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Laparoscopic versus open partial nephrectomy: prospective randomized study for assessment of surgical, functional, and oncological outcomes

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Abstract

Background The purpose of this study was to compare the surgical, functional, and oncological outcomes between open partial nephrectomy (OPN) and laparoscopic partial nephrectomy (LPN).

Methods This prospective, randomized study was performed on patients who underwent partial nephrectomy under general anesthesia. Patients were randomized using the closed envelope method to either LPN or OPN. Baseline demographics and surgical, functional, and oncological outcomes were compared. A per-protocol analysis was used.

Results Randomized study was conducted on 166 patients. The LPN, in comparison to the OPN group, was associated with significantly shorter hospital stay (3 vs. 4 days), less blood transfusion (10% vs. 12%), longer operative time (134 min vs. 124 min), lower visual analog pain score (7 vs. 8), and lower estimated GFR (70.7 ± 17.5 vs. 72.3 ± 14.7).

Conclusions Oncological and functional results were comparable between LPN and OPN. However, LPN was superior to open surgery because of less hospital stay, visual analog pain score, and blood loss.

Keywords Renal mass, RENAL score, Nephron-sparing, Laparoscopic partial nephrectomy

1 Background

The frequency of kidney cancer has progressively increased worldwide during the past two to three decades [1]. For localized renal cell carcinoma (RCC), the EAU (European Association of Urology) guidelines recommend surgery as the only curative method [2]. For patients with RCC greater than 7 cm, partial nephrectomy (PN) and radical nephrectomy (RN) have comparable oncologic results for localized tumors (T2a). However, if the RENAL score is more than 10 at stage T2,

there is an increased risk of recurrence and a decreased overall cancer-specific survival rate [3]. Partial nephrectomy (PN) or nephron-sparing surgery (NSS) is preferable over radical nephrectomy (RN) for treating localized cT1 carcinomas due to the better oncological and quality-of-life outcomes [4, 5]. It is the procedure of choice according to the American Urological Association and the European Association of Urology [6, 7], and when feasible, this indication extends to cover all renal malignancies [8]. In addition, NSS is more effective in treating advanced stages of cancer (T2) than radical nephrectomy and results in better renal function [9, 10].

Open partial nephrectomy (OPN) is the preferred method. However, laparoscopic partial nephrectomy (LPN) has become more common in NSS due to

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advancements in video technology, laparoscopic instrumentation design, and the availability of hemosealant substances [8].

The only limitation of LPN is the surgeon’s lack of experience [11, 12]. Therefore, for difficult malignancies (hilar tumors, apical tumors, VonHippel-Lindau syndrome, mass in horseshoe kidney, and mass in ectopic pelvic kidneys) and critical indications (bilateral tumors, chronic kidney disease (CKD) stage 1 or 2, and solitary kidney), there is still debate about whether LPN is preferable in terms of short- and long-term outcomes.

Earlier research indicated that LPN was more prone to complications and required longer operating time than OPN. However, more recent reports conclude no differences between the two methods [13, 14]. Additionally, compared to OPN, several studies have shown that LPN was linked to fewer complications and shorter periods of ischemia and hospital stay [11, 15].

Based on these previous studies, we conducted this prospective randomized clinical trial to analyze the differences between LPN and OPN in surgical, functional, and oncological outcomes.

2 Methods

Between January 2019 and January 2022, this prospective, randomized study was conducted on 166 patients of both sexes with renal masses of less than 10 cm. The inclusion criteria were patients who were planned to be treated with PN and had an exophytic renal mass (T1a, T1b, and T2a) less than 10 cm in a single kidney, a CDK

stage I or II, or bilateral renal mass with functioning contralateral kidney. Patients with metastatic or locally advanced tumors, renal vein thrombosis, renal mass over 10 cm, central or hilar tumors, uncorrected coagulopathy, and those unfit for anesthesia (ASA score ≥ 3) were excluded. Patients were randomized using the closed envelope method into 83 LPN and 83 OPN (Fig. 1).

To assess the clinical stage of the renal tumor and R.E.N.A.L score system, the patients underwent pelvi-abdominal U/S, multiphasic CT abdomen and pelvis with contrast, or MRI if the patient had elevated kidney function (creatinine > 1.5 gm. /dl). Patients were followed up for one year. R.E.N.A.L score system was used to classify the tumors. Components are: (R) diameter of the mass; (E) exophytic vs. endophytic properties; (N) nearness to the collecting system; (A) anterior or posterior; and (L) location relative to polar lines. Lesions with a nephrometry score of 4–6 points were designated as low complexity, 7–9 as moderate complexity, and 10–12 as the highest complexity lesions [1].

The current research followed the Declaration of Helsinki for studies involving humans, and the study was approved by the faculty Ethical Committee (ID: RC8.11.2022). All participants provided written informed consent before participation.

2.1 LPN procedure

The details of the operative technique were previously outlined in the literature [16]. Operations were performed under general anesthesia. Patients were

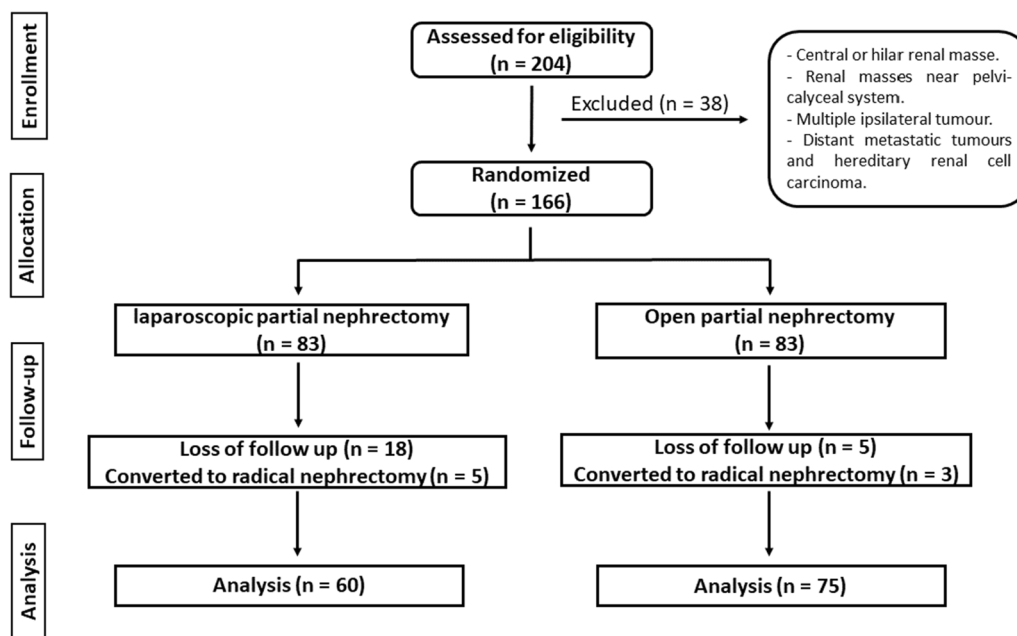


Fig. 1 CONSORT flowchart of RCT participants

positioned in a modified lateral kidney posture. Pneumoperitoneum was initiated using the Veress needle technique and trocar placement. Dissection to the renal hilum was done for good and sufficient exposure of the renal vessels.

Good exposure of the tumor and marking of the excision site were done with electrocautery. Clamping of renal vessels was achieved using laparoscopic Bulldog applicators. A visual assessment was performed during renal mass excision to determine the suitable depth of normal parenchyma to be excised to achieve a negative surgical margin. If an accidental collecting system injury was encountered, repair with suture calyceorrhaphy was done before bed hemostasis, and bipolar coagulation was cautiously applied away from the sutures (Fig. 2-A).

Large vessels were sutured with Vicryl 4/0 and secured with Weck hem-o-lok clips to achieve safe and stable hemostasis (Fig. 2-B). Unclamping and re-assessment of the hemostasis were done to secure residual bleeding points. Approximation of the edges of renal parenchyma was made using suturing in both groups. The sample was taken out using a Pfannenstiel incision after being placed in an EndoCatch bag. Surgical drain was placed in the paracolic gutter.

2.2 OPN procedure

General anesthesia was induced, and then an extraperitoneal flank trans-costal incision (11th rib) was made in each case to acquire access for surgery. Kidney dissection until the pedicle was done with selective artery and vein separation. The fat surrounding the kidney was removed, except for the fat attached to the tumor, and the kidney was then closely examined for any potential satellite lesions. Hot ischemia was applied to all cases using a Bulldog or Satinski clamp to constrict the vein and artery. Then, the tumor was resected with about five millimeters of renal parenchyma as a surgical margin.

Small blood vessels were coagulated, while 4/0 polyglycolic acid was used to oversee large blood vessels, providing the necessary hemostasis against parenchymal hemorrhage. In addition, hemostatic agents such as gel foam were used. With 4/0 polyglycolic acid, the calyces and renal pelvis were rebuilt following their opening. The renal fibrous capsule of the kidney was closed without using parenchymal sutures to avoid damage or tear unless the defect was too extensive. Good intraoperative hydration was ensured. Furosemide and 20% mannitol (1 ml/kg) were given before renal ischemia to reduce damage and reperfusion injury.

We prospectively gathered general characteristics for each subject, including age, sex, smoking status, BMI, baseline HB, baseline GFR, baseline creatinine, American Society of Anaesthesiologists (ASA) score, and comorbidities. Clinical condition characteristics included laterality, complaint, renal score, clinical stage, Fuhrman grade, pathology, and complications. Operative findings included hospital stay, operative time, warm ischemia time, and estimated blood loss. Postoperative data included postoperative GFR, PADUA score, visual analog pain score, stenting, blood transfusion, functional outcomes, such as changes in GFR and creatinine level, and oncological outcomes, such as positive surgical margin. All patients' medical and surgical problems and operating notes were compiled. The day before surgery, the Padua score was assigned. Preoperative aspects and dimensions used for an anatomical (PADUA) renal masses score of 6–7, 8–9, and 10–14 were deemed low, moderate, and high complexity lesions, respectively [17]. The Clavien-Dindo classification was employed to record postoperative complications prospectively [18].

Transfusion was typically performed when a patient's hemoglobin level was below 8 g/dL in a healthy person or below 9 g/dL in a patient with ischemic heart disease.

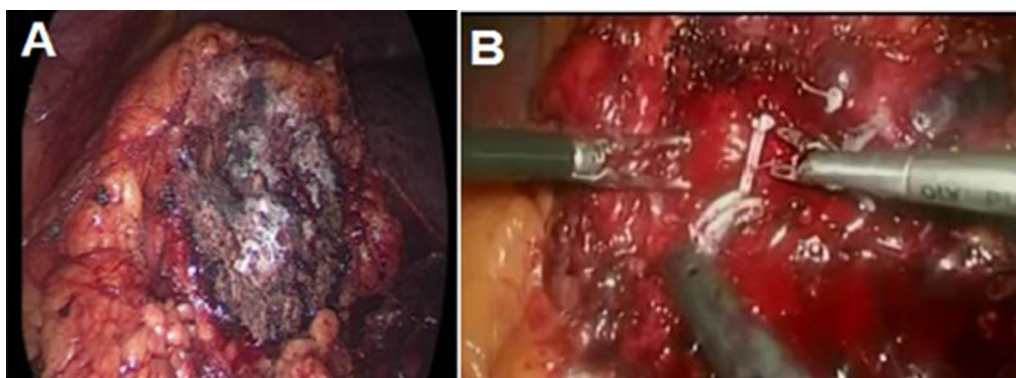


Fig. 2 a Bipolar coagulation for hemostasis of the tumor bed. b Suture renorrhaphy was used with Vicryl 4/0 and secured with Weck hem-o-lok clips

Table 1 Differences between laparoscopic and open surgery group regarding basic characteristics

		Total (N.= 135) N. %	Lap (N.= 60) N. %	Open (N.= 75) N. %	Chi square test	P value
Sex	Female	54 40%	22 36.7%	32 42.7%	.500	.480
	Male	81 60%	38 63.3%	43 57.3%		
Smoking	Yes	65 48.1%	33 55%	32 42.7%	2.03	.154
	No	70 51.9%	27 33.3%	43 57.3%		
Age		Median (IQR) = 46 (39–52)	Median = 46 IQR = 39.00– 52.00	Median = 46.00 IQR = 39.00– 54.00	.255*	0.799
BMI		Median (IQR) = 30 (25–33)	Median = 28 IQR = 24.00– 32.00	Median = 31.00 IQR = 26.00– 34.00	1.63*	0.10
Baseline HB		Median (IQR) = 11.8 (10.5–12.9)	Median = 11.250 IQR = 10.000– 13.000	Median = 12.000 IQR = 11–12.90	1.67*	.095
Baseline GFR		Median (IQR) = 81 (67–98)	Median = 82.00 IQR = 66.00– 99.00	Median = 80.00 IQR = 69.00– 98.00	.922*	.356
Baseline creatinine		Median (IQR) = 1 (0.8–1.2)	Median = .900 IQR = .800– 1.200	Median = 1.000 IQR = .900– 1.200	.835*	.404
ASA score		Median (IQR) = 2 (2.0–2.0)	Median = 2.00 IQR = 2.0–2.0	Median = 2.00 IQR = 2.0–2.0	.148*	.883
Co morbidities	No	61 45.2%	26 43.3%	35 46.7%	.188	.910
	DM	27 20%	12 20.0%	15 20.0%		
	hyper- tension	47 34.8%	22 36.7%	25 33.3%		

LPN laparoscopic partial nephrectomy, OPN open partial nephrectomy, BMI body mass index, HB hemoglobin, GFR glomerular filtration rate, ASA American Society of Anaesthesiologists, DM diabetes mellitus

*Mann–Whitney test was used

The primary outcome was the hospital stay between the studied groups. Secondary outcomes were operative time, warm ischemia time, estimated blood loss, PADUA score, visual analog pain score, stenting, blood transfusion, changes in GFR and creatinine, and positive surgical margin.

2.3 Sample size calculation

The sample size was calculated using G*power software version 3.1.9.2 based on an expected effect size of hospital stay between the studied groups ($d=0.6$) [19], with alpha and power adjusted at 0.05 and 0.8, respectively. The minimum number of patients to be recruited was 90 patients (45 per group). The sample size was increased to 120 patients (60 per group) to compensate for the expected loss of follow-up and the possible use of non-parametric tests.

2.4 Statistical analysis

SPSS 28.0 for Windows was used to analyze the data (SPSS Inc., USA). The Kolmogorov–Smirnov test, which assumes normality at $P>0.05$, was used to determine whether the distribution of the variables under analysis was normal. The per-protocol approach was used for analysis. For parametric data, the information was summarized using the mean and standard deviation (SD). For nonparametric data, medians and interquartile ranges (IQR) were used. For qualitative data, numbers and percentages were used. Comparisons between laparoscopic and open surgery groups at baseline and follow-up were done using the student t test for parametric data and the Mann–Whitney test for nonparametric data. The Chi-square test was utilized for qualitative data. The acceptable significance level in this study was $P<0.05$.

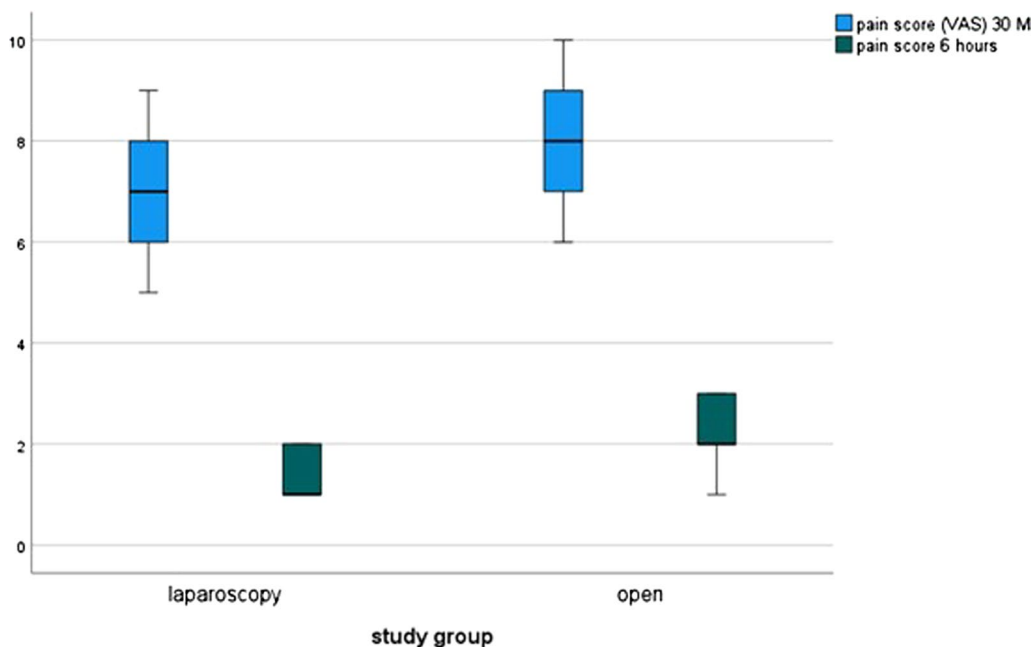
Table 2 Differences between laparoscopic and open surgery group regarding clinical condition

		Total (N. = 135) N. %	Lap (N. = 60)		Open (N. = 75)		Chi-square test	P value
			N.	%	N.	%		
Laterality	Left	78 57.8%	34	56.7%	44	58.7%	.055	.815
	Right	57 42.2%	26	43.3%	31	41.3%		
Complain	Accidently	75 55.6%	38	63.3%	37	49.3%	2.700	.259
	Haematuria	23 17%	8	13.3%	15	20.0%		
	Pain	37 27.4%	14	23.3%	23	30.7%		
	Renal score	Median (IQR)=6.0 (5.0–8.0)	Median =6.5	IQR=5.0–9.0	Median =5.0	IQR=5.0–7.0		
Clinical stage	T1a	45 33.3%	22	36.7%	23	30.7%	9.588	0.008 (HS)
	T1b	79 58.5%	38	63.3%	41	54.7%		
	T2a	11 8.1%	0	0.0%	11	14.7%		
Fuhrman grade	1	36 26.7%	18	30.0%	18	24.0%	1.652	.648
	2	47 34.8%	20	33.3%	27	36.0%		
	3	37 27.4%	14	23.3%	23	30.7%		
	4	15 11.1%	8	13.3%	7	9.3%		
Pathology of specimen	AML	11 8.1%	6	10.0%	5	6.7%	1.166	.884
	Chromophobe RCC	26 19.3%	10	16.7%	16	21.3%		
	Clear RCC	43 31.9%	20	33.3%	23	30.7%		
	Oncocytoma	25 18.5%	10	16.7%	15	20%		
	Papillary RCC	30 22.2%	14	23.3%	16	21.3%		
Calvin grad comp	No	102 75.6%	49	81.7%	53	70.7%	5.19	0.07
	1	11 8.1%	6	10%	5	6.7%		
	2	22 16.3%	5	8.3%	17	22.7%		
Other complications	No	103 76.3%	44	73.3%	59	78.7%	5.38	.25
	Dehydration need fluid replacement	8 5.9%	2	3.3%	6	8.0%		
	Fever need antibiotics	13 9.6%	8	13.3%	5	6.7%		
	Fistula underwent angioembolization	2 1.5%	2	3.3%	0	0.0%		
	Urine leak	9 6.7%	4	6.7%	5	6.7%		

Table 2 (continued)

Bold values indicate the accepted level of significance (S) was ($p < 0.05$), $p \leq 0.001$ was considered highly statistically Significant (HS), and $p > 0.05$ was considered Non statistically Significant (NS)

LPN laparoscopic partial nephrectomy, OPN open partial nephrectomy, HS highly significant

**Fig. 3** Boxplot of pain scores among studied groups

3 Results

The LPN and OPN patients were comparable regarding the baseline characteristics, including age, gender, BMI, Hb, GFR, creatinine, ASA score, and comorbidities, such as hypertension and diabetes mellitus (Table 1).

Additionally, the two groups were comparable regarding clinical characteristics, including laterality, complaint, RENAL score, Fuhrman grade, specimen pathology, and Calvien grade. Regarding the clinical stage, T1a and T1b were higher in the LPN group than in the OPN group (36.7% vs. 30.7% and 63.3% vs. 54.7%, respectively) (Table 2).

Regarding surgical outcomes, hospital stay and estimated blood loss were significantly lower in the LPN group than in the OPN group. In contrast, operative time was significantly longer in the LPN group than in the OPN group ($P < 0.001$). Warm ischemic time was comparable in both groups ($P = 0.349$). PADUA score, pain score, 6-h pain score (Fig. 3), and blood transfusion were significantly lower in the LPN group than in the OPN group ($P = 0.028$). Postoperative stenting was comparable between the two groups ($P = 1.0$) (Table 3, 4).

Regarding functional outcomes, postoperative GFR was significantly lower in the LPN group than in the

OPN group ($P < 0.001$) (Table 4). Regarding oncological outcomes, positive surgical margins were comparable between the two groups ($P = 0.143$) (Table 4).

4 Discussion

Approximately 13–27% of abdominal examinations reveal a renal lesion because of the extensive use of abdominal imaging, which increases renal mass detection [20]. According to worldwide recommendations, PN or NSS is the gold standard for treating localized renal masses whenever possible [21]. Open surgery served as the best and only treatment option for PN for a very long time. However, LPN has recently become more popular because it lessens the invasiveness of open surgery.

Our results revealed that patients in the LPN and OPN groups were comparable in the baseline general and clinical characteristics. A significant difference was observed in the clinical stage; T1a and T1b were higher in the LPN group than in the OPN group (36.7% vs. 30.7% and 63.3% vs. 54.7%, respectively).

In contrast, all patients with clinical stage T2a (eleven patients) underwent OPN. Their tumor characteristics were T2a, Bosniak4,5 and exophytic. So we counseled these patients about renal exploration for partial

Table 3 Differences between laparoscopic and open surgery group regarding operative data

	Total (N. = 135) Median IQR	Lap (N. = 60)		Open (N. = 75)		Mann Whitney test	P value
		Median	IQR	Median	IQR		
Hospital stay	4 (3–5)	3.00	2.00–3.00	4.00	4.00–5.00	8.282	<.001 (HS)
Operative time	125 (122–138)	134.50	124.00–141.00	124.00	120.00–130.00	3.623	<.001 (HS)
Warm ischemic time	22 (20–26)	22.00	20.00–26.00	22.00	20.00–25.00	.936	.349
Estimated blood loss	150 (100–200)	125	100–200	160	120–400	3.21	<.001 (HS)

Bold values indicate the accepted level of significance (S) was ($p < 0.05$), $p \leq 0.001$ was considered highly statistically Significant (HS), and $p > 0.05$ was considered Non statistically Significant (NS)

LPN laparoscopic partial nephrectomy, OPN open partial nephrectomy, HS highly significant

Table 4 Differences between laparoscopic and open surgery group regarding post operative data

	Total (N. = 135) N. %	Lap (N. = 60) N. %		Open (N. = 75) N. %		Chi-square test	P value
		N.	%	N.	%		
Post operative GFR	Mean \pm SD = 70.7 \pm 17.5	Mean \pm SD = 68.7 \pm 20.5		Mean \pm SD = 72.3 \pm 14.7		Student t test = 1.197	<.001 (HS)
PADUA score	Median (IQR) = 7 (6–9)	Median = 8	IQR = 6–9	Median = 7	IQR = 6–8	2.118*	.034 (S)
Pain score	Median (IQR) = 8 (6–9)	Median = 7	IQR = 6–8	Median = 8	IQR = 7–9	4.161*	<.001 (HS)
6 h pain score	Median (IQR) = (1–2)	Median = 1	IQR = 1–2	Median = 2	IQR = 2–3	7.546*	<.001 (HS)
Stenting post operative	Yes	17 12.6%	4 6.7%	5 6.7%	5 6.7%	.000	1.0
	No	118 87.4%	56 93.3%	70 93.3%	70 93.3%		
Blood transfu- sion	100 ml	8 5.9%	0 0.0%	8 10.7%	8 10.7%	7.165	.028 (S)
	500 ml	15 11.1%	6 10.0%	9 12.0%	9 12.0%		
	No	112 83%	54 90.0%	58 77.3%	58 77.3%		
Positive surgical margin	No	127 94.1%	54 90.0%	73 97.3%	73 97.3%	3.891	.143
	Yes- surveil- lance every 6 months for 2 years	2 1.5%	2 3.3%	0 0.0%	0 0.0%		
	Yes- surveil- lance radical nephrectomy 10 months	6 4.4%	4 6.7%	2 2.7%	2 2.7%		

Bold values indicate the accepted level of significance (S) was ($p < 0.05$), $p \leq 0.001$ was considered highly statistically Significant (HS), and $p > 0.05$ was considered Non statistically Significant (NS)

LPN laparoscopic partial nephrectomy, OPN open partial nephrectomy, HS highly significant, GFR glomerular filtration rate

*Mann–Whitney test was used

nephrectomy and the possibility of radical nephrectomy. Renal mass was dissected from the normal parenchyma via avascular plane along the fibrous pseudocapsule. We did a partial nephrectomy by enucleation to preserve more parenchyma during PN.

This study shows that open nephron-sparing surgery indications could be expanding beyond the 7 cm cutoff, and patients with large tumors who are potential candidates for open NSS should be highly selected and well informed of potential complication risks.

Three cases were converted to open due to continuous parenchymal bleeding, unsatisfactory bleeding control after laparoscopic bulldog removal, obscured visual field, and the inability of hot ischemia again.

Smaller masses might be removed laparoscopically based on the experience of the surgeon. However, open surgery is more technically straightforward and less likely to result in tumor rupture, particularly in large masses or with surgeons with less experience in laparoscopic surgery [22].

These results are comparable with Luciani et al. [20], who documented that all patients with high tumor stage underwent OPN. Additionally, Gong et al. [23] documented that the mean tumor size was lower in the laparoscopic cohort.

The current study results indicated that hospital stay and estimated blood losses were significantly lower in the LPN group compared to the OPN group. These results are explained by the following: (a) Laparoscopic proficiency as a result of accumulated knowledge and technical advancements; (b) Laparoscopic magnification allows for precise renal artery dissection and repair of the damaged collecting system; (c) Continuous suturing and the use of Hemo-lok to clamp the suture rather than the standard ligature on the surface of the kidney.

Operative time was significantly longer in the LPN group than in the OPN group, while warm ischemia time was insignificantly different between the two techniques. These findings are comparable with Liu et al. [24] and Luciani et al. [21], who reported shorter hospital stay and less blood loss in the LPN than in the OPN. However, shorter operative time was observed in these studies [21, 24]. Different surgeons' experiences may be a suitable explanation for the longer operative time obtained in our study, as LPN is a technique that has a learning curve. The pooled results of a systematic review and meta-analysis demonstrated the same findings regarding hospitalization and blood loss [1]. Another study reported shorter surgical time, lower operative blood loss, and a shorter hospital stay [25].

Other studies have shown no differences between OPN and LPN [26, 27]. Moreover, shorter ischemia time was reported for LPN [11, 15]. However, these results may be deceptive, given the lack of precise tumor features. Young et al. [28] reported an operative time of 145.3 min in LPN compared to 155.2 min in the OPN and a blood loss of 123 ml in the LPN compared to 135 ml in the OPN.

Our results demonstrated significantly lower PADUA score, pain score, and blood transfusion in the LPN group compared to the OPN group. Additionally, significantly lower postoperative GFR was reported. These findings align with Yu et al. [1], who stated that the LPN group had a significantly lower blood transfusion than the OPN

approach. Also, Liu et al. [24] documented that 3-month GFR was significantly lower in the LPN group than in the OPN group. However, Luciani et al. [21] reported an insignificant difference in PADUA score between the OPN and the LPN groups. Furthermore, Hager et al. [29] studied laparoscopic access and demonstrated a lower pain score at rest and movement.

The analysis of oncological outcomes indicated that positive surgical margins (PSM) were comparable between the two groups ($P > 0.05$). In contrast, Chengyu et al. [30] revealed a higher PSM in the LPN group. However, their subgroup analysis agrees with our results, showing no significant differences in PSM between the two groups for the T1a stage.

Despite being level-1 evidence, this study has some limitations, including being a single-center study. Additionally, using the per-protocol analysis approach could limit the extent to which the findings can be generalized. All patients with T2a clinical stage underwent OPN. Despite these limitations, this study shows that open nephron-sparing surgery indications could be expanding beyond the 7 cm cutoff, and patients with large tumors who are potential candidates for open NSS should be highly selected and well informed of potential complications. Further studies are needed to compare OPN versus LPN in T2 tumors. Furthermore, the study did not compare the postoperative quality of life and cost between both techniques.

5 Conclusions

Oncological and functional results were comparable between LPN and OPN; however, LPN was superior to open surgery regarding hospital stay, visual analog pain score, and blood loss.

Abbreviations

ASA	American Society of Anaesthesiologists
CT	Computerized tomography
E-GFR	Estimated GFR
GFR	Glomerular filtration rate
HS	Highly significant
IQR	Interquartile ranges
LPN	Laparoscopic partial nephrectomy
NSS	Nephron-sparing surgery
OPN	Open partial nephrectomy
PN	Partial nephrectomy
RCC	Renal cell carcinoma
RN	Radical nephrectomy
SD	Standard deviation

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None.

Author contributions

BE: design of the work, interpretation of data, the acquisition, analysis, original draft, substantively revised manuscript. RG: interpretation of data, methodology, TG: data collection, methodology, interpretation of data. MM:

data collection, manuscript writing. IS: supervision, data analysis, manuscript review. All authors have read and approved the manuscript.

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Availability of data and materials

The datasets used and analyzed for the current work are available upon reasonable request from the corresponding author.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Benha Faculty of Medicine (ID: RC8112022). And the Declarations of Helsinki guidelines were followed. All patients gave written consent before participation.

Consent for publication

Not applicable.

Competing interests

No interest conflicts declared.

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