LD 8	2.4 1.2–3.5	RCC all Fuhrman I = 4 II = 4	61.1 49–75	50.8 28–69	52.3 12–135	0/8
Sener et al. (31)	2009	5	LD 5	1.6 1.0–2.3	RCC 3 I = 1 II = 1 III = 1 AML 2	NA	54.4 47–61	15 1–41	0/3

CC = complex cysts; KC = kidney cancer; ONC = oncocytoma; RCC = renal cell carcinoma; LD = live donor; DD = deceased donor; AML = angiomyolipoma.

most disturbing is the report by Nichol et al. (2) in which 38 patients with small renal masses were sent for transplant; 10/38 = 26% had their kidneys removed with benign lesions. Such intervention by members of the Transplant Community could unintentionally create ill will and negatively impact on well-established living donor protocols. In addition, such practices could create incentives for commercial transplantation in vulnerable populations around the world. There is a bright line between who is an altruistic kidney donor and who is a patient with a renal mass, and this should not be blurred (Figure 2). However, we do acknowledge in the most rare of circumstances a patient may harbor emotional and personal reasons for wanting a cancer bearing organ removed, even if amenable to local resection. In such rare circumstances, nephrectomy and subsequent transplant could be entertained.

Patients who have a new SRM detected during living kidney donor evaluation

The issue of proper informed consent is also complicated, and raises ethical concerns regarding what is in the renal donor/tumor patient's best interest. Such conflict arises in the more complex scenario of renal tumor detection during the standard imaging performed for the kidney donor evaluation. In these situations the initial intent of the individual was to donate a kidney, and they had no prior knowledge they were harboring a renal tumor. Sener et al. (32) reported five such cases in which the donor underwent total nephrectomy, and in 2/5 (40%) of cases the tumor was a benign angiomyolipoma (AML). While this was favorable for the two recipients that received kidneys with benign disease, and absolved the two donors of future concern of renal cancer; it points out the imprecision of radiographic diagnosis alone, and the over treatment that would result from pushing patients with small renal tumors to donate their kidney. Cohen et al. (33) described two potential donors that had an SRM detected on imaging studies during their kidney donor evaluation. In these cases the corresponding recipients elected not to receive the tumor bearing kidney, and the potential donors underwent a curative partial nephrectomy. This was ultimately the best treatment for the potential donors, now becoming patients with an SRM.

The decision to continue with renal donation in these circumstances is complex, and involves consideration of donor demographics, total renal function, co-morbidities, psychosocial concerns, and the relationship to the recipient. Some individuals may be strongly motivated to donate, and ask the question what is the chance of developing another kidney cancer in my remaining kidney? In a recent report of 28 556 Scandinavian patients with first RCC the 20-year cumulative incidence of metachronous (contralateral) RCC was 0.8% (34). Using the US SEER database the incidence of metachronous RCC among 43 483 patients with a first RCC was 0.4% up to 10 years (35). These rates may be higher in certain familial cancers or papillary

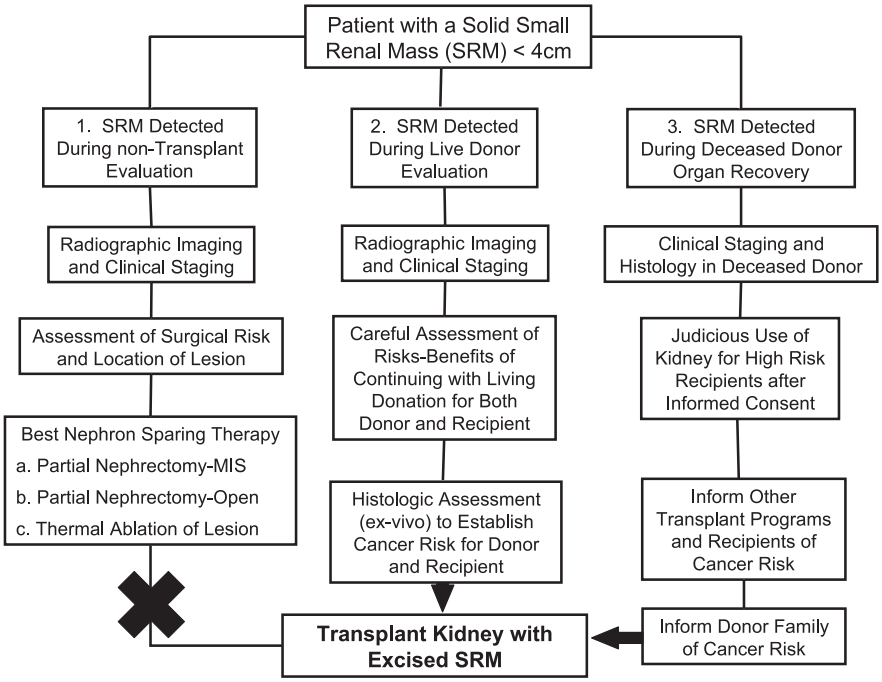

Figure 2: Algorithm for considering the use of a kidney with a small renal tumor for transplant. Patients present in one of three different clinical scenarios. The non-transplant donor with a small renal mass; a living donor who has a small renal mass detected during the living donor evaluation; and a deceased donor in which a small renal mass is detected during organ recovery.

or chromophobe RCC, but SRM with favorable histology would be expected to be less aggressive.

Deceased donors with SRM detected during organ recovery

During organ recovery a small renal tumor may be detected as the kidneys are inspected, or when the surrounding Gerota's fascia is removed. When considering the use of kidneys with small renal tumors (pT1a) from a deceased donor, there is no conflict with the donor since the decision to donate has been made and proper consent for organ recovery has been obtained from the next of kin. There would be an obligation to inform the next of kin of the findings, to establish the possibility of familial cancer risk. One would also expect that during organ recovery an effort to rule out abdominal masses, lymphadenopathy, and inspection of the likely landing sites of kidney cancer in the abdomen, liver and lungs have been screened as well. The risk for local or distant disease by transplanting such an organ lies fully with the recipient, and would require specific informed consent. It would also be important that the organ procurement organization transmit the findings to other potential organ or tissue recipients, which could impact the decision to use the other organs. Although the reported risk of tumor transfer to the recipient is low during the first 5 years (Table 1), there is limited information about this subject, and the practice should be undertaken with caution. It is possible that cases of subsequent tumor recurrence have gone unreported. Some have advocated reserving such organs for higher risk recipients with shorter life expectancies and/or those doing poorly on maintenance dialysis. The use of such organs would require more intense radiographic imaging of the transplanted kidney and the recipient to screen for tumor recurrence post transplant. There have been several reports of local excision of a *de novo* renal cancer in a transplanted kidney with maintenance of allograft function (36,37).

Conclusions

The continued problem of insufficient supply to meet the demand for kidneys for transplant has resulted in an advocacy for using kidneys with small renal tumors. The current evidence is that small renal cell carcinomas, usually <3 cm, have low malignant potential. These tumors, especially if peripherally located in the kidney could be excised, the kidney reconstructed, and then transplanted into a waiting recipient with ESRD (Figure 2). However, there are distinct differences between patients with renal tumors and altruistic renal donors, which should be decoupled. (1) A patient with a small renal tumor (pT1a) is best treated with a nephron sparing partial nephrectomy and should not be considered a renal donor. They are most often >age 60, and have an established survival advantage by maximizing their residual renal function. (2) A potential living donor may have a renal tumor newly detected during their donor evaluation. The risks and benefits of proceeding with total nephrectomy require careful counseling of both the potential donor and the recipient. Alternative living donors are the best solution, but there may be instances where such an individual strongly desires to pursue kidney donation. (3) A small renal tumor may be detected during deceased donor organ recovery. The current evidence is that such tumors can be locally excised and recurrence is uncommon in the transplant recipient. This practice requires increased

efforts for proper tumor staging in the deceased donor, and careful recipient selection and informed consent.

Currently, it would appear that the overall number of kidneys transplanted after excision of small renal tumors in the United States is small. However, if the number increases, it would be important to establish a registry with established criteria for tumor staging and grading. Such a registry should encompass both live donor and deceased donor cases, and be publically and rapidly available to the transplant community. In the future this issue may be further refined by the use of renal biopsy and molecular profiling of SRMs that may more reliably establish the malignant potential of renal tumors.

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