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Risk Factors That Affect Survival in Patients with Renal Cell Carcinoma Invading the Vena Cava

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Abstract

Objectives: To determine which risk factors are associated with overall survival in patients with T3b or T3c renal cell carcinoma. **Materials and Methods**: Retrospective chart review was performed on all patients who underwent a nephrectomy at Lahey Hospital from 1971-2014 and had a diagnosis of pathologic T3b or T3c renal cell carcinoma. Twenty-one potential risk factors were examined and analyzed using Cox Proportional Hazard Survival models. Additional factors examined in this cohort included rate of complications, tumor recurrence, intra-operative death rate, and 30-day mortality rate. **Results**: One-hundred eighty-two patients with stage T3b or T3c renal cell carcinoma met inclusion criteria. Of these, 124 (68%) were stage T3b and 58 (32%) were stage T3c. Median follow-up was 18.5 months. One-hundred and six (58%) patients experienced a complication from surgery. The intra-operative death rate was 1.1% (2 patients). The 30-day mortality rate was 7.1% (13 patients). Seventy-one (39%) patients had disease recurrence at a median of 7 months (range 1 - 232 months). The 5-year disease-specific survival was 40% and the 5-year overall survival was 32%. Of the 21 risk factors analyzed, clear cell histology, positive lymph nodes, and peri-nephric fat involvement were all significant at the $p < 0.05$ level using unadjusted modeling. On multivariable analysis, fully adjusting for all three significant variables, only positive lymph nodes and peri-nephric fat involvement remained significant. **Conclusions:** In patients with T3b or T3c renal cell carcinoma overall survival is associated with lymph node positivity and peri-nephric fat involvement and not tumor thrombus level.

Keywords

Renal Cell Carcinoma, Venous Tumor Thrombus, Vena Cava

1. Introduction

Renal cell carcinoma (RCC) is the most prevalent renal neoplasm, accounting for 90% - 95% of all renal malignancies [1]. A unique characteristic of RCC is its propensity to

invade vascular structures, such as the renal vein and subsequently the inferior vena cava and right atrium. This phenomenon of vascular invasion, known as "tumor thrombus," occurs in an estimated 4% - 10% of renal cell carcinoma cases [2].

In recent years, it has been recognized that patients with tumor thrombus limited to the renal vein have a survival advantage over those with vena cava involvement [3] [4]. The American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) amended their 2010 TNM staging system to re-classify these T3b patients with only renal vein involvement into the T3a category [5].

Over the past few decades, small retrospective studies have reported conflicting results about which risk factors have the best prognostic value for patients with tumor thrombus. In 2006, an international consortium was established to better characterize this disease entity and resolve some of the conflicting results in the literature [6]. Valuable information has and continues to be attained from this large cohort of over 2000 patients but there still remains a need for individual institutions to analyze and critically examine their respective patient populations. This is especially true given the 2010 re-classification of T3b patients with only renal vein involvement and the relative paucity of studies exclusively examining patients with vena cava involvement.

The purpose of this study is to examine a cohort of patients at a single institution with T3b and T3c renal cell carcinoma to determine which risk factors are associated with survival in patients with tumor thrombus involving the vena cava. To better understand the patient population, survival and peri-operative outcomes will be examined.

2. Materials and Methods

Institutional review board approval was obtained. The medical records of all patients who underwent a nephrectomy at Lahey Hospital from 1971-2014 and had a diagnosis of pathologic T3b or T3c renal cell carcinoma were examined. Data was initially extracted from a retrospectively maintained database and supplemented by chart review in instances where risk factors were incompletely documented in the database. Cases prior to 2010 were evaluated and re-staged according to the 2010 renal cell carcinoma TNM staging system provided by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC). All cases meeting criteria for stage T3a were excluded. All laparoscopic or solitary kidney cases were also excluded. Out of the initial 291 cases identified, 182 met inclusion criteria.

Twenty-one potential risk factors were examined (**Table 1**). Patient demographic information included gender, age at surgery, American Society of Anesthesiologist (ASA) physical status classification, smoking history, body mass index, and pre-op creatinine. Disease-specific factors included pathologic stage, Fuhrman grade, histology, tumor size, level of tumor thrombus extension, positive lymph nodes, peri-nephric fat involvement, invasion of the collecting system, metastasis at the time of surgery, and whether patients were symptomatic at diagnosis. Surgical factors included the use and type of cardiopulmonary bypass and surgical margin status. Additional factors examined in this cohort included rate of complications, intra-operative death rate, and 30-day mortality rate.

Table 1. Twenty-one potential risk factors.

	Number	*Percentage*
Sex		
Male	116	64
Female	66	36
pT-Stage		
T3b	124	68
T3c	58	32
Fuhrman Grade		
1	3	2
2	36	20
3	76	42
4	34	19
Unknown	33	18
Histology		
Clear Cell	94	52
Papillary	8	4
Granular Cell	5	3
Chromophobe	2	1
RCC-Subtype Unknown	38	21
Non-Renal Cancer	2	1
Mixed RCC	23	13
Sarcomatoid Component	10	5
Nodal Status		
Positive Lymph Nodes	30	16
Negative Lymph Nodes	146	80
Unknown	6	3
1	3	2
2	36	20
3	76	42
4	34	19
Unknown	33	18
Metastasis at Surgery		
Yes	26	14
No	156	86
BMI		
18.5 - 24.9	14	8
25 - 29.9	31	17
30 - 34.9	8	4

Continued

35 - 39.9	5	2
>40	4	2
Unknown	120	66
ASA		
2	10	5
3	27	15
4	19	10
Unknown	126	69
Symptomatic		
Yes	72	40
No	24	13
Unknown	86	47
Cardiopulmonary Bypass		
Yes	70	38
No	112	62
Minimally Invasive	46	25
Traditional	24	13
Smoking History		
Yes	103	57
No	68	37
Unknown	11	6
Perinephric Fat Involvement		
Yes	79	43
No	102	56
Unknown	1	0.5
Invasion of Collecting System		
Yes	17	9
No	36	20
Unknown	129	71
Surgical Margins		
Positive	47	26
Negative	101	55
Unknown	34	19
Pre-op Renal Embolization		
Yes	74	41
No	23	13
Unknown	85	47
Age		
<60	71	39
≥60	111	61

Continued

Pre-op Cr		
≤1.2	70	38
>1.2	92	51
Unknown	20	11
Date of Surgery		
Prior to 2000	95	52
After 2000	87	48
Tumor Extension		
Infrahepatic	47	26
Intrahepatic	21	12
Suprahepatic	5	3
Cavoatrial Junction	3	2
Atrium	12	7
Unknown	94	52

Overall and disease-specific survival rates were estimated using Kaplan-Meier survival curves. Survival was defined as the time from date of diagnosis to an end-point, including death or recurrence. Potential risk factors were analyzed using Cox Proportional Hazard Survival models to get estimates of the Hazard Ratios for each factor, first unadjusted, and then adjusted. Variables found to be significant on unadjusted analysis were chosen for multivariable modeling. A total of five different models were used. This included three unadjusted models, one multivariable model with three variables in it (fully adjusted), and one multivariable model with two variables in it (partially adjusted). The histology variable was removed from the fully adjusted model to create the reduced model since it was no longer significant on the three-variable model. All statistics were performed using SAS version 9.3.

3. Results

One-hundred eighty-two patients with stage T3b or T3c renal cell carcinoma met inclusion criteria. Of these, 124 (68%) were stage T3b and 58 (32%) were stage T3c. Seven patients were from the 1970s, 30 from the 1980s, 58 from the 1990s, 62 from the 2000s and 25 from the 2010s. Median follow-up was 18.5 months (range 0 - 296 months). There were 116 (64%) men and 66 (36%) women. The average age at surgery was 63 years (range 37 - 88 years). Thirty (16%) patients had positive lymph nodes and 26 (14%) had metastasis at the time of surgery.

One-hundred and six (58%) patients experienced a complication from surgery. Of these, 70% or 66% of the complications were high grade (Clavien-Dindo 3 - 5). The intra-operative death rate was 1.1% (2 patients). The 30-day mortality rate was 7.1% (13 patients).

Seventy-one (39%) patients had disease recurrence at a median of 7 months (range 1 - 232 months). The most common location of recurrence was the lung (24 patients), followed by the liver (16 patients) and bone (16 patients).

Overall, one-hundred fifty (82.4%) patients included in the study died. One-hundred

ten (60.4%) deaths were due to renal cell carcinoma. The 5-year disease-specific survival was 40% and the 5-year overall survival was 32% (Figure 1). Only 7 (3.8%) patients were lost to follow-up.

On unadjusted analysis clear cell histology ($p = 0.0094$), positive lymph nodes ($p = 0.0001$), and peri-nephric fat involvement ($p = 0.0011$) were all significant at the $p < 0.05$ level (Table 2). On multivariable analysis, fully adjusting for all three significant variables, only positive lymph nodes ($p = 0.0003$) and peri-nephric fat involvement ($p = 0.0255$) remained significant (Table 3).

4. Discussion

Historically, cancer staging and subsequent treatment plans were based solely on anatomic extent of the cancer. This paradigm is shifting as electronic health records and a better understanding of cancer biology has facilitated the creation of prognostic and predictive models for many common diseases such as breast, colon, and lung cancer [5].

While there have been great strides for common diseases, rare disease entities such as tumor thrombus remain largely understudied. The current body of literature on venous thrombus in RCC is comprised of conflicting results regarding risk-factors and prognostic indicators. For patients with tumor thrombus involving the vena cava, this lack of consensus on prognostic indicators is further compounded by the fact that studies prior to 2010 included patients with tumor thrombus limited to the renal vein. Various studies [3] [4] [7] [8] have shown long-term survival advantage in these patients with only renal vein involvement and highlight the need for individualized analysis of prognostic indicators for those with vena cava involvement.

In order to identify some of these prognostic indicators, we examined 21 potential risk factors in a group of 182 patients with tumor thrombus involving the vena cava (T3b or T3c RCC). On multivariable analysis, only positive lymph nodes and peri-nephric fat involvement were found to be significantly associated with survival ($p = 0.0003$ and $p = 0.0255$, respectively). Tumor thrombus level was not found to be significant.

	Overall-Survival	Disease-Specific Survival	Disease-Free Survival
# events	150 events	110 events	124 events
Median Time	25 mo (95% CI: 18 to 32)	32 mo (95% CI: 22 to 50)	6 mo (95% CI: 3 to 12 mo)

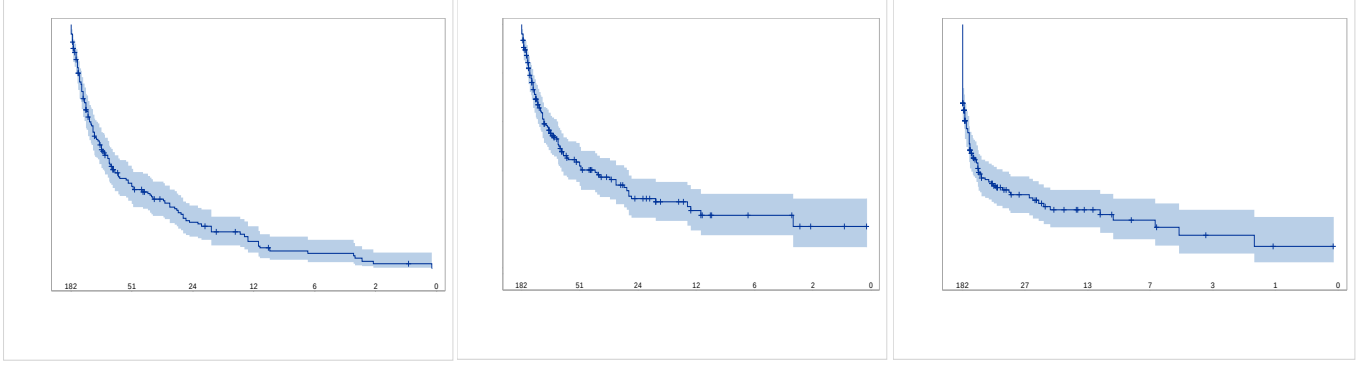

Figure 1. 5-year disease-specific survival and 5-year overall survival.

Table 2. Kaplan-Meier survival estimates for overall survival 3, 5, and 10 –years and p-values from comparison of Kaplan-Meier curves.

Variable/Strata	3 year estimate	5 year estimate	10 year estimate	Log-rank p-value	Wilcoxon p-value
Symptomatic				0.5230	0.4230
No	34% (11%, 57%)	34% (11%, 57%) [3]	11% (8.4%, 31%) [1]		
Yes	46% (34%, 59%) [26]	37% (25%, 49%) [18]	14% (3.7%, 24%) [5]		
Pre op renal embolism				0.4457	0.2551
No	49% (23%, 74%) [6]	49% (23%, 74%) [5]			
Yes	41% (29%, 53%) [24]	32% (21%, 44%) [16]	11% (1.7%, 20%) [4]		
ASA class 4 vs 2/3				0.0555	0.1170
No	48% (28%, 68%) [7]	41% (20%, 62%) [5]	0%		
Yes	19% (0.2%, 38%) [2]	19% ((0.2%, 38%) [2]	0%		
Male gender				0.4013	0.9011
No	41% (29%, 53%) [24]	36% (24%, 48%) [20]	19% (8.8%, 29%) [9]		
Yes	38% (29%, 47%) [34]	29% (20%, 38%) [22]	12% (4.7%, 19%) [8]		
Age under 60 yrs				0.7578	0.6911
No	40% (31%, 50%) [35]	34% (25%, 44%) [28]	15% (7.3%, 22%) [12]		
Yes	38% (26%, 49%) [23]	27% (16%, 38%) [14]	17% (6.7%, 27%) [5]		
BMI > 27				0.8990	0.9045
No	42% (22%, 62%) [7]	42% (22%, 62%) [6]	21% (1.4%, 41%) [2]		
Yes	52% (32%, 72%) [9]	46% (±10.4%)	15% (±10%)		
Smoking Hx				0.0831	0.2668
No	43% (31%, 56%) [23]	38% (25%, 50%) [18]	22% (11%, 34%) [9]		
Yes	34% (25%, 44%) [29]	24% (15%, 34%) [18]	8.4% (2.0%, 15%) [5]		
Creatinine > 13				0.1117	0.2786
No	44% (33%, 55%) [30]	33% (22%, 44%) [19]	17% (7.0%, 26%) [7]		
Yes	34% (23%, 45%) [20]	27% (16%, 38%) [15]	9.8% (1.9%, 18%) [5]		
Cardiopulmonary bypass				0.2587	0.0955
No	40% (31%, 50%) [37]	34% (24%, 43%) [30]	17% (9.5%, 25%) [13]		
Yes	37% (25%, 49%) [21]	28% (16%, 39%) [12]	10% (1.3%, 19%) [4]		
Clear cell histology				0.0090	<0.01
No	26% (17%, 36%) [20]	21% (12%, 30%) [14]	12% (4.6%, 19%) [8]		
Yes	52% (41%, 63%) [38]	42% (31%, 53%) [28]	18% (8.5%, 27%) [9]		
Carcomatoid component				0.5794	0.4428
No	40% (32%, 47%) [56]	32% (24%, 39%) [41]	15% (8.6%, 21%) [16]		
Yes	30% (1.6%, 58%) [2]	30% (1.6%, 58%) [1]			
Path stage T3b vs T3c				0.1672	0.0642
No	40% (31%, 49%) [40]	34% (25%, 43%) [32]	18% (10%, 26%) [14]		
Yes	37% (24%, 50%) [18]	26% (14%, 38%) [10]	7.9% (0.4%, 16%) [3]		
Tumor grade of 3/4 vs 1/2				0.1269	0.0456

Continued

No	55% (39%, 71%) [18]	46% (29%, 62%) [14]	21% (6.7%, 36%) [6]		
Yes	33% (24%, 43%) [27]	25% (16%, 34%) [17]	13% (4.8%, 20%) [6]		
Tumor size >8cm				0.4963	0.1527
No	44% (33%, 54%) [34]	37% (27%, 47%) [26]	15% (6.3%, 23%) [9]		
Yes	35% (24%, 46%) [22]	25% (15%, 35%) [14]	13% (4.6%, 22%) [6]		
Extension level 2/3 vs 1				0.9825	0.8944
No	40% (31%, 49%) [40]	34% (25%, 43%) [32]	18% (10%, 26%) [14]		
Yes	41% (23%, 60%) [10]	33% (15%, 51%) [6]	5.5% (4.8%, 16%) [1]		
Positive lymph nodes				<0.0001	<0.01
No	45% (36%, 53%) [52]	37% (28%, 45%) [38]	17% (10%, 24%) [15]		
Yes	10% (0%, 21%) [3]	3% (0%, 10%) [0]	0%		
Peri-nephric fat involvement				0.0010	0.0035
No	51% (41%, 61%) [42]	44% (33%, 54%) [33]	21% (12%, 30%) [13]		
Yes	25% (15%, 35%) [16]	16% (7.3%, 25%) [9]	7.2% (0.6%, 14%) [4]		
Metastasis at surgery				0.1758	0.7074
No	42% (34%, 50%) [52]	34% (26%, 42%) [39]	16% (9.6%, 23%) [16]		
Yes	26% (8.4%, 43%) [6]	21% (4.1%, 37%) [3]			
Positive surgical margin				0.1583	0.2591
No	49% (39%, 59%) [39]	39% (29%, 49%) [29]	19% (9.7%, 27%) [12]		
Yes	37% (22%, 51%) [14]	34% (19%, 49%) [10]	10% (0.4%, 21%) [3]		

**Wilcoxon test p-value give more weight to early part of Kaplan-meier curves where there are more data. Log-rank test weights all times equally, so differences in curves later in time are given more weight than Wilcoxon test. Gray shading indicates variable missing on >20% of the patients are shaded (n = 145 or less).

Table 3. Table entries show estimated hazard ratio (HR), 95% CI for HR together with the sample size and number of events (outcomes) used to make the model.

Risk Factor in Model(s)	(Three) Unadjusted Models	Fully Adjusted Model (n = 175 with 145 events)	Reduced Model (n = 175 with 145 events)
Histology that is not clear cell	1.54 (95%CI: 1.11 to 2.14), p ≤ 0.01 N = 182 with 150 events	1.25 (95% CI: 0.89, 1.78) p = 0.1989	**[not in model]**
Positive lymph nodes	2.78 (95% CI: 1.82 to 4.24), p ≤ 0.01 N = 176 with 146 events	2.31 (95% CI: 1.47, 3.63) p ≤ 0.01	**2.49 (95% CI: 1.61 to 3.85) p ≤ 0.01**
Perinephric fat involvement	1.73 (95% CI: 1.24 to 2.41), p ≤ 0.01 N = 181 with 149 events	1.49 (95% CI: 1.05, 2.12) p = 0.0255	**1.52 (95% CI: 1.08 to 2.16) p = 0.017**

Check for proportional hazards was done for this model using plots of schoenfeld residuals and computing chi-square tests for rank correlation of residuals with time (p = 0.36 for positive lymph nodes, p = 0.84 for perineph fat involvement).

Tumor thrombus level is one of the most highly scrutinized prognostic implications is the literature. For those with vena cava involvement, most studies show no difference in survival based on extent of tumor thrombus while some have demonstrated an adverse effect on survival for those with tumor thrombus extending to the atrium [2] [11]-[19].

In 2004, the Mayo Clinic assessed 540 patients with RCC with renal venous extension, 191 of which had IVC tumor thrombus. In their paper, they reported primary tumor histological factors as important predictors of prognosis and found no significant difference in survival by thrombus level among patient with IVC thrombus. In their analysis, which included tumor thrombus limited to the renal vein, they found perinephric fat involvement, regional lymph node involvement, distant metastasis, histological tumor necrosis and sarcomatoid component to all be associated with survival. This is in line with other studies [9] [10] which have shown primary tumor characteristics, such as stage, grade, and lymph node involvement to determine outcome rather than extent of tumor thrombus.

Our current study supports this finding as we also found positive lymph nodes and peri-nephric fat involvement, both primary tumor characteristics, to be significantly associated with survival while thrombus level was not significant.

Some limitations of our study include the fact that this is a retrospective study at a single institution. The data also spans multiple decades from 1970 to the present. Given the relatively uncommon diagnosis of tumor thrombosis, it is difficult to get an appreciable number of subjects without spanning multiple decades. However, this opens up the possibility of confounding variables given advancement in technology. Staging was primarily determined by venocavogram and bone scans in the earlier time points while modern staging typically involved CT and/or MRI.

5. Conclusion

In patients with T3b or T3c renal cell carcinoma, overall survival is associated with lymph node positivity and peri-nephric fat involvement and not tumor thrombus level. More studies need to be performed in order to further elucidate various prognostic indicators for this unique patient population.

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Abbreviation Key

RCC = Renal Cell Carcinoma,
BMI = Body Mass Index,
AJCC = American Joint Committee,
UICC = Union for International Cancer Control,
TNM = Tumor, Node, Metastasis,
ASA = American Society of Anesthesiologist,
CT = Computerized Tomography,
MRI = Magnetic Resonance Imaging.