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Cancer Diagnoses after Living Kidney Donation: Linking United States Registry Data and Administrative Claims

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Abstract

Background—Mortality records identify cancer as the leading cause of death among living kidney donors, but information on the burden of cancer outside of death records is limited in this population.

Methods—We examined a database wherein OPTN identifiers for 4,650 living kidney donors in 1987–2007 were linked to administrative data of a U.S. private health insurer (2000–2007 claims) to identify post-donation cancer diagnoses. Skin and non-skin cancer diagnoses were ascertained from ICD-9-CM codes on billing claims. Donors were also matched one-to-one with general insurance beneficiaries by sex and age when benefits began. Diagnosis rates within observation windows were compared as rate ratios.

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Results—The median time from donation to the end of plan insurance enrollment was 7.7 years, with a median observation period of 2.1 years. Skin cancer rates were similar among prior living donors in the observation period and non-donor controls (rate ratio 0.91, 95% CI 0.59–1.40). In contrast, the rate of total non-skin cancers was significantly less common among donors than controls (rate ratio 0.74, 95% CI 0.55–0.99), although reduced relative risk was limited to donors captured earlier in relation to donation. Several cases of cancer diagnosis (uterine, melanoma, other) were identified within the first year after donation. Prostate cancer was significantly more common among living donors compared with controls (rate ratio 3.80, 95% CI 1.42–10.2).

Conclusions—Continued study of cancer after kidney donation is warranted to ensure that evaluation, selection, and long-term follow-up support overall good health of the donor.

Keywords

Administrative claims; Cancer; Kidney transplantation; Living donors; Registries

INTRODUCTION

Living kidney donors help relieve the growing gap between the demand for and supply of kidney transplants, and offer their recipients the best opportunity for dialysis-free survival (1). In the United States (U.S.), the number of kidney transplants from living donors has risen over the past decade from fewer than 2,000 in 1988 to 6,276 in 2010, when living donors supplied 37% of renal allografts nationally. Clinical practice guidelines for the medical evaluation and care of the living donor were recently advanced through the Amsterdam Forum (3). These consensus-based guidelines include recommendations that “living kidney donors should be screened by standard medical guidelines to exclude malignancy,” and that a prior history of some malignancies should generally exclude live kidney donation, including melanoma, testicular cancer, renal cell carcinoma, choriocarcinoma, hematological malignancy, bronchial cancer, breast cancer and monoclonal gammopathy (3). However, the actual evaluation, acceptance and follow-up of the living donor is heterogeneous across transplant programs (4, 5).

Mortality data from the U.S. and other countries have identified cancer as the leading cause of death among prior kidney donors. For example, recent mortality records collected by the Organ Procurement and Transplantation Network (OPTN) found cancer to be the most common cause of death within seven years after kidney donation, accounting for 10.3% of deaths overall and 23.8% of deaths with a reported cause (6). Malignancy was the attributed cause of 43% deaths after kidney donation in a recent study of long-term outcomes at one transplant center in Japan that reported causes for all identified deaths (7). Cancer sub-types were not available in either report.

Currently, follow-up of the health of living donors in the U.S. by the OPTN is limited in scope and duration, as mandated reporting extends only to the second donation anniversary and is characterized by frequent missing data and “loss to follow-up” (8, 9). Aside from inclusion as a cause of death, cancers after living donation are not tracked by the OPTN survey and there is paucity of available information on cancer diagnoses in this population from other sources. We recently linked administrative data from a private insurance provider

to OPTN-supplied identifiers for prior living donors to enable assessment of longer-term post-donation medical outcomes independent of an individual's interaction with the transplant center (10). In the current study, we used these integrated data to examine cancer diagnoses among a large sample of prior living kidney donors in the U.S., including categories of skin, non-skin, and organ-based sub-types. We also sought to compare diagnosis patterns to non-donor controls in the same database.

RESULTS

Among 4,650 prior living kidney donors, 54.6% were women and 76.3% were white race (Table 1). The mean age at donation was 37 years. Eighty one percent of donors were biologically related to their recipient, 7.6% were spouses, and 11.2% were non-spousal unrelated donors. The linked donor sample was similar on the basis of race and sex to all living kidney donors registered in the OPTN in the same period (10). The median times from donation to the end of benefits under the study insurance provider was 7.7 years, with a median observation period of 2.1 years. The rate of total non-skin cancers among the living donor sample was 11.9 cases per 1000 person-years observed, and was significantly less common than among controls (rate ratio 0.74, 95% CI 0.55–0.99). The rate of skin cancers among the living donor sample was 6.1 cases per 1000 person-years observed. The total rate of skin cancers in the donors did not differ significantly from that of the non-donor controls (rate ratio 0.91, 95% CI 0.59–1.40).

Rates of organ-specific cancer diagnoses did not differ significantly in the living donor sample compared to controls, with one exception: prostate cancer was identified more commonly in the prior donors (rate ratio 3.80, 95% CI 1.42–10.2) (Table 2). To examine for direct evidence of *post-donation* screening or specialty healthcare utilization as an explanation for these findings, we compared the frequencies of serum prostate-specific antigen (PSA) testing and of encounters with urologist provider codes among the male donors versus the age-matched sample of non-donor men in the insurance plan. The rate of PSA-testing was 0.19 per year of enrollment among male donors and 0.27 per year of enrollment among the age-matched controls. Encounters with urologist provider codes occurred at 0.14 per year among the male donors versus 0.20 per year among the age-matched controls. PSA testing increased with age, to 0.27 and 0.41 per year among male donors and controls aged 51 to 60 years, respectively, and to 0.30 and 0.38 per year among male donors and controls aged >60 years, respectively. However, testing rates were consistently lower among donors compared with controls across age strata.

Among the other specific cancer types, most rate-ratio point estimates comparing donors to controls were <1.0, suggesting trends towards lower diagnosis frequency among prior donors. Point estimates for diagnosis rate ratios in living donors versus controls were >1.0 for melanoma, central nervous system cancer, and bone cancer, although the ratio estimates were not statistically significant (i.e, confidence intervals include 1.0). The median time from kidney donation to the captured non-skin cancer diagnoses was 9.2 years (range 0.6 to 19.2 years). Three cancer cases diagnosed within one year of kidney donation were classified as uterine, melanoma and "other".

The rate of non-skin cancers among the sub-sample of live donors who enrolled in the study insurance plan within 4.9 years of donation was 5.2 cases per 1000 person-years, compared with 19.4 cases per 1000 person-years among donors who enrolled after a longer duration post-nephrectomy (Table 4). A lower relative risk of non-skin cancers among prior living donors compared with controls was only found among the sub-sample with earlier enrollment in the study insurance plan in relation to donation. Specifically, the donor versus control rate ratio for non-skin cancers was 0.45 (95% CI 0.25–0.79) in those living donors who began benefits under the study plan within 4.9 years of donation. In contrast, the donor versus control rate ratio for non-skin cancers was 0.91 (95% CI 0.64–1.29) in those donors whose benefits began after a longer interval after donation. The rate of skin cancer among the donors did not vary according to the timing from donation to insurance enrollment, at 6 per 1000 person-years. The relative frequency of skin cancer among living donors versus controls was also similar regardless of the timing of capture in the study insurance plan. In a sensitivity analysis using 2 years (rather than 4.9 years) as the cutpoint for defining “early” versus “later” enrollment, the lower relative risk of non-skin cancer among prior living donors compared with controls was again limited to the sub-sample with earlier capture in the study insurance plan in relation to donation, although the risk reduction among donors versus controls was even stronger using within 2 years of donation as the threshold for “early” enrollment. Specifically, the donor versus control rate ratio for non-skin cancers was 0.21 (95% CI 0.08–0.55) in those living donors who began benefits under the study plan within 2 years of donation, while the donor versus control rate ratio for non-skin cancers was 0.90 (95% CI 0.65–1.24) in those donors who began benefits after a longer interval post-donation. As in the primary analysis, use of 2 years to define “early” versus “later” duration from donation to insurance enrollment showed no significant differences in the rate of skin cancer among the donors versus controls.

DISCUSSION

Medical evaluation of the potential living kidney donor focuses on excluding patients with medical abnormalities at the time of assessment, including conditions that pose risk of accelerated kidney disease after donation or may be exacerbated by uni-nephrectomy. Current guidelines for malignancy screening of potential kidney donors consider past treatments that may decrease renal reserve or impact operative risk, as well as concerns for the transmissibility of cancer to the recipient (3, 11). As post-nephrectomy cancer in the donor is not tracked by the OPTN except if reported as a cause of death, we examined a linkage of OPTN living donor registrations with medical claims of a private insurer to study cancer diagnoses in a large sample of prior donors. Based on these integrated data, we made the following key observations: 1) The overall frequency of non-skin cancer after living kidney donation was lower than in non-donor controls, suggesting an impact of pre-donation screening. In contrast, skin cancer frequency was statistically similar among prior living donors and controls. 2) The reduced relative risk of non-skin cancers among prior living donors compared to matched general insurance beneficiaries was limited to the donor sub-sample with earlier capture in the study insurance plan in relation to donation, suggesting that the protective effect of screening dissipates with time. 3) Several cases of cancer

diagnosis were identified within the first year after donation. 4) Prostate cancer was significantly more common among living donors compared with controls.

At least in part as a consequence of pre-donation medical evaluation and screening practices, the long-term likelihood of some medical complications such as diabetes and cardiovascular disease after living kidney donation appear to not exceed, or to even trend lower than, disease rates in the general population (10, 12). Recent linkage of OPTN and Social Security Death Master File records for a national living donor sample found that overall long-term donor mortality rates were not higher than that of matched control subjects from the National Health and Nutrition Evaluation Survey (13). However, the composition of reported deaths after kidney donation does appear to differ from that in the general population. Although cardiovascular disease (including stroke) comprises the leading cause of death in many developed countries including the U.S. and Japan, available mortality reports identify cancer as the most common cause of death after kidney donation in these countries. This may in part reflect effective screening and exclusion of potential donors with advanced or intermediate cardiovascular risk factors at evaluation. While the data available in the current study do not allow investigation of pre-donation screening practices, the reduced rate of non-skin cancers in donors compared to controls, particularly in the sample captured earlier in relation to donation, suggests a protective effect of screening and selection on post-donation cancer risk. Further, counseling during the evaluation process regarding life-style modifications such as tobacco cessation and moderation of alcohol intake may also contribute to a lower incidence of malignancies after kidney donation.

It is notable that relative protection of kidney donors compared to controls for post-donation non-skin cancer diagnoses was limited to the sub-sample captured earlier after donation, suggesting that the benefits of screening and selection for cancer risk dissipate over time. It is also notable that several cases of cancer diagnoses including melanoma and uterine cancer were reported within less than one year of donation. Such cases highlight the importance of ensuring up-to-date health maintenance including gynecological examinations prior to donation to reduce the risk of cervical and uterine cancers that may be detected by screening. Because melanoma may recur and/or be transmissible to the recipient even after a long latency, thorough dermatological history and examination are important components of the donor evaluation (3, 16).

In contrast to the general trend of less frequent non-skin cancer diagnoses among prior donors compared with controls, the rate of prostate cancer diagnoses was significantly *higher* among prior donors. Available evidence does not support a direct relationship of uni-nephrectomy or reduced glomerular filtration rate with the risk of prostate cancer. Rather, major risk factors for prostate cancer include African American race, older age, family history, high levels of insulin-like growth factor 1, as well as diet and lifestyle factors (17). Donors were age-matched to controls in this analysis. Although race information for controls was not available, since black persons comprised 13% of the donor sample, a disproportionately high prevalence of black race among the donors does not seem explain the finding. Screening for prostate cancer can be performed noninvasively by PSA. While the impact of screening on prostate cancer mortality is controversial and routine prostate cancer screening is not endorsed by the United States Preventive Services Task Force and

most cancer guidelines (18), more access to screening programs has been associated with higher prostate cancer detection rates in the general population (19). In the current study, the frequency of PSA testing and urology visits was lower among donors than the controls, and thus overall testing rates do not appear to explain our observation of more common prostate cancer diagnoses among donors versus controls. Further studies should explore whether increased frequency of prostate cancer is seen among prior donors in other contexts, and if so, whether practice patterns or clinical factors explain this observation.

Although not statistically significant, point estimates for rate ratios of cancer diagnoses in living donors versus controls were more than 1.0 for melanoma, central nervous system (CNS) cancer, and bone cancer. As previously stated, a history of melanoma is particularly concerning when evaluating a potential living donor. Aside from the potential for late recurrence and subsequent complications in the donor, melanoma is one of the most commonly reported and lethal donor-derived malignancies in the recipient with a high transmission rate. Transmission to transplant recipients has been reported after apparent dormancy in the donor of decades, supporting the ability of melanoma cells to remain dormant at distant site for decades and then reactivate upon exposure to immunosuppression (16, 20). The Israel Penn International Transplant Tumor Registry, a voluntary registry of more than 250 cases of organs transplanted from donors with a history of malignancy that captures tumor histology, donor risk factors, method of tumor presentation and recipient outcome, has described 13 donors with a history of melanoma (but deemed free of the disease at donation) who provided organs to 28 recipients (21, 22). Melanoma transmission occurred in 21 recipients (75%), of whom 13 (62%) died from metastatic disease. The time to diagnosis ranged from 2.5 to 42 months (median 10.5 months), and the only patients who survived were those who underwent nephrectomy and cessation of immunosuppression. Potential donors should be carefully screened with a thorough history and physical examination. If there is a distant history of skin cancer resection in a living donor, ideally pathology reports should be reviewed to ensure that the cancer was not a melanoma before approving donation. From a recipient risk perspective, a recent Malignancy Subcommittee of the *ad hoc* Disease Transmission Advisory Committee (DTAC) of the OPTN suggested that donors (deceased or living) with a history of CNS tumors graded III–IV by World Health Organization criteria or with history of ventriculoperioteoneal or ventriculoatrial shunt, prior surgery, chemotherapy, radiotherapy or extra-CNS metastasis be considered at high risk for transmission (11). However, more data are needed to quantify the transmission risk of CNS tumors after organ donation, as well as the recurrence risk in the living donor.

Limitations of this study include factors related to the sample and outcome measures. The claims data are derived from a private insurance plan, and uninsured living donors are not captured. Claims are surrogate measures for diagnoses and coding errors are possible. However, emerging validation data regarding lung cancer claims demonstrated a high degree of accuracy for detection of lung cancer diagnoses in cancer registry data and medical records (23, 24). We also employed the same claims-based algorithms that have been previously used to study cancer among kidney transplant recipients (25). The available data limit the capture of diagnoses to benefits periods of the linked health insurance, and we lacked information on pre-donation cancer history or cancer screening practices. With

respect to the non-donor controls, general patients in an insurance plan may be expected to have higher illness burdens than living donors, who are screened for good health at donation. In an effort to restrict the study to primary tumors, cases with claims for more than one type of cancer during observation were categorized by the most commonly coded diagnosis. While this approach may have lost some information for patients with multiple primary tumors, the same algorithm was applied to donors and controls.

In conclusion, we found that non-skin cancer was less common among prior living kidney donors compared to age- and sex-matched controls in this privately insured sample, suggesting a protective effect of screening and selection. However, the protective effect of screening appeared to dissipate with time after donation. Despite evaluation and selection practices, infrequent cancer diagnoses were identified within the first year after donation, and prostate cancer was significantly more common among living donors compared with controls. Further study and monitoring of cancer after kidney donation is warranted to ensure that evaluation, selection, follow-up and long-term care support overall good health of the donor.

METHODS

Data Source and Sample

Study data were assembled by linking OPTN records for prior living kidney donors with administrative data from a national private health insurer. OPTN data includes information on all donors and transplant recipients in the U.S. as submitted by OPTN member centers. After approval by the Health Resources and Services Administration (HRSA) and the Saint Louis University Institutional Review Board, beneficiary identifier numbers from the insurer's electronic databases were linked using names and birthdates to unique OPTN identifiers for living kidney donors. Because of the large sample size, the anonymity of the patients studied, and the non-intrusive nature of the research, a waiver of informed consent was granted per the Department of Health and Human Services Code of Federal Regulations (Title 45, Part 46, Paragraph 46.116). Analyses were performed using Health Information Portability and Accountability Act-compliant, limited datasets with all direct identifiers removed. People were eligible if they had OPTN records of serving as a living kidney donor in October 1987 through July 2007and benefits under the participating insurer after donor nephrectomy at some point in May 2000–December 2007 (the period of available claims data). All study participants were enrolled in medical benefits with this company exclusively during the study window.

Definitions of Outcomes and Covariates

Cancer diagnoses were defined by identification of billing claims with a corresponding diagnosis (International Classification of Diseases Code 9th Edition Clinical Modification (ICD9-CM)) code. The specific codes used are defined in the Appendix (SDC, Materials and Methods). We required two claims on separate dates to define a confirmed cancer case per an algorithm used in prior studies of cancer among kidney transplant recipients (25). To attempt to distinguish primary tumors from metastases, patients with claims for more than one malignancy type were categorized by the more commonly coded cancer. In a secondary

analysis to assess for evidence of screening and/or specialty healthcare utilization as an explanation for the observation of more common prostate cancer among male donors versus age-matched non-donor controls, we sought evidence of PSA testing by claims with corresponding Common Procedural Terminology (CPT) codes (84152, 84153, 84154, G0103) or encounters with provider codes for “urologist” as encoded by the insurance system.

Demographic data available in the OPTN registry and administrative records included age and sex. Time from donation to the start of captured insurance benefits (at or after donation) and age at benefits start were computed using eligibility records of the insurer. Race information was not tracked in the administrative data and thus was not available as a factor for donor-control matching.

Statistical Analyses

To compare the burden of cancer among the donors with a non-donor sample, donors were matched one-to-one with general insurance beneficiaries by sex and age when benefits began. Maximum observation time, as defined by benefits duration, in each matched pair was limited to the shortest available period in the pair. We compared the rates of cancer per observation time (patient-years) among the donors and controls as rate ratios. Cancer rates were also considered among sub-samples of donors defined by timing of the start of insurance enrollment after donor nephrectomy, with “early” and “later” capture defined by time from nephrectomy to enrollment in the study plan of less than versus more than the sample median of 4.9 years, respectively. A sensitivity analysis was also performed using 2 years (rather than 4.9 years) as the cutpoint for defining “early” versus “later” enrollment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Demographic traits of the living donor study sample

N=4,650	**Percentage, or Mean ± SD**
Age at Donation	37.2 ± 10.0
Age at Start of Benefits in Study Plan	42.7 ± 10.5
Female Sex	54.6%
White, Non-Hispanic	76.3%
Race	
African American (non-Hispanic)	13.1%
White (non-Hispanic)	76.3%
Hispanic	8.2%
Other	2.4%
Related to recipient	81.2%

Table 2

Rates of cancer diagnoses among prior living kidney donors and age- and sex-matched non-donor controls

	Living Donors Rate Per 1000 Person-Years	Matched Controls Rate Per 1000 Person-Years	Donor vs Control Rate Ratio (95% CI)
All LKD			
Total Non-skin	11.9	16.2	0.74 (0.55–0.99)*
Total Skin	6.1	6.8	0.91 (0.59–1.40)
By Type, Both Sexes			
Melanoma	1.6	0.9	1.67 (0.61–4.59)
Colon	0.3	1.4	0.22 (0.05–1.03)
Lung	0.8	0.9	0.83 (0.25–2.73)
Kidney	0.3	0.9	0.33 (0.07–1.65)
Lymphoma	0.6	1.6	0.40 (0.13–1.28)
Hodgkin's	--	0.6	--
Leukemia	0.3	0.3	1.00 (0.14–7.10)
Myeloma	0.2	0.5	0.33 (0.03–3.20)
Central nervous system	0.6	0.2	4.00 (0.45–35.8)
Endocrine	0.5	0.5	1.00 (0.20–4.95)
Bone	0.3	0.2	2.00 (0.18–22.1)
Mouth	0.2	0.3	0.50 (0.05–5.51)
Hepatobiliary	--	0.5	--
Esophagus	--	0.2	--
Stomach	--	0.2	--
Bladder	--	0.2	--
Other	0.6	0.6	1.00 (0.25–4.00)
Male-specific			
Prostate	6.5	1.7	3.80 (1.42–10.2)*
Testes	0.3	2.4	0.14 (0.02–1.16)
Female-specific			
Breast	5.2	8.7	0.60 (0.33–1.08)
Ovary	1.2	--	--
Uterus	1.2	1.2	1.00 (0.25–4.00)

CNS, central nervous system

*P<0.05

Table 3

Distribution of time from nephrectomy to cancer diagnosis among the living kidney donor sample

	Cancer Type	Median (years)	Range (years)
Full Donor Sample			
	Skin	4.8	0.1–18.2
	Total Non-skin	9.2	0.6–19.0
Cancers By Type, Full Donor Sample			
	Melanoma	3.6	0.7–13.2
	Colon	11.6	10.1–13.0
	Lung	12.5	4.8–18.4
	Kidney	7.7	4.9–10.5
	Lymphoma	11.5	8.0–15.7
	Leukemia	6.4	3.0–9.8
	Myeloma	8.4	8.4
	Central nervous system	11.2	6.0–13.8
	Endocrine	8.7	1.9–17.9
	Bone	10.9	10.8–10.9
	Mouth	14.5	14.5
	Other	6.2	0.6–12.5
Male-Specific Cancers			
	Prostate	9.1	4.6–19.0
	Testes	2.6	2.6
Female-Specific Cancers			
	Breast	8.6	3.2–16.5
	Ovary	8.4	1.4–11.6
	Uterus	5.2	0.8–7.1

Table 4

Rates of cancer diagnoses among prior living kidney donors and age- and sex-matched controls, considered according to the duration from nephrectomy to insurance plan enrollment

	Living Donors Rate Per 1000 Person-Years	Matched Controls Rate Per 1000 Person-Years	Donor vs Control Rate Ratio (95% CI)
By Time from Donation to Insurance Plan Enrollment*			
Total Non-skin, Early	5.2	11.6	0.45 (0.25–0.79) †
Total Non-skin, Later	19.4	21.4	0.91 (0.64–1.29)
Total Skin, Early	6.1	5.8	1.05 (0.56–1.97)
Total Skin, Later	6.2	7.8	0.79 (0.43–1.45)

*Sub-samples defined by enrollment in the study insurance plan before (“early”) or after (“later”) the median sample time from donor nephrectomy to insurance plan enrollment.

†P<0.05