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Renal cell carcinoma suspected at time of organ donation 2008-2016: A report of the OPTN ad hoc Disease Transmission Advisory Committee Registry

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Abstract

All 179 reports to the OPTN of potential renal cell carcinoma (RCC) transmission from 1/1/2008 through 12/31/2016 were reviewed. Cases were divided into those with donor tumor known or suspected at time of transplant (N = 147 donors), and those in which tumor was initially found after transplant (N = 32). We sought to understand the risk of transplanting either the affected kidney, the contralateral kidney or non-renal organs from donors with a suspected/confirmed unilateral RCC. In the case of RCC found prior to transplant, transplantation of 21 kidneys following excision of tumor, 47 contralateral kidneys and 198 non-renal organs was performed. No cases of RCC transmission were documented in this population. An additional six cases of live donor kidney transplantation involving resection of RCC were reported, also without transmission. Six of 9 other recipients in whom the diagnosis of RCC became available after implantation underwent allograft nephrectomy and 3 received tumor resection. No recurrent RCC was documented. Given the low rate of transmission and available treatment options, consideration should be given to judicious use of organs from donors with small solitary RCC.

KEYWORDS
cancer, complication:malignant, donors and donation, incidence, malignancy, neoplasia:registry

1 | INTRODUCTION

Donor-derived malignancy transmission is a source of morbidity and mortality among transplant recipients. OPTN Policies 15.4 and 15.5 mandate reporting of all suspected donor-derived transmission events to the OPTN.[1] These submitted reports are reviewed by the Ad Hoc Disease Transmission Advisory Committee (DTAC) in a blinded and deidentified manner, to determine the likelihood of donor derivation.

Kidney transplant recipients in the United States have been shown to have a 15-fold increased risk for RCC in the first 3 years after transplantation when compared with the general US population and an increased risk for RCC in comparison with transplant candidates on the waiting list.[2,3] The incidence of donor-transmitted RCC is unknown. It is unclear under what circumstances donors with RCC may safely donate the contralateral kidney, organs other than the kidney, or even the affected kidney after tumor resection. We sought to answer 2 main questions: 1. What is the risk of transplanting either

the affected kidney following tumor resection or the contralateral kidney from donors with a suspected/confirmed unliteral RCC. 2. What is the risk of transplanting non-renal organs from a deceased donor with a suspected/confirmed RCC. Our hypothesis was that organs with resected small solitary RCC at the time of procurement can be safely used. Descriptive statistics are reported. Histology, tumor size and Fuhrman grade are described where available.[4]

2 | METHODS

All suspected RCC cases reported to DTAC during the period of Jan 1, 2008, through Dec 31, 2016, were reviewed in a blinded and deidentified manner to determine the likelihood of donor derivation and to evaluate the organ and recipient outcomes. OPTN Post-Transplant Malignancy forms were collected to identify any additional recipient malignancies. Events were classified by the authors as to whether or not malignancy was confirmed in the donor and the recipient(s) using standard DTAC criteria.[5] This report represents a summary of our assessment of the circumstances and outcomes of the cases reported to DTAC. Cases were divided into donors with tumor suspected at the time of transplant and donors in whom tumor was not suspected but RCC was subsequently identified in at least one recipient after transplantation. Based on the estimated growth rate for RCC,[6,7] tumors that developed two or more years after transplantation were classified as donor tissue derived but not donor transmitted, as we determined that the tumor would not have been identifiable in the organ at the time of procurement and transplantation.

TABLE 1 Cases of RCC suspected at time of procurement or transplant in deceased donors (N = 141)

Management of affected kidney	Size (if noted)	Histology as reported	Furhman grade
Excised pre-transplant	0.4 cm	Clear cell	1
Excised pre-transplant	0.1 cm	Papillary final path adenoma	N/A adenoma
Excised pre-transplant	0.3 cm	Not further specified	2
Excised pre-transplant	0.7 cm	Clear cell	2
Excised pre-transplant	1.2 cm	Clear cell	1
Excised pre-transplant	1.2 cm	Papillary	1
Excised pre-transplant	1.5 cm	Papillary	1-2
Excised pre-transplant	1.7 cm	Cyst with clear cell	Not reported
Excised pre-transplant	1 cm	Clear cell renal ca	2
Excised pre-transplant	2.1 cm	Clear cell	3
Excised pre-transplant	0.2 cm	Clear cell	1
Excised pre-transplant	0.6 cm	Clear cell	Not reported
Excised pre-transplant	Not specified	Tubulo-papillary microadenoma RCC	Not reported
Excised pre-transplant	Not specified	Papillary renal cell carcinoma	Not reported
Excised pre-transplant	Not specified	clear cell	1
Excised pre-transplant	Not specified	Clear cell	Not reported
Excised pre-transplant	Not specified	Not specified	Not reported
Excised pre-transplant	Not specified	Clear cell	1
Excised pre-transplant	Small cyst	Papillary	Not reported
Excised pre-transplant	Specified only as <2 cm	Papillary	2
Excised pre transplant and then explanted	Not specified	Clear cell	1
Explanted post-transplant	0.6 cm	Papillary	1
Explanted post-transplant	0.8 cm	Clear cell RCC vs papillary type	Not reported
Explanted post-transplant	0.4 cm	Clear cell renal ca	2
Explanted post-transplant	Not specified	Not further specified	Not reported
Explanted post-transplant	Not specified	Renal clear cell adenocarcinoma	2
Explanted post-transplant	Not specified	Renal cell CA	2
Resection post-transplant	0.8 cm	Type I papillary RCC	1
Resection post-transplant	1 cm	Multilocular cystic rcc	N/A determined not to be RCC
Resection post-transplant	not specified	Clear cell	2

Of the 179 donors from whom reports were submitted to the DTAC, 169 were deceased donors (DD) and 10 were live donors (LD). From the 169 DD, 321 kidneys were recovered, and of those, 160 were transplanted into 154 different recipients. One hundred and sixty-one kidneys were recovered and then discarded. From the 10 live donors, all kidneys were transplanted. After review of final pathology data and consideration by the committee, cases were categorized by whether or not an RCC was present in the donor and by whether or not a transmission of RCC had likely occurred.

In some cases, Organ Procurement Organizations (OPOs) were queried for additional information. UNOS requires reporting of possible transmission events and a 45-day post-report update. All data obtained from these queries was reviewed. Data from UNOS malignancy reporting forms were reviewed to see if any of the recipients involved in these DTAC reports were later reported as having RCC.

This study used data from the Organ Procurement and Transplantation Network (OPTN). The OPTN data system includes data on all donors from which at least one organ was used, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the OPTN, and has been described elsewhere.[8] The Health Resources and Services Administration (HRSA), US Department of Health and Human Services provides oversight to the activities of the OPTN contractor. IRB exemption for this project was obtained from HRSA.

3 | RESULTS

3.1 | RCC suspected at procurement/transplant

In 147 living or deceased donors, the transplant team knew of or suspected RCC at the time of organ procurement/transplantation. In 64 cases, both kidneys (total 128 kidneys) were discarded. In another 47 cases, organs other than the affected kidneys (47 contralateral kidneys,198 non-renal organs) were transplanted. In the remaining 36 cases, kidneys containing RCC were used for transplat from 30 deceased donors (Table 1) and 6 live donors (Table 2).

Use of deceased donor kidneys with RCC detected in the perioperative period occurred in two settings. In 21 of these cases, the tumors were excised prior to transplantation, and in 9 cases, the final diagnosis of tumor became available after the kidney had been implanted. Donor ages ranged from 25 to 71 years (median 51 years) with male: female of 2.75:1. Tumor sizes ranged from 0.1 to 2.1 cm (median 0.75 cm). Specific histology was available in 22 cases and included 14 clear cell RCC, 7 papillary and 1 combined clear cell/papillary tumor. Fuhrman nuclear grade was provided in 20 cases, including 10 Grade 1, 8 Grade 2, 1 Grade 1-2, and 1 Grade 3 lesions.

One of the 21 patients who received a kidney with pre-transplant tumor excision underwent elective explant. None of the remaining 20 patients has developed RCC during follow-up.

Six of the 9 patients in whom RCC was diagnosed post-implantation underwent allograft explant. The remaining three underwent partial resection and have not had evidence of tumor recurrence.

In six cases, RCC was recognized in living donors at the time of transplant. All 6 events were managed successfully by pre-operative or early post-operative resection, with no transmission or recurrence of disease.

Forty-seven contralateral kidneys were transplanted. One of these contralateral kidneys was subsequently explanted when the affected kidney pathology was confirmed as RCC. Explant pathology did not show RCC. None of the remaining recipients of contralateral kidneys developed RCC.

No recipient of non-renal organs is reported to have developed donor-derived RCC (N = 198 organs). In three these cases, the lesion was ultimately not proven to be an RCC but since the decision to use those organs was made in the setting of suspected RCC, we kept those few cases in the analysis.

3.2 | RCC not recognized at procurement/transplantation diagnosis made with recipient disease

Ten cases were identified after transplantation when tumor was not recognized in the donor and at least one recipient was subsequently diagnosed with RCC.

3.2.1 | Late donor tissue derived malignancies, not considered as transmissions

For the purpose of this report, late RCC from donor tissue is defined as a report of an RCC in the transplanted kidney greater than 2 years after the kidney transplant. These reports were not analyzed as transmissions, as we estimate that presumed donor malignancy

TABLE 2 Cases of RCC suspected at time of procurement or transplant in living donors (N = 6)

Management of affected kidney	Size (if noted)	Histology as reported	Furhman grade
Excised pre-transplant	0.6 cm	Papillary	1
Excised pre-transplant	0.7 cm	Clear cell	2
Excised pre-transplant	0.9 cm	Papillary	1
Excised pre-transplant	1 cm	Multilocular cystic	1
Excised pre-transplant	not specified	Clear cell	1
Resection post-transplant	0.5 cm	Clear cell	1

was likely not reasonably diagnosable at the time of procurement/transplant. There were 11 DD recipients and one LD recipient identified with late donor tissue derived RCC.

4 | DISCUSSION

Discovery of a potentially malignant renal tumor in an organ donor represents a complex risk/benefit assessment for both the transplant team and potential recipients. Rapid decisions must be made regarding use or discard of the kidney with the lesion, the contralateral kidney and non-renal organs from the deceased donor. In the live donor situation, lesions are usually detected prior to donation with subsequent donor exclusion, except for the few reported cases where a small RCC is known or suspected at the time of donation and the lesion is excised prior to implantation. However, this also raises ethical issues.[9]

The true frequency of RCC in deceased organ donors is unknown. Our data suggest a frequency of <0.2% of deceased donors during the time period we studied, (169 suspected RCC reports to DTAC/76 179 deceased donors recovered) but this could be higher as some kidneys might have been discarded for other reasons without detection of small lesions. For example, the Louisiana Organ Procurement Agency reviewed 558 consecutive donors and found 5 with RCC (frequency of 0.9%).[10]

Data concerning transmission frequency of RCC have also been problematic. In 1995, Penn reported on primary RCC in donor kidneys of 47 recipients collected by the Cincinnati Transplant Tumor Registry and some of these cases appeared to represent donor transmission.[11] Buell et al[12] reported on five cardiothoracic transplant recipients of organs from donors with a history of RCC and noted transmission in two cases in which vascular extension of tumor was present. However, these data derive from a voluntary registry in which the denominator is unknown.

In 2010, a review of SRTR data from over 40 000 primary renal transplant recipients with Medicare claims for RCC post-transplant revealed 368 patients (0.9%) who developed RCC within 3 years of transplantation.[13] While it was unclear how many of these cases might have been donor transmitted, donor age was a risk factor and did not interact with recipient age, suggesting that some of these post-transplant RCC cases could represent transmission.

Prior to the current report, the largest report of kidneys transplanted after excision of small RCC came from Brisbane, Australia. Nicol et al[14] reported on 43 kidney transplants used after excision of <3 cm tumors without transmission of RCC. Several case reports also exist of successful RCC excision prior to transplantation from both LD and DD.[15,16] Finally, a recent review of case reports, case series, and registry studies found RCC to be one of the most common types of cancers transmitted through transplantation (20 RCC transmitted out of 104 cases of donor-transmitted cancers) but with the best survival (over 70% recipients surviving at least 24 months) compared to other cancer types such as lung and melanoma.[17]

Our results are in line with recent studies[18,19] that have supported the feasibility of considering the use of organs from donors with small RCC resected prior to transplant. Yu et al[20] found no evidence of RCC recurrence in 97 cases with pre-transplant RCC resection. One example of recurrence occurred in 22 cases in which the contralateral kidney was used. Sundarajan et al[21] documented an improved quality of life in 20 kidney recipients who received organs following excision of small renal cancers with no evidence of transmission. An overview of the use of donors with small renal cancers is provided by Lugo-Baruqui et al.[22] Separate reports have documented good outcomes when using restored kidneys from individuals who have undergone nephrectomy for treatment of small RCC.[9,23,24]

As our study is an observational review of nationally required data, we have the unique perspective of being able to catalog the decisions made by US transplant teams regarding organs from donors with suspected or proven RCC in the United States between 2008 through 2016. The most common scenario reported to the DTAC was unilateral RCC in a deceased organ donor in which the affected kidney and the contralateral kidney were both discarded. In these cases, non-renal organs were used from these donors with no reported cases of RCC transmission to recipients to date. The next most common scenario was the finding of a unilateral RCC in a deceased organ donor in which the affected organ was discarded, and the unaffected kidney and non-renal organs were transplanted into recipients. In these cases, no RCC transmission was reported in recipients of the contralateral or non-renal grafts by review the Safety Portal of OPTN Post-Transplant Malignancy forms. Most of these recipients of contralateral (unaffected) kidneys have had a minimum of 3 years follow-up during which we would expect them to develop a radiographically visible (>2 cm) tumor if non-detected RCC was present at time of procurement/transplant. Although reporting post-transplant malignancy is mandatory, it is possible that some centers failed to do this which would be a limitation of the current study.

Given that some unaffected kidneys from donors with RCC can be safely used, can we anticipate characteristics that predict this safe use? When the unaffected kidney was used, the tumors were more likely to have a lower Fuhrman grade[1] and more likely to be papillary by histology. The sizes (when reported) were roughly similar between the two groups. We can only speculate as to whether these characteristics contributed to center decision to use or discard the unaffected kidney. Fuhrman grade and size were not reported in all confirmed RCC cases. Other factors such as donor age and gender were uniformly available but not helpful in predicting safe use of a contralateral kidney. It is unclear from this study what other data inform the decision to use versus discard a contralateral kidney, such as donor age, sex, the presence of non-malignant renal pathology findings or recipient factors. A transplant center might be more willing to "take a chance" on a kidney with findings suggestive of a longer expected survival in the recipient. Our findings suggest that there is a higher likelihood of using a kidney contralateral to one with RCC if the RCC pathology is papillary (versus clear) and the Fuhrman grade is low. This is actually counterintuitive since papillary tumors

include chromophilic tumors and are more likely to be multi-focal and bilateral compared to clear cell histology.

Importantly, another way that kidneys were safely used from donors with RCC was after lesion excision. Some cases were treated with successful cryoablation after living or deceased donation. Long-term post-cryoablation kidney function and other follow-up data were unavailable for these recipients.

When considering the specifics of donor malignancy transmission, DTAC came to realize that very small tumors in the transplanted kidney, detected many years post-transplant can be considered to arise from donor tissue. We acknowledge that a discrete time point to distinguish donor and recipient origin, or transmitted vs de novo RCC, does not exist. In 15 cases of suspected RCC in the transplanted kidney reported to DTAC as possible transmission events, the length of time between transplant and detection of tumor led us to exclude the event as a transmission. In several reports, the mean growth rate of RCC tumor diameter ranged from 0.4 cm/year to 1.6 cm/year.[6,25] Two of the 10 lesions reported by Siu et al did not grow at all. Fujimoto et al found tumor volume doubling time to be a mean of 468 days (range of 372-579 days).[26] From these data, we can assume that the average RCC might increase in diameter at a rate of about 0.6 cm/year, or a doubling time of 1-2 years. Based on these assumptions, an allograft RCC that is 1.8 cm or less by three years post-transplant could be expected to have been macroscopically invisible at time of transplant. The average growth rate estimated by Gofrit et al[7] exceeds and that of Chawla et al[6] fall below this estimate. Thus, it is possible that some examples of late-arising tumors actually represent donor transmission and were incorrectly classified in this retrospective analysis. But by definition, these would represent slow-growing tumors and this must be weighed against the alternative of continued dialysis as addressed by Sundararajan et al[21] in their quality of life survey administered to patients who received tumor-resected kidney transplants.

Although the majority of possible RCC cases reported to the DTAC during the time period were confirmed as malignant, a handful of tumors thought to be malignant on frozen section were eventually determined to be benign. Unfortunately, in this group, some kidneys were discarded or were explanted after transplantation. These cases highlight the importance of obtaining an accurate and final pathologic diagnosis prior to explanting organs and obtaining as accurate a diagnosis as possible prior to discarding organs.

When programs use a kidney from a donor with suspected or known RCC, the patient should understand the risks, as best as can be explained. There are fairly well validated renal cancer nomograms available that would be helpful in explaining risk to patients, such as https://www.mskcc.org/nomograms/renal/post_op. For example, an excised 1.5 cm papillary RCC would predict a 98% 5-year recurrence-free probability. For patients accepting what might be a small risk of incomplete tumor excision, planned follow-up and imaging for these recipients should be clearly outlined and communicated at the time of consent to surgery.

There are some important limitations to our observational retrospective study of registry data. There were missing data regarding tumor size, location in the kidney, and precise histology. Current OPTN policy does not require reporting groups to conduct any recommended evaluation. Appropriate specimens were not always available, further limiting testing that could be done to document transmission. Despite these limitations, the mandatory reporting structure for suspected disease transmissions gives this registry the benefit of being the most thorough available collection of the US experience of potential RCC transmissions during the time period studied.

There are two possible ways to interpret this retrospective data: 1) Transplant teams are too conservative and should use kidneys contralateral to an RCC, non-renal organs, and affected kidneys after RCC excision or 2) transplant teams are getting it exactly right, since no cases of tumor transmission have been reported from the donors in whom a confirmed RCC was found prior to transplant. Finding a small RCC as early as possible in the evaluation of a deceased donor allows more time for a reliable pathology reading and time to consider the risks versus benefits of using an unaffected contralateral kidney and using the affected kidney after RCC excision. However, the evidence to date suggests that excision of small well-differentiated renal cell carcinomas prior to transplant provides outcomes similar to those in patients who receive kidneys from donors without RCC. Use of contralateral kidneys and non-renal organs from these patients is not associated with an increased risk of RCC. The only adverse events were associated with transplantation of kidneys that contained RCC not detected at the time of transplant. Therefore, continued vigilance and close inspection of donor kidneys for suspicious lesions is recommended. Judicious use of non-renal organs, contralateral kidneys, and affected kidneys after tumor excision should be considered as safe ways to expand the donor pool.

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CONFLICT OF INTEREST

None.

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