

Clinical-Kidney cancer  
Trends and outcomes in contemporary management renal cell carcinoma  
and vena cava thrombus

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Received 9 December 2018; received in revised form 12 April 2019; accepted 13 May 2019

## Abstract

**Introduction:** We sought to analyze the safety, efficacy, and national trends in the use of robotic radical nephrectomy (RN) and inferior vena cava thrombectomy in patients with renal cell carcinoma.

**Patients and Methods:** We analyzed 872 patients from the National Cancer Database dataset who underwent open ( $n = 838$ , 96.1%) or robotic ( $n = 34$ , 3.9%) radical nephrectomy with inferior vena cava thrombectomy for cT3b renal cell carcinoma between 2010 and 2014. Length of stay (LOS), 30-day readmissions and 30-day mortality were compared between the 2 groups. As internal validation, we performed a multi-institutional analysis of 20 patients (9 open [45%] vs. 11 robotic [55%]) undergoing RN with a level II thrombus. Patients were compared in terms of baseline characteristics, peri- and postoperative outcomes. Uni- and multivariable models were used adjusting for clinical and tumor characteristics.

**Results:** Baseline characteristics were similar between the 2 groups in both datasets. In the National Cancer Database, robotic approach was associated with 26% reduction in LOS ( $P < 0.001$ ) but no difference in readmissions (odds ratio [OR] = 0.91; 95% confidence interval [CI] = 0.05, 4.50;  $P = 0.925$ ) or 30-day mortality (OR = 2.72; 95% CI = 0.40, 10.86;  $P = 0.211$ ). In multicenter database, open group had significantly greater blood loss (600 vs. 100.0 mL,  $P = 0.020$ ). The rate of blood transfusion was higher in the open group, but was not significant (44.4% vs. 18.2%,  $P = 0.336$ ). Robotic group had a shorter LOS (1 vs. 5 days;  $P = 0.026$ ). No difference was seen between the open and robotic groups in terms of operative time (226 vs. 260 minutes,  $P = 0.922$ ) and postoperative complications ( $P > 0.999$ ).

**Conclusion:** In select cases and experienced hands, robotic approach offers a reasonable alternative to open surgery without an increased complication rate. © 2019 Elsevier Inc. All rights reserved.

**Keywords:** Renal cell carcinoma; Inferior vena cava thrombus; Robotic radical nephrectomy; Open radical nephrectomy; Thrombectomy

## 1. Introduction

Due to incidental detection, the majority of renal cell carcinoma (RCC) are diagnosed as organ confined disease

[1]. However, approximately 25% of RCC cases are diagnosed with advanced stage disease [2]. Inferior vena cava (IVC) extension in locally advanced disease has a reported incidence of up to 10% [3]. Among them, approximately 44% of patients will have distant metastases [4]. Therefore, complete surgical resection is the only curative option in these patients. Guidelines recommend surgical

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management with radical nephrectomy (RN) and IVC thrombectomy in this setting [5].

RN and IVC thrombectomy is a technically challenging surgery with a late convalescence, high complication rate and up to 10% perioperative mortality [6]. Depending on the level of thrombus, occlusion of the IVC and the presence of collateral veins, thrombectomy can be extremely challenging. Therefore, it is traditionally managed with an open approach [7]. However, robotic case series up to level III have been published since the emergence of the surgical robot [8–10].

Little data exists regarding the safety of the robotic approach compared to open surgery, especially in level II tumor thrombi. Therefore, we used the National Cancer Database (NCDB) to analyze the trends in the use of robotic surgery in treating cT3b masses, and compare safety and feasibility of the 2 approaches. Furthermore, we utilized a contemporary cohort of patients and performed a similar comparative analysis using a multi-institutional database.

## 2. Materials and methods

### 2.1. National Cancer Database

#### 2.1.1. Data source and eligibility

The NCDB is a collaborative project of the American College of Surgeons and the American Cancer Society and contains patient-level and hospital-level data from 1,500 commission on cancer hospitals, including an estimated 70% of all new cancer diagnoses in the United States [11]. The NCDB data file included 390,884 patients diagnosed with kidney cancer between 2004 and 2014. Patients with non-cT3b kidney cancer were excluded ( $n=383,829$ ) as were patients that did not undergo RN + IVC thrombectomy ( $n=2,787$ ). Additionally, patients diagnosed prior to 2010 were excluded as the NCDB does not maintain surgical modality data on these patients ( $n=1,782$ ). Patients that did not have pT3 or pT4 on final pathology were excluded to ensure accuracy of the analysis ( $n=14$ ). Additionally, patients that received treatment other than or in addition to RN + thrombectomy before surgery or within 30 days after surgery such as immunotherapy, hormone therapy, radiation or any palliative care were excluded ( $n=120$ ).

Using the SURG\_APPR variable in the NCDB dataset, patients with codes (1 = Robotic Assisted and 2 = Robotic Converted to Open) were in the robotic group and patients with code (5 = Open or approach unspecified) were in the open group. No patients in the laparoscopic groups were included. Overall, there were 872 patients included that met eligibility criteria including 838 (96.1%) open patients and 34 (3.9%) robotic RN + IVC thrombectomy patients.

#### 2.1.2. Covariates and statistical analysis

Clinical and tumor-specific variables were compared between the open and robotic approaches patients including age, gender, race, insurance, income and education based on zip-code, distance to the hospital from the patient's home,

Charlson-Deyo score (0, 1,  $\geq 2$ ), year of diagnosis, hospital type, clinical stage, time to first treatment from diagnosis, receipt of regional lymph node dissection. The 3 outcomes analyzed included length of stay (LOS), unplanned hospital readmissions (UHR) and 30-day mortality.

Clinical and tumor-specific categorical variables were compared with chi-squared tests of independence or Fisher's exact tests and continuous variables were compared with Mann-Whitney U tests. Outcomes were compared using univariable and multivariable regression models including binary logistic regressions for 30-day mortality and UHR while a Poisson regression model was used for LOS. Multivariable models included pretreatment clinical and tumor-specific characteristics associated with open vs. robotic approach at the  $P < 0.20$  level as well as the outcome analyzed at the  $P < 0.20$  level. All statistical analysis was performed using R.

### 2.2. Multi-institutional database

#### 2.2.1. Data source and eligibility

The second database we used was an IRB-approved multi-institutional database of kidney cancer patients, to identify patients who underwent RN and IVC thrombectomy from 2014 to 2017. Data were available from 4 institutions with 6 surgeons; 2 performed open procedures and 4 performed the robotic. Mayo classification was used for assessing thrombus level. Only patients with a level II thrombus were included. According to Mayo classification, level II thrombus is described as a thrombus extending into the IVC over 2 cm, but not to the hepatic vein [3]. Overall, there were 9 patients that underwent surgery via an open approach and 11 patients that underwent surgery via a robotic approach. None of the patients had metastatic disease in more than one site. Angioembolization was not performed in any of the patients. There were 2 cases of intraoperative conversion from robotic to open approach and were included in the robotic arm as intent to treat analysis.

#### 2.2.2. Covariates and statistical analysis

Between the open and robotic RN patients, we compared baseline demographic and tumor-specific covariates including age, gender, body mass index, Charlson-comorbidity index, hypertension, diabetes, baseline estimated glomerular filtration rates (eGFR), tumor size and tumor laterality. Pathologic variables including histologic subtype, presence of sarcomatoid features, grade and pathologic stage were compared. Furthermore, whether the RN was cytoreductive and whether a lymph node dissection was performed was included in the analysis. Peri- and postoperative outcomes including estimated blood loss, blood transfusion rates, LOS, complications and eGFR decline at discharge were compared. Continuous variables were compared with

Mann-Whitney U tests while categorical variables were compared with Fisher's exact tests.

### 3. Results

#### 3.1. National Cancer Database

##### 3.1.1. Patient, tumor and treatment-specific covariates

There were no statistically significant differences in any characteristics were observed between the open and robotic groups including age (63.4 vs. 66.1 years,  $P = 0.177$ ),

Charlson score ( $P = 0.755$ ), hospital type ( $P = 0.401$ ), year of diagnosis (2012 vs. 2014,  $P = 0.411$ ) or tumor size (9.1 vs. 10.0 cm,  $p = 0.790$ ) (Table 1). There were 2 conversions (5.8%) to open in the robotic group. Use of robotic surgery did not increase over the years ( $P = 0.441$ ) (Fig. 1). Types of treatment facilities are shown in Fig. 2.

##### 3.1.2. Length of stay

The median LOS for the overall cohort was 6 days (IQR 4–8; Range 1–105). The median LOS was 4 days

Table 1  
Distribution of patient, tumor and treatment specific covariates in NCDB

	Open RN + IVC thrombectomy	Robotic RN + IVC thrombectomy	P value
N	838 (96.1%)	34 (3.9%)	
Age	63.4 (27–90)	66.1 (45–85)	0.177
Gender			0.374
Female	260 (31.0%)	13 (38.2%)	
Male	578 (69.0%)	21 (61.8%)	
Race			0.223
White	722 (87.3%)	33 (97.1%)	
Black	70 (8.5%)	1 (2.9%)	
Other	35 (4.2%)	0 (0.0%)	
Primary insurer			0.616
None	36 (4.2%)	1 (2.9%)	
Private	377 (45.3%)	12 (35.3%)	
Medicaid	52 (6.2%)	3 (8.8%)	
Medicare	350 (42.0%)	17 (50.0%)	
Other	18 (2.2%)	1 (2.9%)	
Income			0.468
<\$47,999	371 (44.5%)	13 (38.1%)	
≥ 48,000	462 (55.5%)	21 (61.8%)	
Education (No HS diploma)			0.303
≥ 13%	369 (44.2%)	12 (35.3%)	
<12.9%	465 (55.8%)	22 (64.7%)	
Residence			0.807
Metropolitan	626 (77.5%)	28 (82.4%)	
Urban	158 (19.6%)	6 (17.6%)	
Rural	24 (3.0%)	0 (0.0%)	
Distance	26.9 (0.5–1977.3)	18.5 (2.7–165.4)	0.103
Charlson-Deyo score			0.755
0	606 (72.3%)	25 (73.5%)	
1	173 (20.6%)	8 (23.5%)	
2+	59 (7.0%)	1 (2.9%)	
Hospital type			0.401
Community	18 (2.2%)	1 (2.9%)	
Comprehensive community	164 (19.9%)	6 (17.6%)	
Academic	579 (70.2%)	22 (64.7%)	
Integrated network	64 (7.8%)	5 (14.7%)	
Year of diagnosis	2012 (2010–2014)	2012 (2010–2014)	0.411
Tumor size (cm)	9.1 (0.8–33.8)	10.0 (0.3–16.0)	0.790
Clinical N stage			>0.999
cN0	693 (82.7%)	29 (85.3%)	
cN1	116 (13.8%)	4 (11.8%)	
cNx	29 (3.5%)	1 (2.9%)	
Clinical M stage			0.152
cM0	610 (76.0%)	27 (87.1%)	
cM1	193 (24.0%)	4 (12.9%)	
Days to surgery From diagnosis	14 (0–472)	11 (0–127)	0.861
Regional lymph Node dissection	562 (67.8%)	18 (54.5%)	0.112

IVC = inferior vena cava; NCDB = National Cancer Database; RN = radical nephrectomy.

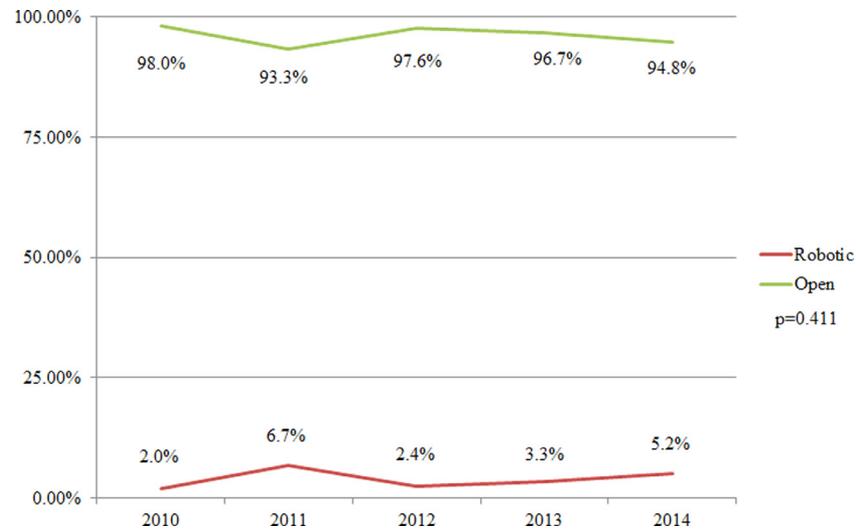


Fig. 1. Use of robotic radical nephrectomy and IVC thrombectomy by year.

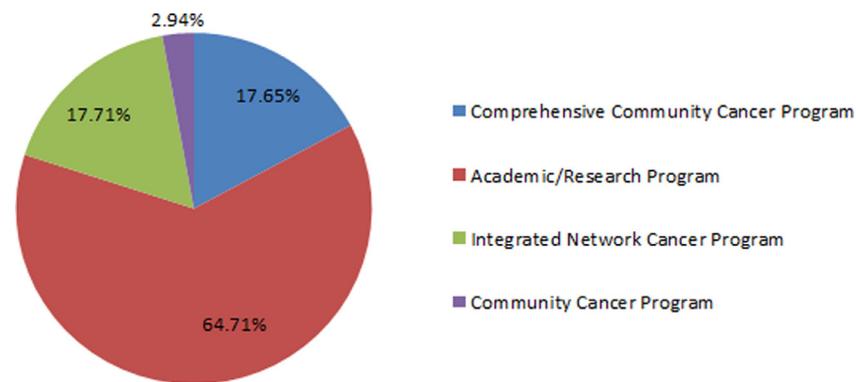


Fig. 2. Distribution of robotic IVC thrombectomy by types of facility.

(IQR 2–7; Range 1–40) vs. 6 days (IQR 4–8; Range 1–105) in favor of the robotic approach ( $P = 0.001$ ). In univariable analysis, the robotic approach was associated with a 24% reduction in the LOS ( $\beta = -0.27$ ; 95% CI =  $-0.42, -0.13$ ;  $P < 0.001$ ). In multivariable analysis adjusting for age, Charlson-Score, LND and cM1, this was confirmed with the robotic approach being associated with a 26% reduction in the LOS ( $\beta = -0.30$ ; 95% CI =  $-0.46, -0.15$ ;  $P < 0.001$ ) (Table 2).

### 3.1.3. Unplanned hospital readmissions (UHR)

Overall, there were 33 (3.8%) UHR with no statistically significant difference between the open vs. robotic approaches (3.8% [ $n = 32$ ] vs. 2.9% [ $n = 1$ ]) in univariable analysis ( $P = 0.790$ ). Furthermore, in multivariable analysis adjusting for age, Charlson-Score, LND, cM1, robotic approach was not associated with a difference in UHR (OR = 0.94; 95% CI = 0.05, 4.75;  $P = 0.952$ ) (Table 2).

### 3.1.4. 30-day mortality

Overall, there were 18 (2.6%) deaths occurring within 30 days of surgery with no statistically significant

difference between the open vs. robotic approaches (2.4% [ $n = 16$ ] vs. 8.0% [ $n = 2$ ]) in univariable analysis ( $P = 0.104$ ). Of the 2 deaths in the robotic group, 1 was in a patient who had their procedure converted to open. Furthermore, in multivariable analysis, robotic vs. open approach was also not associated with a difference in 30-day mortality (OR = 2.72; 95% CI = 0.40, 10.86;  $P = 0.211$ ) when adjusting for age and Charlson-score (Table 2).

## 3.2. Multi-institutional database

### 3.2.1. Patient and tumor characteristics

Baseline characteristics are summarized in Table 3. Baseline tumor characteristics were similar, including the tumor size (10.0 cm vs. 8.4 cm,  $P = 0.743$ ). There were 2 patients in both groups with metastatic disease at baseline ( $P > 0.999$ ).

### 3.2.2. Perioperative outcome, and complications

Two patients were converted to open surgery. One case was converted due to the fibrotic tissues around the IVC

Table 2  
Length of stay, unplanned hospital readmissions and 30-day mortality in NCDB

	Univariate			Multivariate			
	Open	Robotic	<i>P</i> value	Open	Robotic	95% CI	<i>P</i> value
Length of stay (days)	6 (4–8)	4 (2–7)	0.001	Ref.	$\beta = -0.27$	-0.42, -0.13	<0.001
UHR	32 (3.8%)	1 (2.9%)	0.790	Ref.	OR = 0.94	0.05, 4.75	0.952
30-day mortality	16 (2.4%)	2 (8%)	0.104	Ref.	OR = 2.72	0.40, 10.86	0.211

NCDB = National Cancer Database; UHR = unplanned hospital readmissions.

Table 3  
Patient and tumor-specific characteristics of patients undergoing open vs. robotic radical nephrectomy + IVC thrombectomy in multi-institutional database

	Open	Robotic	<i>P</i> value
N	9 (45.0%)	11 (55.0%)	
Age	65.0 (30.0–85.0)	64.0 (49.0–78.0)	0.696
Male	8 (88.9%)	6 (54.5%)	0.157
BMI	30.2 (22.8–39.5)	27.7 (21.4–45.5)	0.549
Hypertension	4 (50.0%)	4 (50.0%)	>0.999
Diabetes	1 (12.5%)	3 (37.5%)	0.569
Baseline eGFR	59.6 (30.4–80.6)	71.6 (44.5–112.9)	0.142
Tumor size	10.0 (6.0–18.5)	8.4 (5.0–15.7)	0.743
Tumor in right kidney	8 (88.9%)	8 (100%)	>0.999
Cytoreductive nephrectomy	2 (22.2%)	2 (18.2%)	>0.999
Lymph node dissection*	2 (22.2%)	7 (70.0%)	0.070
Histologic subtype*			>0.999
Clear cell	8 (88.9%)	8 (72.7%)	
Papillary	0 (0.0%)	0 (0.0%)	
Chromophobe	0 (0.0%)	2 (18.2%)	
Leiomyosarcoma	1 (11.1%)	1 (9.09%)	
Sarcomatoid features	1 (11.1%)	2 (18.2%)	>0.999
Grade*			>0.999
1	0 (0.0%)	0 (0.0%)	
2	1 (14.3%)	2 (22.2%)	
3	4 (57.1%)	4 (44.4%)	
4	2 (28.6%)	3 (33.3%)	
Pathologic T stage			0.336
pT3a	5 (55.6%)	8 (72.7%)	
pT3b	4 (44.4%)	2 (18.2%)	
pT4	0 (0.0%)	1 (9.09%)	
Pathologic N status			0.842
pN0	5 (55.6%)	4 (36.3%)	
pN1	1 (11.1%)	2 (18.2%)	
pNx	3 (33.3%)	5 (45.4%)	
Pathologic M status			0.711
pM0	1 (11.1%)	0 (0.0%)	
pM1	0 (0.0%)	1 (9.09%)	
pMx	8 (88.9%)	10 (90.9%)	

Categorical variables compared with fisher's exact tests; Continuous variables compared with Mann-Whitney U Tests – Medians (Range) presented.

*P* values in bold indicate statistical significance at the  $P < 0.05$  level.

BMI = body mass index; eGFR = estimated glomerular filtration rates.

and the second case was converted due technical challenges in clamping the proximal end due to perceived tumor extension. The open group tended to have significantly greater blood loss (600 vs. 100.0 mL,  $P = 0.020$ ) and a significantly longer LOS (5 vs. 1 days;  $P = 0.026$ ). The rate of blood transfusions was higher in the open group, but not significant ( $n = 4$ , 44.4% vs.  $n = 2$ , 18.2%,  $P = 0.336$ ). No

difference was seen amongst the 2 groups in terms of operative time (226 vs. 260 minutes,  $P = 0.922$ ), postoperative complications ( $n = 2$ , [22.2%] vs.  $n = 1$  [9.09%],  $P > 0.999$ ) and major (Clavien  $\geq 3$ ) complications ( $n = 1$  [11.1%] vs.  $n = 0$  [0%],  $P > 0.999$ ) (Table 4). The 2 complications in the open group were a postoperative pulmonary embolus causing death and a hematoma that was treated

Table 4

Outcome of patients undergoing open vs. robotic radical nephrectomy + IVC thrombectomy from the multi-institutional database

	Open	Robotic	P value
Conversion to open	0 (0.0%)	2 (18.2%)	n/a
Operative time	226.0 (149.0–449.0)	260.0 (165.0–381.0)	0.922
Estimated blood loss	600.0 (350.0–7500.0)	100.0 (25.0–2300.0)	0.020
Blood transfusions	4 (44.4%)	2 (18.2%)	0.336
Length of stay	5 (0–17)	1 (1–5)	0.026
Postoperative Complications			
Any	2 (22.2%)	1 (9.09%)	>0.999
Major (Clavien 3+)	1 (11.1%)	0 (0.0%)	>0.999
Positive surgical margin	6 (66.7%)	2 (18.2%)	0.175
% change eGFR discharge	–5.5% (–45.8% – 87.0%)	–24.5% (–39.4% – 12.9%)	0.864

Categorical variables compared with Fisher's exact tests; Continuous variables compared with Mann-Whitney U Tests – Medians (Range) presented.

P values in bold indicate statistical significance at the  $P < 0.05$  level.

eGFR = estimated glomerular filtration rates; IVC = inferior vena cava.

conservatively. The 1 complication in the robotic group was urinary retention that was treated with conservatively with an alpha-blocker.

#### 4. Discussion

The benefit of minimally invasive surgery over open surgery is rapid convalescence, decreased bleeding, and shorter LOS [12]. Our results from our multi-institutional series demonstrated that robotic approach resulted in decreased bleeding shorter LOS in patients who underwent RN and level II IVC thrombectomy for RCC. The NCDB analysis demonstrated a decreased LOS and equivalent unplanned readmission and 30-day mortality rates.

Regardless, IVC thrombectomy should be performed with caution, as it has a mortality rate of 4% to 10% [13], which correlates with our results. Uncontrolled hemorrhage and pulmonary thromboembolism are 2 possibly fatal complications of this procedure. In IVC thrombectomy, dislodgement of tumor thrombus can result in pulmonary embolus as also occurred in our series. Care should be taken to minimize the disruption of the thrombus during IVC mobilization [8]. We did not see perioperative mortality in the robotic group. For the robotic approach, minimal manipulation of the kidney is necessary prior to IVC control, thus possibility leading to lower risk of emboli.

Due to the aforementioned risks and challenges, patient selection is key. Cross sectional imaging gives valuable input. Characteristics of the thrombus should be assessed carefully. Level II thrombus can range from 2 cm into the IVC to the hepatic vein bifurcation. Therefore, there is a variability in the size of the thrombus. The degree of IVC obstruction, the presence and the size of collaterals affect the surgical outcome. Collateral veins can allow us to transect the IVC, or they can make the surgery more difficult. Presence of lymph nodes is another factor, since large and inflamed lymph nodes are not easy to dissect from the IVC. Moreover, space is limited in robotic approach, and thus tumor size and volume play a key role. Therefore, smaller

kidneys and more endophytic located tumors are better candidates for robotic approach. For left kidney tumors, right kidney may have to be clamped, which would require the mobilization of the aorta. Surgeons should be prepared for complicated situations where vascular surgery can be involved robotically or by converting to open surgery.

Despite the more than a decade long robotic surgery experience, a significant majority of T3b tumors in the nation were operated by an open approach. This is expected, since open surgery remains the standard of care in this setting. Furthermore, the majority of robotic cases were performed at academic centers. Due to the perioperative mortality rate [6], care must be taken to minimize the risks of the procedure, and surgeons should have a low threshold for conversion to open surgery [9]. We have seen an acceptable conversion rate in both datasets. Regardless, considering the stage of the disease, oncological principles should take precedence over the modality of the surgery.

Despite the aforementioned challenges and risks, the complication rate and consequent unplanned hospital readmission rate in NCDB was similar between the 2 groups. Furthermore, robotic approach is associated with a decreased LOS. Our results are supported by the findings of Gu et al., who reported a comparative analysis of open vs. robotic radical nephrectomy with IVC thrombectomy. Their results demonstrated lower estimated blood loss (250 mL vs. 1,000 mL,  $P < 0.001$ ) and lower transfusion rate (6.5% vs. 54.8%,  $P < 0.001$ ), and a shorter LOS (5 vs. 9 days,  $P < 0.001$ ) [14]. The weakness of their study was the baseline differences between the 2 groups. They performed a 1:1 match pair analysis to overcome this difference. Furthermore, their cohort was a mix of level I and II thrombi, whereas we analyzed level II thrombi only. Regardless, both studies demonstrate the feasibility of the robotic approach in select cases.

Since our study is of retrospective design, there is an inherent selection bias. In both datasets, baseline characteristics were similar between the 2 groups. However, the equivalency of the 2 groups may result from the unaccounted tumor/thrombus characteristics. The presence of

collaterals, lymph nodes, and local invasion are key factors in assessment of case difficulty and were not adjusted for. In our multi-institutional cohort, we restricted our analysis to level II thrombi to standardize the thrombus characteristics and analyze a technically more difficult cohort. Thrombus characteristics were not analyzed in the NCDB cohort due to the lack of data.

The low number of patients is another limitation, however due to the rarity of curable level II IVC thrombus cases, this is difficult to overcome. In fact, the majority of studies in literature have low sample sizes despite the multi-institutional designs [15]. While considered a limitation, what this may show is that proper selection of patients leads to successful robotic outcomes. Furthermore, ours is one of the 2 studies that compare open approach with robotics [14]. However, our results alone cannot establish robotic surgery as an equal to the open approach. While we do demonstrate that the robotic approach is a safe and less morbid alternative in selected cases, generalizability of our results is questionable, since the robotic group is comprised of highly experienced surgeons. Even though NCDB represents a more generalizable cohort, sample size is too limited and surgeries were most likely performed by experienced high-volume surgeons. However, NCDB does not possess granular data regarding thrombus characteristics, and therefore is limited to pT3b tumors. Regardless, surgical experience is a prerequisite for performing robotic IVC surgery, and only experienced robotic surgeons should attempt this complex procedure. This holds true for open surgery as well. Finally, the NCDB cohort was made up of patients up to 2014, which marks the earlier periods of IVC thrombectomy reports. As the experience grows in the urologic community, future updates on the NCDB is likely to include a higher rate of robotic cases.

## 5. Conclusion

Robotic RN and IVC thrombectomy for a level II thrombus was associated with comparable transfusion rate and a shorter LOS compared to open RN. In select cases and experienced hands, robotic approach offers a reasonable alternative to open surgery without an increased complication rate.

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