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Original Article

Standardized analysis of laparoscopic and robotic-assisted partial nephrectomy complications with Clavien classification

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Abstract

Background: Laparoscopic partial nephrectomy (LPN) and robotic-assisted partial nephrectomy (RPN) are accepted as alternatives of open partial nephrectomy for managing renal tumors. However, LPN and RPN are technically challenging procedures. This report analyzed, according to the Clavien classification, the complications after LPN and RPN.

Methods: We analyzed consecutive LPN ($n = 85$) and RPN ($n = 93$) cases at our institution between April 1994 and December 2012. The data were retrospectively reviewed from a prospectively collected database. All complications that occurred within 3 months postoperatively were recorded and classified according to the modified Clavien classification system.

Results: The mean tumor size was 3.90 ± 1.77 cm. The mean operative time was 255.0 ± 83.5 minutes, and the mean warm ischemia time was 31.6 ± 22.0 minutes. The overall complication rate was 18.5%. Clavien Grades I, II, IIIa, and IIIb complications accounted for 3.93%, 11.2%, 2.81%, and 1.69% of patients, respectively. The most common complication was perioperative hemorrhage that required blood transfusion. Delayed bleeding occurred in seven patients, and four patients underwent angiographic embolization. The proportions of intermediate and high PADUA (Preoperative Aspects and Dimensions Used for an Anatomical) score (≥8) and RENAL (Radius/Exophytic/Nearness to collecting system/Anterior/Location) score (≥7) were 70.8% and 74.2%, respectively. A higher PADUA or RENAL score was associated with a significantly greater complication rate ($p = 0.024$ and $p = 0.02$, respectively).

Conclusion: The overall complication rate in the present study was comparable to that reported in previous studies, although our patients had a larger mean tumor size and higher-complexity procedures.

Keywords: complications; laparoscopy; nephron-sparing surgery; renal tumors; robotics

1. Introduction

Open partial nephrectomy provides excellent long-term oncologic and renal functional outcomes and is currently the standard therapy for managing selected small renal tumors.[1,2] Since the first reports on laparoscopic partial nephrectomy (LPN) by Winfield et al[3] and McDougall et al,[4] this minimally invasive procedure has been broadly accepted and gradually developed. However, the relatively longer learning curve associated with laparoscopic suturing has deterred many urologists from performing LPN. Robotic-assisted partial nephrectomy (RPN) was introduced in 2004, offering advantages such as a magnified three-dimensional view and decreased technical difficulty in intracorporeal suturing, and it has already become a viable alternative to open partial

Conflicts of interest: The authors declare that there are no conflicts of interest related to the subject matter or materials discussed in this article.

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nephrectomy and LPN.[5] However, LPN and RPN are still technically challenging procedures associated with different types of complications.[6–8] In this study, we present the results of our experience with minimally invasive surgery and the method of standardizing complications according to the modified Clavien classification system.

2. Methods

We analyzed 178 consecutive patients who had undergone LPN or RPN at our institution between April 1994 and December 2012. We prospectively collected preoperative baseline demographic data and perioperative data. Information regarding age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, tumor characteristics [tumor size, Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) score, Radius/Exophytic/Nearness to collecting system/Anterior/Location (RENAL) nephrometry score], operative time, estimated blood loss (EBL), and transfusion data were documented. Complications were recorded prospectively and graded according to the modified Clavien classification system (I, II, IIIa, IIIb, IVa, IVb, or V).[9] As several previous studies had shown an association between increasing PADUA and RENAL scores and increasing complication rates,[10–14] a subset analysis was performed to compare complications for simple and complex tumors by using these parameters as objective measures of complexity. All patients underwent preoperative contrast-enhanced computed tomography with three-dimensional volume reconstruction for the evaluation of vascular anatomy, tumor location, depth of invasion, and proximity to the renal sinus or hilum. Maximal tumor diameter (Max T) was calculated using the preoperative computed tomography images.

This study was conducted according to the provisions of the Declaration of Helsinki.

2.1. LPN

A total of 85 patients underwent LPN. Eighty-four procedures were performed via the transperitoneal approach using Veress needle or Hasson access. Only one patient underwent LPN using the retroperitoneal approach because of a history of left hemicolectomy for descending colon cancer 11 years before the operation. The procedure for LPN has been described elsewhere; however, we offer here a brief description, as follows[15]: the hilar vessels and the kidney were dissected from the surrounding tissues, and the perirenal fat covering the tumor was preserved. If it was difficult to clearly identify the tumor invasion area, intraoperative ultrasonography was performed. The hilar vessels were then clamped with laparoscopic bulldog clamps if needed. The renal arteries were clamped first, and the renal veins were clamped based on the surgeon's preference. Subsequently, the tumor was excised using cold scissors and ensuring an adequate safe margin. The frozen section was not routinely examined but only checked in cases of uncertainty. The opened collecting system was repaired using sutures. Hemostasis was achieved by applying energy via electrocautery or an argon beam coagulation and bolster suture. Tissue sealants and thrombogenic agents were used according to the surgeon's decision. Renorrhaphy was performed with traditional tied suture closures with the assistance of Hem-o-locks.

2.2. RPN

RPN was performed in 93 patients using the da Vinci Si Surgical System, and all procedures were performed using the transperitoneal approach with 30° down optics. The procedures were performed with a technique similar to that used for LPN, differing slightly in the subtle variation of renorrhaphy using a sliding-clip method, which has been described previously.[16] Bolster was not routinely used in RPN.

2.3. Definition of complication

Intraoperative hemorrhage was defined as bleeding that required blood transfusion perioperatively. Postoperative bleeding was defined as hematoma confirmed on cross-section imaging or bleeding that required interventions such as reoperation or angioembolization. Urine leakage was defined as urine extravasation, which required prolonged drain maintenance, drain reinsertion, or ureteral stent insertion. Ileus was defined as intestine hypomobility, requiring prolonged hospitalization or nasogastric tube insertion. All complications that occurred perioperatively or within 3 months postoperatively were recorded.

2.4. Statistical analysis

We used SPSS version 18.0 (SPSS Inc., Chicago, IL, USA) for all statistical analyses. The baseline characteristics of the patients are presented as mean ± standard deviation for continuous variables and n (%) for categorical variables. The Mann–Whitney U test was used to compare the numerical variables and Fisher's exact test or Pearson's Chi-square test was used to compare the categorical values. For all statistical analyses, $p < 0.05$ was considered significant. The 95% confidence interval (CI) for the odds ratio (OR) was calculated.

3. Results

Baseline patient demographics and tumor characteristics are listed in Table 1. The mean tumor size on preoperative imaging was 3.90 ± 1.77 (range, 1.40–10.7) cm. The tumor was on the right side in 102 patients (57.0%). Pathological analysis indicated carcinoma in 119 (66.9%), angiomyolipoma in 48 patients (27.0%), oncocytoma in five patients (2.81%), and benign/other in six patients (3.37%). The mean operative time was 255.0 ± 83.5 (range, 100–620) minutes, and the mean warm ischemia time was 31.6 ± 22.0 (range, 0–100) minutes. A total of 33 patients (18.5%) had at least one complication. In 32 patients, complications occurred within 30 days postoperatively, and one patient experienced delayed bleeding requiring angiographic embolization on

Table 1
Baseline characteristics of patients and renal tumors.

Variable	$n = 178$
Age, y	57.1 ± 14.1
BMI	25.1 ± 3.63
Sex	
Female	73 (41.0)
Male	105 (59.0)
ASA score	
1	22 (12.4)
2	115 (64.6)
3	33 (18.5)
LOS (d)	6.14 ± 2.91
Surgical procedures	
LPN	85 (47.8)
RPN	93 (52.2)
Preoperative creatinine	0.94 ± 0.35
Pathology	
Malignancy	119 (66.9)
AML	48 (27.0)
Oncocytoma	5 (2.81)
Benign/other	6 (3.37)
Tumor size (Max T, cm)	
<4	109 (61.2)
4–7	56 (31.5)
>7	13 (7.30)
PADUA score	
6	13 (7.30)
7	39 (21.9)
8	43 (24.2)
9	34 (19.1)
10	28 (15.7)
11	17 (9.55)
12	3 (1.69)
13	1 (0.56)
RENAL score	
4	13 (7.30)
5	14 (7.87)
6	19 (10.7)
7	42 (23.6)
8	38 (21.3)
9	36 (20.2)
10	14 (7.87)
11	2 (1.12)

Data are presented as mean ± SD for continuous variables and *n* (%) for categorical variables.
ASA = American Society of Anesthesiologists; BMI = body mass index; LOS = length of stay; LPN = laparoscopic partial nephrectomy; RPN = robotic-assisted partial nephrectomy.

postoperative Day 40. In our experience, three LPNs were converted to laparoscopic radical nephrectomy; of these, two were converted owing to a positive margin revealed by frozen section. The other LPN case was converted owing to ST depression immediately prior to tumor excision. These LPNs were excluded from the analysis. No LPN cases were converted to open surgery.

3.1. Hemorrhagic complications

The mean EBL was 417 (range, 20–4300) mL. Hemorrhage developed in 17 patients (9.55%) intraoperatively, and in eight (4.49%) postoperatively. A total of 21 patients (11.8%) required blood transfusion. Angiographic embolization was performed in four patients (2.2%) with delayed bleeding on postoperative Day 7, Day 18, Day 26, and Day 40, respectively. Another three patients with delayed bleeding were treated conservatively.

3.2. Urinary leakage

Two patients (1.1%) experienced urine leakage, and both underwent ureteral stent insertion. After ureteral stent insertion, drainage volume from the Jackson–Pratt (JP) drains decreased, and the stents were then removed without subsequent complications. No patients required an exploratory operation.

3.3. Other complications

Overall, 33 patients (18.5%) had complications, including hemorrhage in 24 patients (13.5%), urine leakage in two patients (1.12%), postoperative ileus in two patients (1.12%), lung atelectasis in one patient (0.56%), lymph leakage in one patient (0.56%), pneumonia in one patient (0.56%), parotitis in one patients (0.56%), and left lower leg compartment syndrome in one patient (0.56%). The patients who had infections such as pneumonia and parotitis were treated conservatively with parenteral antibiotics upon admission. The patient who had left lower leg compartment syndrome had a ruptured angiomyolipoma with substantial hematoma formation around the upper pole of the right kidney. The operation was completed using the laparoscopic technique after a prolonged operation time of 450 minutes. Fasciotomy was performed for the compartment syndrome. The patient recovered well after the fasciotomy, and the wound was closed after 6 days.

3.4. Clavien grading system

Table 2 lists the perioperative complications according to the modified Clavien grading system.[9] Two patients had more than one complication, and in total, there were 35 postoperative complications. Most complications were Grade I (3.93%) or Grade II (11.2%) and were treated conservatively with antibiotics or blood transfusion. Grades IIIa and IIIb complications accounted for 2.81% and 1.69% of all patients, respectively, and were managed by invasive procedure under local or general anesthesia. No life-threatening Grade IV complications requiring intensive care or operation-related death were observed.

3.5. Risk factors of complications

No association between overall complications and age, BMI, ASA score, or robotic-assisted procedures was recorded. Univariate analysis showed that a longer length of stay ($p = 0.003$) and a higher PADUA score ($p = 0.024$) and RENAL score ($p = 0.002$) were related to ≥Grade I complications (Tables 3 and 4). Multivariate logistic regression test

Table 2
Detailed analysis of Clavien grade complications.

Grade	Complications (no.)	Treatment	*n* (%)
I	Lymph leakage (1)	No special therapy	7 (3.93)
	Ileus (2)	Prolonged admission	
	Lung atelectasis (1)	Bedside respiratory training	
	Delay bleeding (3)	Bed rest	
II	Bleeding (18)	Blood transfusion	20 (11.2)
	Pneumonia (1)	Parenteral antibiotics	
	Parotitis (1)	Parenteral antibiotics	
IIIa	Bleeding (4)	Angiographic embolization	5 (2.81)
	Urine leakage (1)	Ureteral stent insertion	
IIIb	Hematuria (1)	Ureteral stent insertion	3 (1.69)
	Urine leakage (1)	Ureteral stent insertion	
	Compartment syndrome (1)	Fasciotomy	

Table 3
Univariate analyses of numerical variables.[a]

	No complications	≥1 complication	*p*
Age (y)	56.9 ± 13.3	57.9 ± 17.2	0.19
BMI	25.0 ± 3.48	25.6 ± 4.27	0.31
LOS (d)	5.59 ± 1.48	8.64 ± 5.40	0.003
PADUA score	8.41 ± 1.48	9.19 ± 1.67	0.024
RENAL score	7.26 ± 1.66	8.31 ± 1.57	0.002

Data are presented as mean ± SD.
BMI = body mass index; LOS = length of stay; PADUA = Preoperative Aspects and Dimensions Used for an Anatomical score; RENAL = Radius/Exophytic/Nearness to collecting system/Anterior/Location.
[a] Mann–Whitney *U* test.

showed that the rate of complications of ≥Grade II increased in patients with higher PADUA score (OR for score 9–14 vs. that for 6–8: 2.46; 95% CI, 1.03–5.87; $p = 0.042$) and RENAL score (OR for score 8–11 vs. that for 4–7: 3.10; 95% CI, 1.23–7.80; $p = 0.016$; Table 5). No significant relation between the incidence of complications in the early phase (first 20 cases) and the following cases was found ($p = 0.217$).

4. Discussion

The use of grading scale in reporting complications has facilitated standardization.[9,17] Several reports have discussed complications involving LPN or RPN in the Western literature, but more investigations are encouraged in Asian countries. In this study, the overall complication rate was 18.5%.

Table 4
Univariate analyses of categorical variables.[a]

	n	≥1 complication, *n* (%)	*p*
ASA			0.754
1	22	3 (13.6)	
2	112	19 (17.0)	
3	33	7 (21.2)	
Operative method			0.770
LPR	85	15 (17.6)	
RPN	93	18 (19.4)	

ASA = American Society of Anesthesiologists; LPR = laparoscopic partial nephrectomy; RPN = robotic-assisted partial nephrectomy.
[a] Pearson's Chi-square test.

Table 5
Multivariate analysis of risk factors of complications of ≥Grade II.[a]

	n	Complications, *n* (%)	OR (95% CI)	*p*
PADUA score				0.042
6–8	95	9 (9.47)	2.46 (1.03–5.87)	
9–14	83	17 (20.5)		
RENAL score				0.016
4–7	88	7 (7.95)	3.10 (1.23–7.80)	
8–11	90	19 (21.1)		

CI = confidence interval; OR = odds ratio; PADUA = Preoperative Aspects and Dimensions Used for an Anatomical score; RENAL = Radius/Exophytic/Nearness to collecting system/Anterior/Location.
[a] Multiple logistic regression—forward stepwise method.

Nevertheless, most complications were classified as low-grade (Clavien Grade I or II). Two factors were significantly related to increasing complication rate: higher PADUA and RENAL scores. The mean blood loss was 417 ± 530 (range, 20–4300) mL, the mean warm ischemia time was 31.6 ± 22.0 (range, 0–100) minutes, and the mean operative time was 255.0 ± 83.5 (range, 100–620) minutes. Hemorrhage was the most common complication and accounted for 75.8% of all complications. Urine leakage, which only occurred in two patients (1.1%), was relatively uncommon and was treated with indwelling ureteral stent. A total of eight patients had complications that were greater than Clavien Grade III, including patients who had delayed bleeding, and these patients were all treated successfully with angiographic embolization. Three patients required laparoscopic radical nephrectomy, and no patient required open conversion. Several studies have compared complications in patients treated with RPN and LPN at high-volume centers. Benway et al[7] compared 129 consecutive RPNs to 118 consecutive LPNs performed by three experienced minimally invasive surgeons at three academic centers. Complication rates for RPN and LPN were 8.6% and 10.2%, respectively, and the study concluded that RPN was a safe and viable alternative to LPN. The microscopic positive margin rate was higher in patients undergoing RPN (3.9%) compared to those undergoing LPN (0.8%), but without statistical significance. Haber et al[18] performed a matched cohort study of 150 patients undergoing RPN or LPN, which did not reveal any difference in warm ischemia time (18.2 minutes vs. 20.3 minutes), operative time (200 minutes vs. 197 minutes), or surgical margin status (each 0%). The overall complication rates were similar, including 16.0% for RPN and 14.7% for LPN. In 2011, Spana et al[8] reported the largest multi-institutional RPN experience thus far, which provided data from 450 patients at four institutions, with a mean operative time of 188 ± 68 minutes, mean blood loss volume of 213.2 ± 222.9 mL, and mean warm ischemia time of 20.2 ± 9.23 minutes, and one RPN that was converted to open operation.[8] The overall complication rate was 15.8%, and the percentage of low-grade (Clavien Grades I and II) complications was 77.1%. A slightly higher overall complication rate, longer operative time, and larger volume of EBL were found in our study compared with previous studies. A greater tumor size, higher BMI, and centrally located tumors were

associated with a longer warm ischemic time.[19] In our study, the mean tumor size (3.90 cm) was relatively larger compared with those of previous studies by Benway et al[7] (2.76 cm), Spana et al[8] (2.91 cm), and Haber et al[18] (2.63 cm). In our study, the larger tumor size may have had an impact consisting of longer warm ischemia and operative times. The relationship between perioperative outcomes of minimally invasive partial nephrectomy and PADUA or RENAL score has been reported in several studies. In the present study, we found a correlation between tumor complexity and rate of complication. A similar conclusion has been reported in a study by Ficarra et al.[10] They found that patients with a PADUA score of 8 or 9 had a 14-fold higher risk of complications when compared with patients having a PADUA score of 6 or 7. Patients with a score of ≥10 had a 30-fold higher risk compared with patients with scores of 6–7. The overall complication rate was 22.6%. Kong et al[20] showed an overall complication rate of 17.9% in a partial nephrectomy series in Chinese patients. They concluded that the PADUA system was an independent predictor for perioperative complications. Patients with intermediate and high risk had a 4- and 37-fold higher risk of complication, respectively. Ellison et al[21] reported that a higher RENAL score was associated with a greater proportion of major complications (≥Clavien Grade III). Bylund et al[13] reported a series of a total of 162 partial nephrectomies with routinely recorded PADUA and RENAL scores. Most of the cases were minimally invasive with hand-assisted laparoscopic, pure LPN, or RPN techniques. The median EBL was 200 mL with a median warm ischemia time of 24 minutes and a median operative time of 211 minutes. The complication rate in our study was comparable with that reported in previous reports, although tumor complexity was higher in our patients. The proportion of intermediate and high PADUA scores (≥8) in our study was 70.8%, which was higher than that reported in the studies by Ficarra et al[10] (56.8%), Bylund et al[13] (49.4%), and Kong et al[20] (56.4%). The proportion of intermediate and high RENAL scores (≥7) in our study was 74.2%, which was higher than that reported in previous reports by Ficarra et al[10] (48.1%) and Ellison et al[21] (54.7%).

The main limitation of our study was that our data represent a retrospective analysis from a single institution, which may result in inherent biases that accommodate such observations. As in other retrospective studies for review of complications, a large amount of Clavien Grades I and II complications can be missed, even with careful chart review. This is observed in our study, with its relatively small number of Grade I complications.

In conclusion, minimally invasive nephron-sparing surgeries including LPN and RPN have an acceptably low complication rate. Most postoperative complications are Clavien Grade I or II, and the most common complications are hemorrhagic. These complications were managed without an invasive procedure. Despite the high complexity of renal tumors in this report, the complication rate remains comparable to previously reported data.

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