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Use of Nephron Sparing Surgery among Renal Cell Carcinoma Patients with Diabetes and Hypertension

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Summary

Objectives—Nephron-sparing surgery (NSS) is recommended for renal cell carcinoma (RCC) patients at risk for chronic kidney disease. We assessed the prevalence of NSS among RCC patients with pre-existing diabetes and/or hypertension who participated in a population-based epidemiological RCC study.

Methods and Materials—Patients with RCC were enrolled in the United States Kidney Cancer Study (KCS), a case-control study in the metropolitan areas of Detroit and Chicago from 2002-2007. After determining whether patients had diabetes and/or hypertension, we ascertained the proportion of patients from the Detroit site who received NSS. Bivariate and multivariate analyses were performed to evaluate associations between these CKD risk factors and receipt of NSS.

Results—We identified 835 patients treated with radical nephrectomy (78%) or NSS (22%) from 2002-2007. Among this cohort, 60% had pre-existing diabetes and/or hypertension. Patients with both diabetes and hypertension were more than twice as likely to receive NSS (OR 2.42, 95% CI 1.47-3.96). Conversely, patients with only hypertension (OR 1.33, 95% CI 0.92-1.93) or diabetes (OR 0.97, 95% CI 0.92-1.93) were no more likely to receive NSS than patients with neither risk factor.

Conclusions—The more frequent utilization of NSS among patients with both diabetes and hypertension suggests growing recognition by urologists of the importance of these risk factors for future development of CKD among patients facing surgical therapy for RCC. However, the concurrent observation that patients with only one of these CKD risk factors did not receive

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increased utilization of NSS highlights an immediate opportunity to improve the surgical treatment of patients with RCC.

Keywords

renal cell carcinoma; nephrectomy; diabetes; hypertension; physician practice patterns

Introduction

Nephron-sparing surgery (NSS) (i.e., partial nephrectomy and ablative therapy) is accepted widely as a safe and often preferred option in the management of patients with RCC. For most patients with smaller renal tumors, NSS yields cancer control outcomes indistinguishable from those achieved by radical nephrectomy. [1-3] Although a European randomized study led by the EORTC demonstrated an overall survival benefit with radical nephrectomy, a recent population-based analysis of more contemporary cases suggested improved overall survival with NSS. [4,5] Moreover, NSS offers the additional benefits of greater preservation of renal function and less overtreatment of benign tumors and clinically indolent malignancies.[6,7] Based on these advantages, current American Urological Association guidelines recommend NSS (and partial nephrectomy in particular) as the favored treatment for most patients with a small renal mass.[8]

Nevertheless, NSS has been an underutilized treatment for patients with RCC. [9,10] What is unknown, however, is whether these overall trends exist also among patient populations at greater risk for adverse renal functional outcomes. In particular, because kidney surgery itself has a demonstrable effect on kidney function and the risk of CKD, [11] patients with diabetes and hypertension—two of the most common and important risk factors for developing chronic kidney disease (CKD) [12, 13]—are at especially heightened risk of developing long-term renal dysfunction after radical nephrectomy.

In this context, we used data from a large epidemiological study to assess how frequently urologists are performing NSS among patients with diabetes and/or hypertension. Given the high prevalence of these CKD risk factors, a better understanding of how frequently NSS is performed among this patient population will inform ongoing efforts to optimize the surgical management of patients with RCC.

Materials and Methods

Analytic Cohort

Our analysis includes patients with RCC who enrolled in the National Cancer Institute's (NCI) United States Kidney Cancer Study (KCS), a population-based case–control study conducted in the metropolitan areas of Detroit, Michigan (Wayne, Oakland, and Macomb Counties) and Chicago, Illinois (Cook County) from 2002 through early 2007. Eligible cases for this study included resident Caucasian and African-American men and women aged 20 to 79 years, newly diagnosed with histologically confirmed carcinoma of the renal parenchyma (ICD-02-C64.9) from February 1, 2002 through January 31, 2007 in Detroit, or January 1, 2003 through December 31, 2003 in Chicago. The KCS oversampled African-Americans (who have a higher incidence of RCC) as the study's primary focus was racial disparities in the diagnosis of RCC. In Detroit, potential cases were identified through the Metropolitan Detroit Cancer Surveillance System, an NCI Surveillance, Epidemiology, and End Results (SEER) program member. In Chicago, investigators identified potential cases from pathology reports issued at local hospitals. Additional details regarding case recruitment are summarized elsewhere. [14] The study was approved by the Institutional Review Boards at all participating institutions.

During the study interval, KCS investigators identified 1,918 men and women diagnosed with RCC in the two study regions. Because our analysis relied in part on SEER data that were available only for Detroit cases, we limited our study to the 1,603 patients diagnosed in Detroit. Among this sample, 1,018 and 951 patients consented to the interview or the interview *and* medical record review, respectively. From the latter group, we excluded patients who did not undergo surgery, did not have complete tumor size and/or comorbidity data, underwent prior dialysis, and/or had metastatic disease, yielding a final analytic cohort of 835 patients.

Patient-level Covariates

For each case in the analytic cohort, KCS personnel ascertained demographic and clinical characteristics from the following sources: 1) in-person interview; 2) medical record abstraction; and 3) SEER tumor registry. The presence of pre-existing CKD was based on patient self-report during the in-person interview, and was considered as a dichotomous (i.e., “yes/no”) variable. Our primary exposure variables were pre-existing diabetes and hypertension, which were assessed based on patient self-report during the epidemiologic interview. Although patient age at onset of diabetes was assessed by the in-person interview, the KCS did not explicitly distinguish between type I and type II diabetes, and there was no information describing disease severity (e.g., number of medications, hemoglobin A1c levels). Because RCC can cause secondary hypertension, patients were defined as having hypertension only if this diagnosis preceded the RCC diagnosis by at least two years. For this study, we considered diabetes and hypertension as dichotomous variables (i.e., present or absent), and we assigned patients in the analytic cohort to one of four categories: (1) diabetes only; (2) hypertension only; (3) diabetes and hypertension; and (4) no diabetes or hypertension.

Outcomes

We obtained information regarding the type of surgical procedure received from the KCS medical record abstraction. Our primary outcome of interest was receipt of NSS, which we defined as either partial nephrectomy or tumor ablation (i.e., radiofrequency ablation or cryotherapy).

Statistical Analyses

We initially performed bivariate analyses with chi-square tests to evaluate the associations between (1) patient characteristics and diagnosis of diabetes and/or hypertension; (2) patient characteristics and type of surgery (radical nephrectomy vs. NSS); and (3) patient diagnosis of diabetes and/or hypertension and receipt of NSS. We determined unadjusted odds ratios by performing logistic regression with our four exposures of interest (i.e., no diabetes or hypertension, diabetes alone, hypertension alone, and diabetes and hypertension). We then determined adjusted odds ratios by performing multivariate logistic regression to evaluate the association between receipt of NSS and a pre-existing diagnosis of diabetes and/or hypertension. Our models adjusted for age (as continuous variable), body mass index (as continuous variable), race/ethnicity (as dichotomous variable), and pre-existing CKD (as dichotomous variable). These multivariate logistic regression models also utilized generalized estimating equations to account for clustering of patients with surgeons' practices. All statistical testing was two-sided, carried out using computerized software (SAS v9.1, SAS Institute, Cary, NC) and performed at the 5% significance level.

Results

We identified 835 patients with kidney cancer treated surgically from 2002 through 2007. Over 60% of the analytic cohort had diabetes and/or hypertension (43% hypertension alone,

4% diabetes alone, 14% diabetes and hypertension); patients with these comorbidities were more likely to be older, Black, and to have a BMI > 30 (all $p < 0.001$) (Table 1).

Overall, NSS was performed for 22% of patients in the analytic cohort. After decreasing from 22% to 14% between 2002 and 2003, the proportion of patients receiving NSS increased to 30% in 2005 before declining to 22% in 2006 ($p = 0.012$). Utilization of NSS varied significantly by both tumor size and histology (Table 2). NSS was performed more frequently for patient with tumors demonstrating papillary renal cell histology ($p < 0.001$). This finding may be due to the typically smaller size and multifocal nature of this tumor type.

Figure 1 presents the unadjusted proportions of patients with diabetes and/or hypertension treated with NSS both overall and stratified by tumor size. Among the entire cohort, patients with both diabetes and hypertension were significantly more likely to receive NSS (30% vs. 20% of patients without diabetes/hypertension, $p = 0.02$). We observed similar (but not statistically significant) trends among patients with tumors ≤ 4 cm (Figure 1).

In multivariable analyses, we found that patients with both diabetes and hypertension were more than twice as likely to receive NSS compared to those with neither diabetes nor hypertension (OR 2.42, 95% CI 1.47-3.96). This relationship was consistent for patients with tumors ≤ 4 cm (OR 2.31, 95% CI 1.19-4.50), a population for which NSS is frequently both feasible and appropriate. Conversely, patients with hypertension or diabetes alone were no more likely to be treated with NSS, even among those with tumors 4 cm or smaller (hypertension alone: OR 1.30, 95% CI 0.83-2.03; diabetes alone: OR 0.80, 95% CI 0.28-2.26) (Table 3).

Comment

Although the EORTC trial demonstrated an overall survival benefit for patients treated with radical rather than partial nephrectomy, the limitations of that study (i.e., problems with accrual, early closure, and limited surgeon experience with NSS) are acknowledged by many. [4, 15] A recent observational analysis of contemporary SEER-Medicare data, in contrast, identified an overall survival benefit for patients with kidney cancer treated with NSS, compared to those undergoing radical nephrectomy. [5] In our large and contemporary sample of patients with RCC, only 22% of all patients received treatment with a nephron-sparing approach. Notably, patients with both diabetes and hypertension were more than twice as likely to receive NSS as those with neither comorbid condition. Conversely, the presence of only one risk factor was not associated with an increased likelihood of receiving NSS, even among patients with tumors 4 cm or smaller.

Previous reports have demonstrated that population-level utilization of NSS has increased progressively during the last decade. [7,8,16] During the course of this study, there was not a consistent increase in the utilization of NSS. Because individual centers generally report much higher utilization rates (approaching 90% among patients with small tumors)[17,18] there is a need for continued need for efforts aimed at accelerating the use of NSS among patients with RCC regardless of the care setting. This is particularly true for patients with T1a tumors (i.e., < 4 cm) and possibly for patients with larger T1b tumors (i.e., > 4 cm but < 7 cm). NSS was exceedingly rare among patients with larger tumors in our cohort, which may reflect bias toward treatment at community-based practice settings, rather than specialized tertiary centers. Our data indicates that this concern is particularly relevant for patients with diabetes and/or hypertension, who are at increased risk of CKD even before undergoing kidney cancer surgery.

Our findings should, however, be interpreted in the context of several limitations. First, in this study we classified diabetes and hypertension as dichotomous (i.e., yes/no) exposure variables. In truth, these conditions exist on a continuum of severity, and the risk of CKD increases as diabetes and hypertension are more poorly controlled.[19] Because we did not measure severity of diabetes or hypertension, it is possible that our analyses failed to detect greater utilization of NSS among patients with more advanced comorbidity. Additional studies will be required to better understand the utilization and outcomes of NSS with more severe diabetes and hypertension. Second, our measurement of diabetes, hypertension, and CKD was based on patient self-report. Therefore, it is susceptible to recall bias that could affect the measured prevalence of each CKD risk factor. That being said, existing literature indicates that there is a strong concordance between patient self-report and the medical record for the diagnoses of diabetes and hypertension. [20] Future analyses from other data sources (i.e., databases of administrative claims) will be useful for validating our findings. Third, our sample included only those patients who consented to both the interview and medical record review. If the non-responders in our study have more severe diabetes and/or hypertension, some degree of selection bias could exist. Fourth, the presence of CKD was a self-reported, binary “yes/no” variable for RCC patients in the case-control KCS study. Again, this makes our analysis susceptible to recall bias. Furthermore, given the small number of patients with self-reported CKD in our cohort, this condition is potentially underreported among our cohort. In addition, we acknowledge that the severity of pre-existing CKD is also a factor in the decision to pursue nephron-sparing surgery, and we were unable to adjust for this concern using the available data. Finally, despite the population-based nature of the KCS sample, the analytic cohort was drawn from only one metropolitan area and our findings might therefore be influenced by unique local practice patterns.

These limitations notwithstanding, our findings have important implications for the care delivered to patients with RCC and concurrent renal function-relevant comorbidities. Namely, the more frequent utilization of nephron-sparing techniques among patients with both diabetes and hypertension suggests growing recognition by urologists of the importance of these risk factors for future development of CKD among patients facing surgical therapy for RCC. However, the concurrent observation that having only one CKD risk factor (i.e., diabetes or hypertension) was not associated with increased utilization of NSS highlights the continued need to expand the use of excisional and ablative NSS techniques among patients at heightened risk for CKD.

There are in fact several potential strategies for addressing this challenge. One approach is to develop novel mechanisms for disseminating the strong recommendations for partial nephrectomy included in the recently-released AUA guidelines for management of patients with small renal masses. This might occur through standard educational and training forums, but might also be accelerated by efforts aimed at establishing surgical quality collaboratives that leverage physician-led learning as a mechanism for increasing utilization of NSS. [21] In addition, efforts to expand the use of NSS would be informed greatly by a better understanding of patient and physician attitudes regarding the surgical management of RCC. For instance, it may be that patients are actually driving utilization of radical nephrectomy even when they are fully and carefully informed of the pros and cons of a NSS approach. Indeed, many patients with breast cancer prefer radical mastectomy over breast-conserving surgery with adjuvant radiation, even though oncologic outcomes are equivalent between the two treatment strategies.[22] It is entirely possible therefore that some patients with renal tumors amenable to partial nephrectomy actually prefer to have a radical nephrectomy. From a surgeon's perspective, moreover, it is possible there are pragmatic barriers to offering partial nephrectomy or ablative therapies including, for instance, a lack of the ancillary clinical services (e.g., interventional radiology) needed to perform and/or manage the

complications associated with NSS in more isolated clinical settings.[16,23] Furthermore, we do not know physician attitudes and understanding regarding the implications of hypertension and diabetes on long-term kidney function, especially among those patients with normal kidney function at the time of initial evaluation. For instance, hypertension is very common overall, which may blunt physician concern for long-term kidney disease among this patient population. In this context, further qualitative research that explicitly measures patient preferences and physician barriers to adoption may inform future interventions in this area.

Additional research is also needed to improve our understanding of the long-term implications of not performing NSS in patients with diabetes and/or hypertension, the two leading causes of CKD in the United States.[12,13] Although previous work has demonstrated an increased risk of elevated creatinine levels among diabetic and hypertensive patients treated by radical versus partial nephrectomy,[6,24,25] there are no data that specifically clarify the comparative long-term risk of CKD, cardiovascular disease, and mortality in this large subpopulation of patients with RCC. Once available, these data will help urologists to better integrate comorbidity into the surgical decisionmaking process for patients with RCC, and may also provide a better evidence base for expanding the utilization of NSS among patients with RCC who are already at risk for CKD.

Conclusions

The more frequent utilization of NSS techniques among patients with both diabetes and hypertension suggests growing recognition by urologists of the importance of these risk factors for future development of CKD among patients facing surgical therapy for RCC. However, the concurrent observation that the presence of only one of these CKD risk factors was not associated with increased utilization of NSS highlights an immediate opportunity to improve the surgical treatment of patients with RCC.

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Figure 1. Use of NSS among patients with diabetes and/or hypertension

This figure demonstrates receipt of NSS based on pre-existing diabetes or hypertension. The y-axis shows the proportion who received NSS. The black bars represent patients with no prior diabetes or hypertension. The white bars present patients with diabetes only. The dark gray bars represent patients with hypertension only. Finally, the light gray bars represent patients with diabetes and hypertension. * $p=0.02$ for comparison of use of NSS between patients with diabetes and hypertension and those with no diabetes or hypertension. **There were no patients among this subgroup with diabetes only who received NSS.

Table 1

Patient characteristics by presence of diabetes and/or hypertension.

	Total (n=835)	No diabetes or hypertension (n=327)	Diabetes only (n=32)	Hypertension only (n=362)	Diabetes and hypertension (n=114)	p *
	n	n (%)	n (%)	n (%)	n (%)	
Year of diagnosis						0.713
2002	148	64 (43)	7 (5)	66 (45)	11 (7)	
2003	152	59 (39)	5 (3)	68 (45)	20 (13)	
2004	201	78 (39)	8 (4)	85 (42)	30 (15)	
2005	194	73 (38)	9 (5)	80 (41)	32 (16)	
2006**	140	53 (38)	3 (2)	63 (45)	21 (15)	
Age at diagnosis						<0.001
20 - 44	105	79 (75)	4 (4)	20 (19)	2 (2)	
45 - 54	184	91 (49)	5 (3)	65 (35)	23 (13)	
55 - 64	283	92 (33)	12 (4)	133 (47)	46 (16)	
64 - 74	198	45 (23)	9 (5)	111 (56)	33 (17)	
75 - 79	65	20 (31)	2 (3)	33 (51)	10 (15)	
Sex						0.204
Male	468	180 (38)	14 (3)	215 (46)	59 (13)	
Female	367	147 (40)	18 (5)	147 (40)	55 (15)	
Race						<0.001
White	629	272 (43)	26 (4)	255 (41)	76 (12)	
Black	206	55 (27)	6 (3)	107 (52)	38 (18)	
Body mass index***						<0.001
<25	161	99 (61)	1 (1)	52 (32)	9 (6)	
25 - 30	283	124 (44)	10 (4)	125 (44)	24 (8)	
30 - 35	209	63 (30)	8 (4)	111 (53)	27 (13)	
35+	174	39 (22)	13 (7)	70 (40)	52 (30)	
Patient report of CKD****						0.009
Yes	10	2 (20)	0 (0)	3 (30)	5 (50)	

	Total (n=835)	No diabetes or hypertension (n=327)	Diabetes only (n=32)	Hypertension only (n=362)	Diabetes and hypertension (n=114)	p [*]
	n	n (%)	n (%)	n (%)	n (%)	
<i>No</i>	824	325 (39)	32 (4)	358 (43)	109 (13)	
Tumor size						0.197
<i>4 cm</i>	438	159 (36)	20 (5)	193 (44)	66 (15)	
<i>> 4 cm</i>	397	168 (42)	12 (3)	169 (43)	48 (12)	
Histology						0.278
<i>Clear cell</i>	601	245 (41)	22 (4)	254 (42)	80 (13)	
<i>Papillary</i>	122	34 (28)	6 (5)	58 (47)	24 (20)	
<i>Chromophobe</i>	53	22 (41)	2 (4)	26 (49)	3 (6)	
<i>Cystic</i>	45	18 (40)	2 (4)	20 (45)	5 (11)	
<i>Other histology</i>	14	8 (57)	0 (0)	4 (29)	2 (14)	
Fuhrman Grade						0.725
<i>1</i>	93	39 (42)	6 (6)	34 (37)	14 (15)	
<i>2</i>	396	154 (39)	14 (4)	176 (44)	52 (13)	
<i>3</i>	194	77 (40)	5 (3)	80 (41)	32 (16)	
<i>4</i>	42	18 (43)	1 (2)	19 (45)	4 (10)	

* p-value for comparison between CKD risk factor categories;

** includes cases from early 2007;

*** missing in 8 cases;

**** missing in 1 case, and based on patient self-report

Table 2
Patient characteristics by surgical procedure strata

	Radical nephrectomy (n=652)	Nephron sparing surgery (n=183)	p [*]
	n (%)	n (%)	
Year of diagnosis			0.012
2002	115 (78)	33 (22)	
2003	130 (86)	22 (14)	
2004	162 (81)	39 (19)	
2005	136 (70)	58 (30)	
2006 ^{**}	109 (78)	31 (22)	
Age at diagnosis			0.325
20 - 44	80 (76)	25 (24)	
45 - 54	142 (77)	42 (23)	
55 - 64	213 (75)	70 (25)	
64 - 74	163 (82)	35 (18)	
75 - 79	54 (83)	11 (17)	
Sex			0.079
Male	355 (76)	113 (24)	
Female	297 (81)	70 (19)	
Race			0.086
White	500 (79)	129 (21)	
Black	152 (74)	54 (26)	
Body mass index^{***}			0.255
<25	117 (73)	44 (27)	
25 - 30	222 (78)	61 (22)	
30 - 35	169 (81)	40 (19)	
35+	139 (80)	35 (20)	
Patient report of CKD^{****}			0.464
Yes	7 (70)	3 (30)	
No	644 (78)	180 (22)	
Tumor size			<0.001
4 cm	279 (64)	159 (36)	
> 4 cm	373 (94)	24 (6)	
Histology			<0.001
Clear cell	496 (83)	105 (17)	
Papillary	69 (57)	53 (43)	
Chromophobe	41 (77)	12 (23)	
Cystic	33 (73)	12 (27)	
Other histology	13 (93)	1 (7)	

	Radical nephrectomy (n=652)	Nephron sparing surgery (n=183)	p [*]
	n (%)	n (%)	
Fuhrman Grade			0.195
1	73 (78)	20 (22)	
2	304 (77)	92 (23)	
3	156 (80)	38 (20)	
4	38 (90)	4 (10)	

* p-value for comparison between CKD risk factor categories;

** includes cases from early 2007;

*** missing in 8 cases;

**** missing in 1 case, based on patient self-report

Table 3

Multivariable analyses evaluating association between pre-existing diabetes and/or hypertension and receipt of NSS.

	All tumor sizes		Tumor size ≥ 4 cm	
	Unadjusted OR (95% CI)	Adjusted OR (95% CI) ^a	Unadjusted OR (95% CI)	Adjusted OR (95% CI) ^a
No diabetes or hypertension*	1.00	1.00	1.00	1.00
Diabetes only	0.76 (0.28-2.05)	0.97 (0.37-2.53)	0.67 (0.23-1.93)	0.80 (0.28-2.26)
Hypertension only	1.17 (0.81-1.69)	1.33 (0.92-1.93)	1.16 (0.75-1.81)	1.30 (0.83-2.03)
Diabetes and hypertension	1.75 (1.08-2.84)	2.42 (1.47-3.96)	1.67 (0.93-3.00)	2.31 (1.19-4.50)

* reference category.

^a regression model adjusts for patient age, race, body mass index, and history of CKD, with correction for clustering at physician level.