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Title: Laparoscopic versus open partial nephrectomy for anatomically complex renal tumors (renal score ≥ 7).

Short title: Partial nephrectomy for complex renal tumors.

Abstract

Purpose: The aim of this study was to compare the safety and efficiency of laparoscopic partial nephrectomy (LPN) and open partial nephrectomy (OPN) for complex renal tumors with a RENAL nephrometry score of ≥ 7 .

Materials and methods: We evaluated the data of 63 patients who had undergone LPN (n=32) or OPN (n=31) for renal tumors with a RENAL nephrometry score of ≥ 7 between 2016 and 2022, retrospectively. We compared the preoperative, functional and oncological outcomes among the groups. The warm ischemia time (WIT) of < 25 minutes, no surgical complications and negative surgical margins were defined as trifecta.

Results: No differences in the diameter of the tumor (4.15 ± 1.28 cm, 5.62 ± 2.84 cm, $p=0.552$), in the pathological stage and the median RENAL nephrometry score (8.00 [7-10], 8 [7-11], $p=0.257$) were observed between the OPN and the LPN groups. There were no differences regarding the trifecta outcomes, the operative time, the estimated blood loss, WIT, the complication rates, and the length of hospital stay among the groups. The percentage decrease in glomerular filtration rate at the early and the last follow-up were similar. The mean follow-ups after LPN and OPN were similar (13.69 ± 7.46 months, 18.68 ± 12.28 months, $p=0.55$, respectively).

Conclusions: The laparoscopic approach has a similar protection of renal function without compromising functional and oncological results in comparison with OPN for anatomically complex renal tumors. Therefore, laparoscopic approach is also safe with partial nephrectomy for complex renal tumors.

Keywords: Laparoscopy, partial nephrectomy, renal tumors.

Makale başlığı: Anatomik olarak kompleks böbrek tümörleri için laparoskopik ve açık parsiyel nefrektomi (böbrek skoru ≥ 7).

Kısa başlık: Kompleks böbrek tümörleri için parsiyel nefrektomi.

Öz

Amaç: Bu çalışmanın amacı, RENAL nefrometri skoru ≥ 7 olan kompleks böbrek tümörlerinde laparoskopik parsiyel nefrektomi (LPN) ve açık parsiyel nefrektomi (APN) yöntemlerinin güvenlik ve etkinliğini karşılaştırmaktır.

Gereç ve yöntemler: 2016-2022 yılları arasında RENAL nefrometri skoru ≥ 7 olan böbrek tümörleri için LPN (n=32) veya APN (n=31) uygulanan 63 hastanın verilerini retrospektif olarak değerlendirdik. Gruplar arasında preoperatif, fonksiyonel ve onkolojik sonuçları karşılaştırdık. İskemik sıcaklık süresi (İSS) < 25 dakika, cerrahi komplikasyon olmaması ve negatif cerrahi marjlar trifekta olarak tanımlandı.

Bulgular: Tümör çapı ($4,15 \pm 1,28$ cm, $5,62 \pm 2,84$ cm, $p=0,552$), patolojik evre ve median RENAL nefrometri skoru ($8,00$ [7-10], 8 [7-11], $p=0,257$) açısından APN ve LPN grupları arasında fark gözlenmedi. Trifekta sonuçları, ameliyat süresi, tahmini kan kaybı, İSS, komplikasyon oranları ve hastanede kalış süresi açısından gruplar arasında fark yoktu. Erken ve son takiplerde glomerüler filtrasyon hızındaki yüzde azalma benzerdi. LPN ve APN sonrası ortalama takip süreleri benzerdi (sırasıyla $13,69 \pm 7,46$ ay, $18,68 \pm 2,28$ ay, $p=0,55$).

Sonuç: Anatomik olarak kompleks böbrek tümörlerinde LPN, fonksiyonel ve onkolojik sonuçları tehlikeye atmadan böbrek fonksiyonlarının korunmasında APN ile benzer sonuçlar göstermektedir. Bu nedenle, kompleks böbrek tümörlerinde parsiyel nefrektomi için laparoskopik yaklaşım da güvenlidir.

Anahtar kelimeler: Laparoskopi, parsiyel nefrektomi, böbrek tümörleri

Introduction

Renal cell carcinoma (RCC) is the second most prevalent urological malignancy, accounting for 3-5% of all malignant tumors in adults [1]. With the growing use of imaging technology over the last two decades, the incidence of RCC has increased, and cases are frequently discovered incidentally [2]. Surgery is the primary therapy method for localized RCC which is common seen in practice. Partial nephrectomy (PN) has been considered as the standard treatment to treat localized RCC, with comparable oncological outcomes and faster recovery of renal function than radical nephrectomy (RN) [3, 4]. Additionally, PN can reduce the risk of severe cardiovascular events [5].

With significant advancements in laparoscopic procedures and tools over the last decade, the PN surgical approach has gradually transformed from open partial

nephrectomy (OPN) to laparoscopic partial nephrectomy (LPN) [6, 7]. While there is a learning curve associated with LPN, its usage has expanded since it is thought to offer less invasive, equivalent oncological results to OPN and similar rates of urological complications [8]. LPN has offered a minimally invasive alternative to OPN, which is still one of the most demanding and challenging urological surgical procedures. Studies in the literature have shown that the two techniques have similar functional and oncological results [9]. Indeed, the anatomical characteristics and the diameter of the tumor are the main factors that play a role in the decision of surgeons to perform LPN or not.

There are scoring systems that evaluate the anatomical features of renal masses and patient characteristics to predict partial nephrectomy complication rates [10, 11]. A prediction of ischemia time evaluation tool, the RENAL nephrometry score system (RENAL-NS) has also been established and is strongly correlated with the occurrence of postoperative problems following PN [11].

It was aimed to investigate the clinical outcomes in patients undergoing OPN and LPN for anatomically complex renal masses (RENAL-NS ≥ 7) in this study.

Materials and methods

We retrospectively reviewed the data of 189 patients who underwent LPN and OPN at our center between January 1, 2016 and December 31, 2022. 126 patients with missing data; loss to follow up; solitary kidneys; synchronous bilateral, metachronous, multiple ipsilateral tumors; distant metastasis; hereditary RCC syndrome and RENAL-NS < 7 were excluded from the study. 63 patients with solitary tumors who had initially been diagnosed with anatomically complex (RENAL-NS ≥ 7) renal tumors without any evidence of metastasis and undergone LPN (N=32) or OPN (N=31) in our clinic were included. The demographic, intraoperative, and postoperative information were extracted from the designed and updated data. This study adhered to the principles of the Helsinki Declaration and permission was obtained from Pamukkale University Non-Interventional Clinical Research Ethics Committee for the study (Approval number: 60116787-020/31829).

RENAL-NS was used to classify the complexity of 63 consecutive tumors undergoing PN and to minimize subjectivity or bias on the evaluation. RENAL-NS using the depth, degree of proximity to the collecting system, size and location were used to calculate the complexity of the renal tumor [12]. Two urological oncologists (in order to reduce the level of false evaluation) used the RENAL-NS to classify the patients based on computed tomography and magnetic resonance imaging findings at diagnosis and the microscopic tumor size in the postoperative pathology report assessed by a single

pathologist. The longest tumor diameter, measured using the macroscopic tumor size as the gold standard, was accepted as the main tumor size. Using this scoring system, complex renal tumors are determined as having a RENAL-NS ≥ 7 .

The clinical outcomes of the patients were obtained from the data that are constantly updated. LPN was performed on all patients through a transperitoneal approach by a single advanced laparoscopic surgeon. Surgical technique of LPN: Following creation of pneumoperitoneum, the renal hilum was dissected to accommodate the laparoscopic vascular bulldog clamps. After clamping of the renal artery using the laparoscopic bulldog clamp, tumor resection was performed circumferentially with the cold scissors after considering a safety margin around the tumor and leaving the renal parenchyma intact. Intraoperative ultrasound was not used in any case. The argon beam coagulator was used to provide rapid hemostasis of diffuse parenchymal bleeding. Inner layer renorrhaphy was completed with 2-0 Monocryl® suture. Previously, the opened pelvicalyceal system was not sutured either in our technique. Hem-o-lok® clips were placed at the end of the running suture to obtain proper tension. In cases where a hemostatic agent was needed, hemostyptic agents (FloSeal) were used to stop minor bleeding. The bulldog clamps were removed to minimize warm ischemia time (WIT) after the defect base was sutured. OPN was performed via a retroperitoneal approach (flank incision) by a single experienced surgeon. The kidney was mobilized and not cooled by using mannitol before clamping the renal hilum in all cases in both laparoscopic and open procedures. The Satinsky clamp was used to clamp both the renal artery and vein. Wedge excision was used to remove a tumor and a small amount of normal tissue around it with the cold scissors without controlling the safety margin by frozen sections as in all laparoscopic procedures. The collecting system defect was controlled using 2-0 Vicryl®, the bleeding vessels were controlled using 2-0 polypropylene suture and 1-0 Vicryl® over the Surgicel® was used to reconstruct the cortical edges by approximating the edges of the cortex and hemostyptic agents (FloSeal) were used prior to removal of the Satinsky clamp. The modified Clavien grading system was used for evaluating the postoperative complications [13].

In the laparoscopic surgery group, the laparoscopic surgeon suggested and performed laparoscopic surgery on all patients regardless of the tumor size and/or complexity, and none of the patients' procedures were switched to open surgery perioperatively. Similarly, in the open surgery group, all patients were preoperatively assigned to open surgery and managed by the open surgeon without any change in the primary decision. The potential for selection bias was minimized this way.

The patients were followed-up according to the European Association of Urology (EAU) guidelines. The estimated glomerular filtration rate (eGFR) was used to assess the renal function. eGFR was calculated by the Modification of Diet in Renal Disease equation [14]. The Renal function decrease on the postoperative first day and at the sixth month were compared. WIT <25 minutes, no surgical complications and negative surgical margins were defined as trifecta [15]. In the first year, the follow-up was conducted every three months; in following 2 years, it was conducted every six months, and then annually. During each scheduled visit, an abdominal computed tomography was performed. Magnetic resonance imaging was performed in patients with renal failure or hypersensitivity to contrast agents.

Statistical analysis

The statistical analysis was carried out using the SPSS 23.0 (IBM, Armonk, NY, USA). The Shapiro-Wilk test was used for checking the normality of the data. The mean normally distributed data were analyzed using the student's t Test and the analyses of non-normally distributed data were carried out using the Mann-Whitney U test. The Wilcoxon signed rank test was used for the non-normally distributed related samples. The Chi-square or the Fisher's exact test was used to compare the Nominal data. Kaplan-Meier models were used to predict survival analysis and a P value of lower than 0.05 was determined as statistically significant.

Results

No statistically significant differences were found in the mean diameter of the tumor (4.15 ± 1.28 cm, 5.62 ± 2.84 cm, $p=0.552$), the BMI, the ASA score, the pathological stage, the RENAL-NS (8.00 [7-10], 8 [7-11], $p=0.229$), gender, age and the co-morbidities between OPN and LPN groups as demonstrated in Table 1 ($p>0.05$). No significant differences were found in the transfusion rate, the operative time, the rate of postoperative complications, the length of hospital stay (LOS), the Fuhrman nuclear grade, and the follow-up time as displayed in Table 2 ($p>0.05$). Only one patient in the laparoscopic group had positive surgical margin (PSM) and none of the patients in the open group had PSM. Major complications (>Grade 3) were observed in four patients in the laparoscopic group; three of these had urine leakage and were treated by inserting double-J stents and one of them continued to have urine leakage and was treated via percutaneous nephrostomy. One patient had open surgery due to intestinal hernia from one of the port sites as shown in Table 2. Three patients had urine leakage in the open group and all of them were treated with double-J stents. No operation-associated mortality was observed during the perioperative period in either group. None of the

patients received perioperative transfusion; however, 7 (21.8%) patients in the LPN group and 6 (19.3%) patients in the OPN group underwent postoperative transfusion due to low postoperative hemoglobin levels without any hemodynamic instability. The Trifecta outcomes were similar among the groups with no recurrence in either of the groups. No significant differences were found in the estimation of GFR changes after the first postoperative day (-7.91 ± 10.819 , -6.42 ± 15.13 , $p=0.665$) and the sixth month (-6.97 ± 5.5 , -9.55 ± 13.443 , $p=0.586$), as shown in Table 3.

Discussion

Partial nephrectomy has been performed with an increasing trend, whenever technically feasible, even for larger tumors (T1b/T2) to improve kidney function recovery, thereby reducing the incidence of cardiovascular or metabolic disorders [16-18]. In this study, in which the RENAL-NS was chosen as standardized scoring systems to prevent selection bias between groups and to facilitate the outcomes, we compared the clinical outcomes in patients who had undergone OPN and LPN for anatomically complex renal masses (RENAL-NS ≥ 7) and found no difference in the demographic, preoperative and the intraoperative outcomes including estimated blood loss (EBL), WIT, the operation time, the trifecta outcomes, the GFR changes and the complication rates between the groups.

Laparoscopic partial nephrectomy offers a number of advantages despite its technical difficulties, including the ability to better stitch under vision magnification, reduce venous bleeding due to pneumoperitoneum, and aid in the coagulation of tiny veins [19]. Although controversial opinions arise, when performing a nephron sparing surgery, the tumor should be resected within 20 minutes of WIT to minimize renal ischemic damage [20]. In the literature, WIT values between 19 and 38 minutes have been reported in patients undergoing LPN for renal masses larger than 4 cm or complex (RENAL-NS ≥ 7) [21-24]. A recent study that evaluated 137 patients with R.E.N.A.L. score ≥ 10 , ischemia time was found to be significantly lower in OPN than LPN group with 20.06 min vs 30.69 min, respectively [25]. In another study, evaluated 63 patients with stage T1b solitary tumor and they revealed that WIT was significantly longer in LPN group than OPN, with 25.5 mins vs 16 mins, respectively [26]. In this study there were no WIT differences between LPN and OPN groups and mean WIT of 16.06 mins and 16.25 mins are comparable to what has been reported previously for renal tumors of ≥ 4 cm or complex renal masses (RENAL-NS ≥ 7). The shorter WIT may have resulted from the early unclamping technique used during our laparoscopic approach.

Simmons et al. [22] reported the mean LOS as 3.5 days, the mean EBL as 284 ml and the mean operative time as 3.8 hours in patients treated with LPN for renal tumors larger than 4 cm. In another study reported favorable perioperative outcomes in patients undergoing LPN for renal tumors greater than 7 cm [23]. And also, in a study recently conducted there were no differences between OPN and LPN patients with R.E.N.A.L. score ≥ 10 in duration of operation, estimated blood loss, blood transfusion rate and duration of postoperative hospital stay [25]. Chiancone et al. [27] also suggested that OPN patients was found to be similar to LPN patients in terms of operation time while estimated blood loss, blood transfusion rates were significantly lower in LPN group. In another study, no difference was found between the OPN and LPN groups in terms of intraoperative erythrocyte suspension transfusion and hospital stay, but estimated blood loss and operation time were found to be significantly higher in the LPN group [26]. In line with the literature, LPN had similar perioperative outcomes, EBL, LOS, and operative time with OPN in this study.

Regardless of the method, urological complications were rarely observed. Complication rates for LPN have been reported in the literature as between 21.4% and 33% [10]. Rais Bahrami et al. [28] retrospectively reported that LPN for tumors over 4 cm was associated with an increased risk of complications. Complications above Clavien grade 3 were reported at a rate of 4.9% in patients undergoing LPN for complex renal masses (RENAL-NS ≥ 7) [24]. In the study which another classification system was used, PADUA score ≥ 10 patients were evaluated and there was a statistically significant difference in complication rate between the OPN and LPN groups in favor of the laparoscopic approach even though no significant difference in terms of grade ≥ 3 postoperative complications [27]. Tsivian et al. [23] reported 2 (7.4%) intraoperative and 3 (11%) postoperative grade 3 complications according to the modified Clavien classification in patients undergoing LPN for renal tumors greater than 7 cm. Liu et al. [25] assessed that there were no significant differences between OPN and LPN groups in terms of complication rates, and they had 3.7% grade 3 complication rate in OPN patients and 1.5% in LPN group. In this study, the rate of postoperative complications for OPN and LPN were 38.7% and 31.3%, respectively. Our results demonstrated that in spite of the low complication rate in LPN, the complication rate (over Clavien grade 3 classification) was lower in the OPN group, although the difference was not significant. Neither of the two groups demonstrated any Clavien grade 5 postoperative complications. Thus, in our experience, LPN proved to be similar to OPN in the management of complex renal tumors. This situation may be due to the surgeon

performing LPN receiving appropriate and sufficient laparoscopy training during her residency training [29].

When considered from another perspective, in the study of Porpiglia et al. [19] on clinical T1b renal tumors evaluating the perioperative outcomes of OPN, LPN and RAPN, the median (IQR) first postoperative day (POD) eGFR drop was lower in the LPN group compared to OPN. There were no statistically significant differences between the groups when comparing the GFR recovery at the third POD and at the first month. Similarly, in another study, no significant differences were observed between the groups regarding GFR levels in the preoperative, first postoperative day, the sixth month, and the last visit, although GFR had an elevated course in the LPN group [26]. Differently, they revealed that the eGFR preservation in the OPN group was superior to that in the LPN group in another study [25]. In this study, GFR recovery was similar at the first POD and at the sixth month after surgery in both groups.

When we evaluate oncological outcomes, Long et al. [24] reported the rate of PSM as 1.1% with a RENAL-NS of ≥ 7 treated by LPN. Additionally, there are studies reporting PSM rates as 6.5% and 5.3%, in patients with kidney tumors >4 cm treated with LPN [22, 28]. On the other hand, there are studies that claimed no differences between OPN and LPN groups in terms of PSM [25-28]. In our study, we found similar PSM rates in LPN and OPN such as literature, demonstrating that LPN is feasible and safe and can be performed with acceptable oncological outcomes almost similar to OPN.

Porpiglia et al. [19] reported that trifecta was achieved in 63.2% and 62.4% (LPN and OPN, respectively) in clinical T1b renal tumors. Other studies comparing the trifecta outcomes in LPN achieved desired outcomes in 31%, 33% and 48% of the study group [15, 30]. In a study that contained high volume of patients, 'trifecta' was achieved in 53% OPN, 52% LPN and there were no differences between OPN and LPN patients [31]. Similarly, in our study, the trifecta outcomes of 65.6% and 48.4% were achieved in LPN and OPN, respectively, with no significant difference.

This study had several limitations such as its' single center retrospective design and small subject size. Moreover, the use of eGFR instead of renal scintigraphy to assess the differences in renal function between the preoperative and postoperative periods may have caused bias. And also, we should also be aware that certain procedures, such as controlled selective renal hypotension on demand via a retroperitoneal approach, can be used during a laparoscopic partial nephrectomy to reduce the damage that warm ischemia does to kidney function. Another limitation is that the surgical approach was not randomized, and the choice was based on clinical and radiological findings. Moreover, no

propensity score matching was carried out. Nevertheless, there were no differences in the patients' baseline variables.

In conclusion, laparoscopic partial nephrectomy provides similar oncological and functional results when compared to OPN and it represents a feasible and safe procedure for complex tumors. Our study showed that in experienced centers, even complex renal tumors can be managed with LPN with similar oncological outcomes and low complication rates. These findings may help improve clinical decision-making for complex renal tumors.

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Table 1. Preoperative characteristics of patients and tumors according to surgical procedures.

	LPN (n = 32)	OPN (n = 31)	p value
Age (year), mean ± SD	56.72±14.63	58.19±14.70	0.665
Gender (n), %			
Female	11 (46.9)	15 (54.8)	0.259
Laterality n (%)			0.260
Right	12 (37.5)	16 (51.6)	
Left	20 (62.5)	15 (48.4)	
No. hypertension (%)	15 (34.4)	17 (34.4)	0.633
No. diabetes mellitus (%)	10 (31.3)	8 (25.8)	0.527
BMI (kg/m²), mean ± SD	28.21±4.36	27.69±4.10	0.593
ASA score n (%)			0.664
1	7 (21.9)	6 (19.4)	
2	21 (65.6)	24 (77.4)	
3	4 (12.5)	1 (3.2)	
Tumor size (cm), mean ± SD	4.15±1.28	5.62±2.84	0.552
RENAL nephrometry scoring, median	8.00 (7-10)	8 (7-11)	0.257
7	10	14	
8	12	10	
9	3	4	
10	7	2	
Radius component			0.001
1	12	7	
2	20	15	
3	0	9	
Exophytic/endophytic component			0.044
1	11	20	
2	15	9	
3	6	2	
Nearness component			0.342
1	3	3	
2	9	14	
3	20	14	
Location component			0.167
1	3	2	
2	19	25	
3	10	4	

OPN= Open partial nephrectomy; LPN= Laparoscopic partial nephrectomy; BMI= Body mass index; ASA= American Society of Anesthesiologists; R.E.N.A.L= Radius, exophytic/endophytic, nearness of tumor to collecting system, anterior/posterior, hilar tumor touching main renal artery or vein and location relative to polar lines)

* The Student's T Test, Mann-Whitney U test, the Chi-square or the Fisher's exact test were used

Table 2. Perioperative and postoperative results according to the surgical technique.

	LPN (n=32)	OPN (n=31)	p value
Warm ischemia time (min), mean	16.06±4.24	16.25±3.85	0.809
Estimated blood loss (mL), mean	120±21.47	118.55±38.21	0.853
Duration of operation (min), mean	111.84±12.67	113.39±11.05	0.609
Hospitalization time (day), mean	5.94±4.57	6.9±3.17	0.336
Postoperative complications n (%)			0.648
Grade <3	6 (18.8)	9 (29)	
Grade ≥3	4 (12.5)	3 (9.7)	
Wound site infection n (%)	1 (3.1)	0	0.325
Urine leakage n (%)	2 (6.3)	3 (9.7)	0.618
Preoperative hemogram	13.78±1.67	13.39±1.88	0.390
Postoperative hemogram	12.72±1.85	12.53±1.35	0.639
Erythrocyte suspension transfusion n (%)	7 (21.8)	6 (19.3)	0.805
Fuhrman nuclear grade n (%)			0.76
Grade I	8 (25)	7 (22.6)	
≥Grade II	17 (53.1)	18 (58.1)	
pT stage n (%)			0.71
pT1a	11 (34.4)	10 (32.3)	
≥pT1b	14 (43.8)	15 (48.4)	
Benign	7 (21.9%)	6 (19.4)	
Follow-up time (month), mean	13.69±7.46	18.68±12.28	0.55
Trifecta Outcomes			0.207
Trifecta (yes) n (%)	21 (65.6)	15 (48.4)	
Trifecta (no) n (%)	11 (34.4)	16 (51.6)	

* The Student's T Test, the Chi-square and the Fisher's exact test were used

Table 3. Effects of open and laparoscopic partial nephrectomy on renal function

	LPN (n=32)	OPN (n=31)	p value
GFR measurements			
Preoperative	87.47±26.75	90.0±20.96	0.672
Postoperative 1 st day	82.09±22.04	81.0±25.55	0.567
Postoperative 6 th month	83.03±19.08	77.87±24.38	0.108
Δ GFR			
Postoperative 1 st day	-7.91±10.819	-6.42±15.13	0.665
Postoperative 6 th month	-6.97±-5.5	-9.55±13.443	0.586

OPN= Open partial nephrectomy; LPN= Laparoscopic partial nephrectomy; GFR= Glomerular filtration rate
 Δ GFR= Change in glomerular filtration rate, MDRD GFR (mL/min/1.73 m²)

* The Student's T Test, Kaplan-Meier models were used

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