

Clinical-Kidney cancer
A preoperative nomogram to predict major complications after robot assisted partial nephrectomy (UroCCR-57 study)

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Abstract

Objective: To generate a nomogram based on preoperative parameters to predict the occurrence of a major complication within 30-days of robotic partial nephrectomy.

Materials and methods: The study included 1,342 patients with a clinically localized renal tumor who underwent robotic partial nephrectomy (RPN) between 2010 and 2017 at 7 academic centers. The primary outcome was the major complication rate. A multivariable logistic regression model was fitted to predict the risk of major complications after RPN. Model-derived coefficients were used to calculate the risk of major complications. Local regression smoothing technique was used to plot the observed rate against the predicted risk of major complications.

Results: In multivariate logistic regression, male gender (odds ratio [OR]: 2.93; $P=0.03$), Charlson comorbidity index (OR: 1.13; $P=0.05$), ECOG PS (OR: 1.66; $P=0.02$), low hospital volume ($P < 0.05$), and high RENAL score (OR: 4.73; $P=0.01$) were significant predictors of major postoperative complications. A preoperative nomogram incorporating these risk factors was constructed with an area under curve of 75%.

Conclusions: Using standard preoperative variables from this multi-institutional RPN experience, we constructed and validated a nomogram to predict postoperative complications after RPN. We believe this tool can be relevant to help weighing treatment options for a more tailored management of patients with small renal masses. © 2019 Elsevier Inc. All rights reserved.

Keywords: Partial nephrectomy; Robotic surgical procedures; Nephrometry scores; Complications; Nomogram

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1. Introduction

Partial nephrectomy (PN) is the preferred option to treat small renal tumors when technically feasible [1]. The robotic approach has been widely adopted over the past 10 years, allowing the treatment of more complex tumors and widening the indications of minimally invasive PN.

Although robotic PN (RPN) is now used routinely, it remains a relatively morbid operation with complications reported in up to 30% of the cases [2]. In this context, identifying patients at greater risk of postoperative complications is critical to reduce perioperative morbidity as well as healthcare costs and guide therapeutic decision at a time when there is increasing evidence that ablative therapies and active surveillance can provide optimal oncological control [3].

There have been numerous studies reporting risk factors associated with complications after RPN. It has been suggested that RPN complications could be driven by tumor complexity [4], tumor environment [5], patients' comorbidities [6], and provider's volume [7]. While these studies emphasize on some of these risk factors, they do not provide any tool that can predict complications.

Our objective was to develop and internally validate a nomogram to predict the risk of major postoperative complications after RPN.

2. Materials and methods

2.1. Patients and study design

After institutional review board approval (UroCCR database—ClinicalTrials.gov: [NCT03293563](#)/CNIL agreement DR-2013-206), we retrospectively reviewed the data of 1,342 patients with clinically localized renal tumor who underwent RPN at 7 academic medical centers between 2010 and 2017. We specifically focused on preoperative clinical, laboratory, and radiological variables that were available before surgery.

2.2. Surgical technique

Standardization of surgical technique was not possible due to the multicenter and retrospective design of the study. All surgeries were performed with the da Vinci Si Surgical System (Intuitive, Sunnyvale, CA). Both retroperitoneal and transperitoneal approaches were used. The technique used for RPN, including sliding-clip renorrhaphy [8] and the use of early unclamping [9] have already been described and were relatively homogeneous among centers. Drain placement was left at the surgeon's discretion.

2.3. Covariates

Demographics, preoperative blood tests, and radiological characteristics were collected prospectively in a

computerized database. Demographics included: age, gender, American Society of Anesthesiologists classification, body mass index, Charlson's comorbidity index (CCI), history of cardiovascular disease, history of hypertension, history of diabetes, history of smoking, Eastern Cooperative Oncology Group (ECOG) score, anticoagulant/antiplatelet treatments, and previous abdominal surgery. Radiological characteristics included tumor size, RENAL and Mayo adhesive probability (MAP) score. Preoperative blood tests included hemoglobin, platelet, and white blood cells, estimated glomerular filtration rate calculated using the abbreviated Modification of Diet in Renal Disease formula. Cardiovascular disease was defined as a history of angor, myocardial infarction, congestive heart failure, or peripheral vascular disease. Previous abdominal surgery was defined as any open or laparoscopic procedure in the peritoneal cavity. Hospital volume (HV) was categorized based on a previous publication into 4 quartiles according to the caseload per year: low HV (<20/y); moderate HV (20–44/y); high HV (45–70/y); and very high HV (>70/y) [10].

2.4. Radiological parameters

Preoperative CT scans and/or MRI were analyzed to evaluate RENAL and MAP scores. Imaging was reviewed independently at each institution. The RENAL score was calculated as described by Kutikov [11]. Tumors were stratified as low (score 4–6), intermediate (score 7–9), and high (score 10–12) complexity. The MAP score was calculated as described by Davidiuk by measuring posterior renal fat thickness and the importance of perinephric fat stranding [12].

2.5. Grading of complications

Perioperative complications occurring within 30-days of surgery were graded using the modified Clavien-Dindo scale [13]. Minor complications were classified as Clavien II or less, while major complications were grade III or greater. Complications were reported according to the EAU guidelines statement [14].

2.6. Statistical analysis

Continuous data are presented as median and range and categorical data as number of patients (percentage of sample). Analyses were performed to develop a model utilizing preoperative factors for predicting major postoperative complications occurring within 30-days of surgery. Associations were summarized using odds ratios and 95% confidence intervals from univariable and multivariable logistic regression models. Significant variables following multivariate competing risks analysis were used to construct a predictive nomogram. We used STATA/SE 13.0, and the nomolog program to generate a Kattan-style nomogram, based on a binary logistic regression model. The predictive

accuracy of the nomogram was evaluated using receiver operating characteristics curves. The internal validity of the prediction model was evaluated by 200 bootstrap resamples. The extent to which our predictive model under- or overestimates risk of postoperative complications was evaluated graphically with a nonparametric, local regression smoothing technique. All statistical tests were 2 sided, with significance set at a *P* value <0.05. Analyses were all conducted with STATA 13.0 (College Station, TX).

3. Results

A total of 1,342 patients were included in this study. [Table 1](#) summarizes the characteristics of the population. In total, 875 (65%) men and 467 (35%) women with a median age of 60 years (range, 50–67) and a body mass index of 28 (range, 24–33) were included. History of hypertension (46%), smoking (27%), diabetes (14%), and cardiovascular disease (18%) were the leading concurrent medical diagnoses. When considering comorbidity scores, ECOG performance status was ≥ 1 in 23% of the cohort, American Society of Anesthesiologists score was >2 in 27% of the patients, and median CCI score was 3 (range, 2–5). Median tumor size was 33 mm (range, 20–47). Median RENAL and MAP scores were 7 (range, 5–9), and 2 (range, 0–4), respectively. A total of 588 (44%), 582 (43%), and 171 (13%) tumors were classified as low, intermediate, or highly complex, respectively. Median preoperative estimated glomerular filtration rate was 86 ml/min (range, 71–100 ml/min) and median preoperative hemoglobin was 13.8 mg/dl (range, 13–15 mg/dl). Numbers of procedures per center is reported on [supplementary table 1](#)

Overall, 326 patients (24%) had a complication including 189 (14%) \leq grade 2 and 137 (10%) \geq grade 3. There were 7 (0.5%) deaths within 30 days of RPN.

Univariate and multivariate logistic regression analyses were carried out to identify independent predictors of major (\geq grade 3) postoperative complications ([Table 2](#)). In univariate analysis, male gender, CCI, ECOG PS, tumor size, RENAL score, HV, and history of cardiovascular disease were all significant predictors of major complications. In multivariate analysis, male gender, CCI, ECOG PS, HV, and RENAL score remained significant predictors of major complications.

The nomogram is shown in [Fig. 1](#). For example, a man (4.4 pts) with an ECOG performance status of 1 (3 pts), CCI of 6 (4.7 pts), an intermediate tumor (4.2 points), and operated at a low volume hospital (9.2 pts) will have a total of 25.5 points which means a 40% risk of major complication.

The AUC, that evaluates the predictive discrimination of the model, was 0.75. After internal validation using bootstrapping, the AUC was 0.74 ([Figs. 2 and 3](#)).

The local regression nonparametric smoothing plot is depicted in [Fig. 4](#). Our nomogram overestimates the risk of major complication for values between 0% and 40%

Table 1
Characteristics of the study population.

Variable		
Patients, <i>n</i>		1,342
Patient factors		
Age, median (IQR)	60	(50–67)
Gender, <i>n</i> (%)		
Male	875	(65.20)
Female	467	(34.80)
Comorbidities, <i>n</i> (%)		
Cardiovascular disease (%)	243	(18.11)
Hypertension	624	(46.50)
Diabetes	186	(13.86)
History of smoking	357	(26.60)
BMI, median (IQR)	28	(24–33)
ASA classification, <i>n</i> (%)		
1–2	984	(73.32)
3–4	358	(26.68)
ECOG, <i>n</i> (%)		
0	1,028	(76.60)
≥ 1	314	(23.40)
Charlson's comorbidity index, median (IQR)	3	(2–5)
Previous abdominal surgery, <i>n</i> (%)	407	(30.33)
Anticoagulant/antiplatelet treatments, <i>n</i> (%)	390	(29.06)
Laboratory blood test		
Hemoglobin, median (IQR)	13.8	(12.6–14.6)
Platelet, median (IQR)	221	(189–268)
eGFR preop, median (IQR)	86	(71–100)
White blood cells, median (IQR)	7.2	(6–9)
Radiographic characteristics		
Tumor size, median (IQR)	32	(20–47)
RENAL score, median (IQR)	7	(5–9)
RENAL score, <i>n</i> (%)		
Low	588	(43.82)
Intermediate	582	(43.37)
High	171	(12.74)
MAP score, median (IQR)	2	(0–4)
Surgical technique		
Surgical approach, <i>n</i> (%)		
Transperitoneal	1,138	(84.80)
Retroperitoneal	204	(15.20)
Hilar clamping, <i>n</i> (%)		
Off-clamp	161	(12)
On-clamp	1181	(88)
Hospital volume		
Low HV (<20/y)	164	(12.22)
Moderate (20–44/y)	352	(26.23)
High HV (45–70/y)	503	(37.48)
Very high HV (>70/y)	323	(24.07)
Complications		
Overall complication, <i>n</i> (%)	326	(24.29)
Major complications, <i>n</i> (%)	137	(10.21)

ASA = American Society of Anesthesiologists; BMI = body mass index; ECOG = Eastern Cooperative Oncology Group; MAP = Mayo adhesive probability.

and underestimates this risk for values between 50% and 80%.

4. Discussion

The purpose of this study was to develop a preoperative model to predict complications in patients who undergo

Table 2
Univariate and multivariate analysis for the prediction of postoperative complications.

Variables	Univariate analysis			Multivariate analysis		
	Odds ratio	95% CI	P	Odds ratio	95% CI	P
Age	0.99	0.98–1.01	0.74			
Sex	2.28	1.41–3.68	0.001	2.93	1.06–7.11	0.03
BMI	1.01	0.98–1.04	0.5			
CCI	1.15	1.05–1.25	0.001	1.13	1.02–1.37	0.05
ASA classification	1.39	0.89–2.18	0.14			
ECOG PS	2.08	1.39–3.14	<0.001	1.66	1.07–3.71	0.02
Anticoagulant/antiplatelet treatments	0.87	0.58–1.31	0.503			
Tumor size	1.01	1–1.03	0.02	1	0.98–1.02	0.81
RENAL score						
Low	Ref					
Intermediate	1.84	1.15–2.93	0.01	2.56	1.02–4.98	0.04
High	4.49	2.64–7.65	<0.001	4.73	1.46–8.71	0.01
MAP score	1.13	0.98–1.31	0.08	0.98	0.78–1.21	0.83
Hemoglobin	0.98	0.81–1.21	0.91			
eGFR preop	0.99	0.98–1.00	0.79			
Comorbidities						
Cardiovascular disease	1.58	1.03–2.61	0.05	1.43	0.56–3.66	0.45
Hypertension	1.28	0.85–1.94	0.23			
Diabetes	0.81	0.42–1.51	0.51			
History of smoking	1.42	0.91–2.22	0.11			
Surgical approach, n (%)						
Transperitoneal	Ref					
Retroperitoneal	1.21	0.61–2.41	0.59			
Hilar clamping, n(%)						
Off-clamp	Ref					
On-clamp	0.47	0.11–2.05	0.32			
Hospital volume						
Low HV (<20/y)	Ref			Ref		
Moderate (20–44/y)	0.72	0.39–1.34	0.31	0.11	0.19–0.63	0.01
High HV (45–70/y)	0.56	0.31–1.04	0.06	0.15	0.03–0.58	0.007
Very high HV (>70/y)	0.43	0.21–0.84	0.01	0.10	0.02–0.41	0.001

Bold values indicate $p < 0.05$.

RPN. Gender, CCI, ECOG PS, RENAL nephrometry score, and HV were independent predictors of major complications. These risk factors were used to generate a nomogram that was able to predict major complications with an AUC of 0.75.

To our knowledge, this is the first reported nomogram that takes into account patients, environment, and tumor related factors. We chose to focus on preoperative variables, so the nomogram could be used for patient counseling and treatment decision-making. We believe this tool can be relevant to help weighing the different treatment options contributing to the shift towards more tailored treatment in patients with small renal masses.

Our study has several interesting findings. First, we found a relatively strong linear relationship between comorbidity indices (CCI and ECOG PS) and the occurrence of complications. This is in accordance with previous studies suggesting a major impact of patients' comorbidities on PN outcomes. Tomaszewski et al. highlighted that high-risk patient status (defined as age >75 years or CCI >2) was the most accurate predictor of postoperative complications [15]. Similarly, Bauman et al. showed that cerebrovascular

disease and chronic obstructive pulmonary disease were significant predictors of complications after RPN [16]. Mari et al. also showed that ECOG score was an independent predictor of major surgical complications [17].

Surprisingly, we observed that male gender remained a significant predictive factor in multivariate analysis even after having controlled for comorbidities. The impact of gender on postoperative outcomes in patients undergoing major surgery has been well reported in multiple studies of patients undergoing major surgical procedures [18,19]. Most of these studies showed that male patients had higher complications. Several explanations have been suggested. It is possible that male patients have a higher threshold for pain and therefore seek medical attention later than women [20], which could lead to delayed diagnosis and more serious complications. It is also possible that male patients have undiagnosed comorbidities which could underestimate their Charlson comorbidity index [21].

Second, we found that tumor complexity, evaluated by the RENAL score, was a significant predictor of major complications. The impact of RENAL score has been assessed in several retrospective studies with conflicting

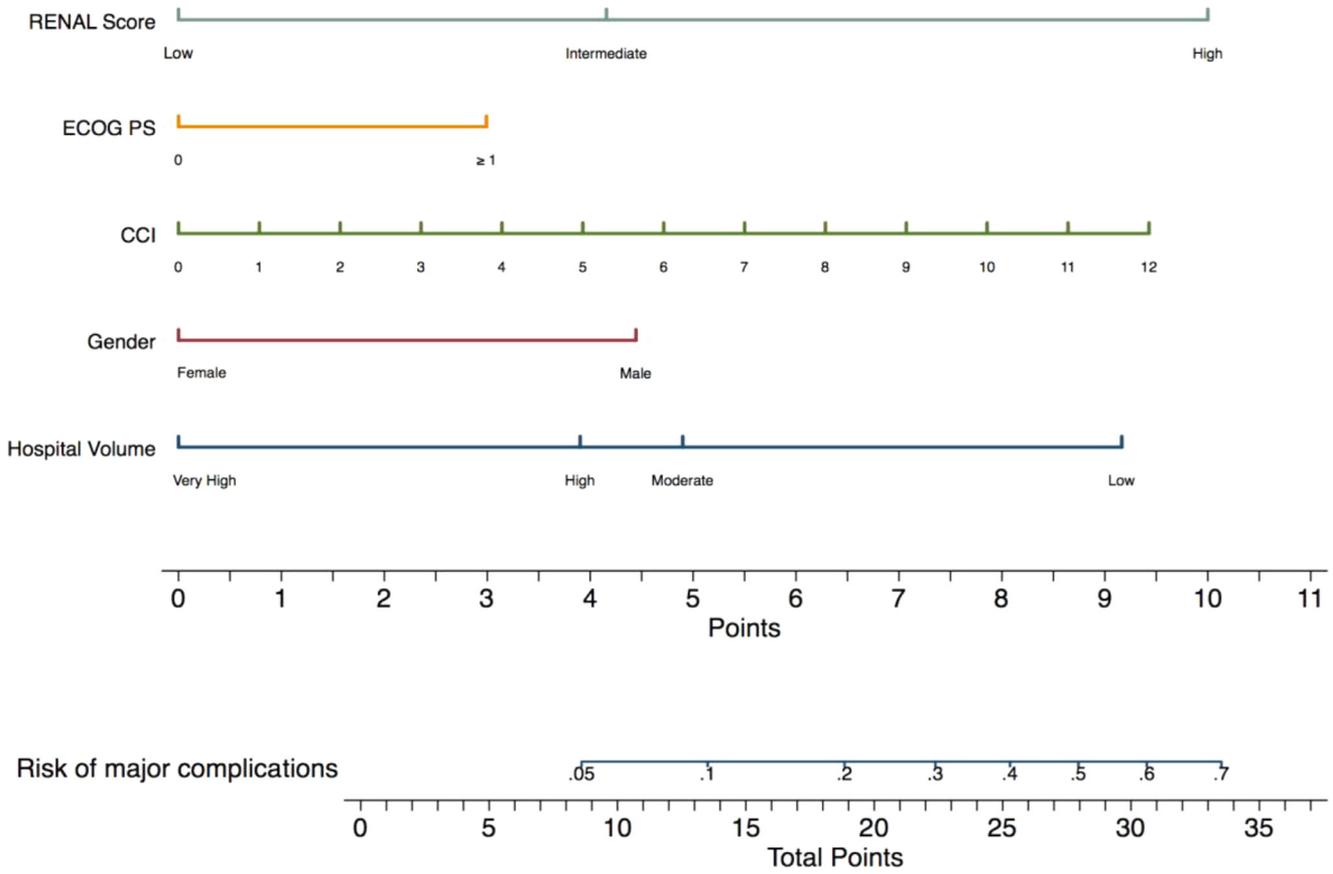


Fig. 1. Nomogram to predict major postoperative complications.

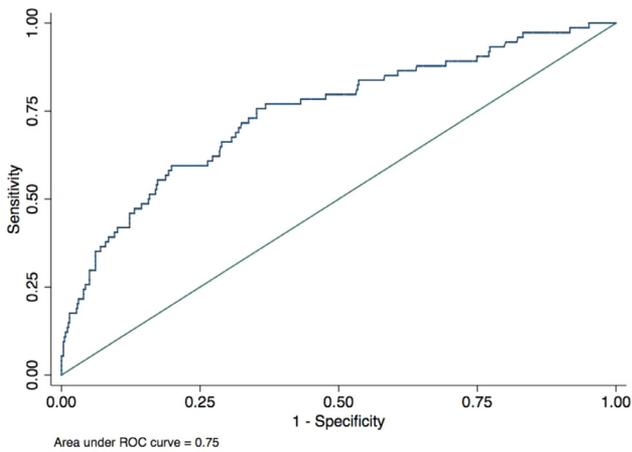


Fig. 2. Development cohort receiver-operating characteristic (ROC) curve.

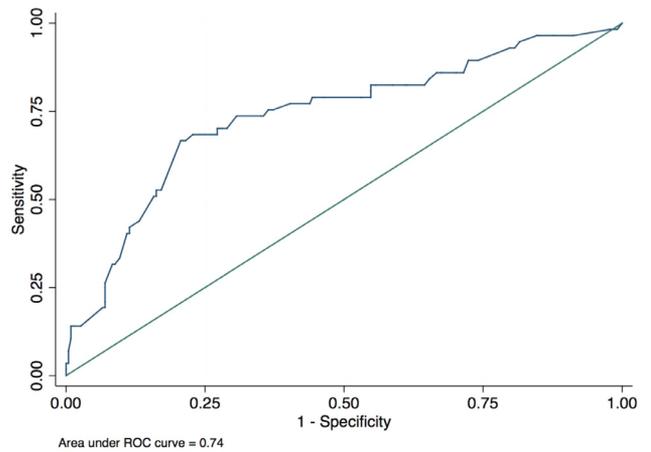


Fig. 3. Internal validation receiver-operating characteristic (ROC) curve.

results. The initial Fox Chase Cancer study reported a strong correlation between tumor complexity and the occurrence of complications [22] but other groups found less convincing results [23,24]. A positive association was reported by Rosevear [25] and Hew [26] but only highly complex tumors, suggesting little benefit of stratifying between low and intermediate groups. On the other hand, Png and Hayn showed similar complication rates between complex and noncomplex tumors [27,28]. One explanation

of this controversy could be the relatively low proportion of highly complex tumors in these series, which could therefore be underpowered.

Another interesting finding is that the MAP score had no impact on postoperative outcomes. This is in line with previous work [29,30] and strengthens the idea that the MAP score is mostly a determinant of intraoperative difficulties (operative time, blood loss, and risk of conversion), rather than a factor contributing to postoperative morbidity.

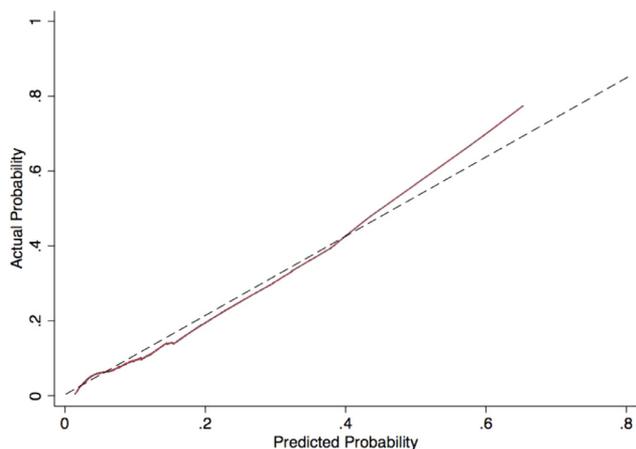


Fig. 4. Local regression nonparametric smoothing plot that shows performance of nomogram relative to observed rates of postoperative complications. Perfect prediction would correspond to slope of 1 (diagonal 45° line).

Finally, our study found that HV was a key determinant of complications after RPN. The impact of HV on perioperative outcomes of RPN has been investigated in several studies. A French multicenter study showed that higher HV was associated with better perioperative outcomes, including diminished length of stay and morbidity [10]. Monn used NIS data and found that patients who underwent RAPN at high volume hospitals had lower rates of complications and transfusions [31]. This volume effect may be explained by the standardization of both surgical technique and management of small renal masses at high-volume tertiary centers.

Nomograms are considered the most accurate tools to build a prognostic model that generates a probability of a clinical event [32]. While they are widely reported in oncology, their use for surgical issues is relatively limited. We believe this is mostly due to “cultural” reasons (i.e. surgeons might have been less exposed to nomograms than oncologists). We tried to design a simple prognostic tool, based on a limited number of variables. By assigning points to only 4 variables, one can simply and quickly estimate the likelihood of a postoperative complication. We additionally provide an online tool that can be easily accessed and used in clinical practice (<https://kidneyroboticsurgery-complications-calculator.org>) to rapidly provide a risk estimation the physician can use to counsel the patient.

The strengths of our study include a large cohort size, accurate evaluation of preoperative variables, and the choice to focus on preoperative factors to maximize clinical utility. Nonetheless, there are some limitations. The major shortcomings were those inherent to the retrospective design. There were subtle differences in surgical technique and perioperative management across centers that could contribute to flaw our results. However, this multi-institutional approach may also allow findings to be more applicable at other centers. The impact of surgeon experience and/or HV is of great interest when evaluating outcomes after

surgical procedures. In the field of robotic assisted PN, published data suggest that HV is a more powerful determinant of postoperative morbidity than surgeon’s experience which is the reason why we decided to include it in our predictive model [10,33]. In this scenario, surgeons’ experiences were voluntary omitted in this report. There was no central imaging review which may have induced heterogeneity to calculate MAP and RENAL scores. It should also be emphasized that the information provided can help the process of decision-making process but does not replace it. Finally, our model has not been validated in an independent cohort.

5. Conclusions

RENAL score, CCI, gender, ECOG PS, and HV were the most important predictive factors of major complications after RPN. We developed a nomogram and a web friendly interface based on these factors to identify patients with a high probability of major complications. We believe this nomogram can help treatment decision making and patient counseling.

Conflict of interest

Karim Bensalah, Nicolas Doumerc, Christophe Vaessen, Alexandre De la Taille, Gregory Verhoest, and Franck Bruyere are consultants for Intuitive Surgical. Other authors have nothing to disclose.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.urolonc.2019.05.007>.

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