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ORIGINAL ARTICLE

Prospective Randomized Study Comparing Laparoscopic and Open Partial Nephrectomy for Treatment of Renal Tumors: Surgical and Functional Outcomes.

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ABSTRACT

Background: The role of the open approach for partial nephrectomy is currently called into question by laparoscopy, although comparative studies on this issue are limited.

Objective: To compare surgical and renal functional outcomes after open partial nephrectomy (OPN) and laparoscopic partial nephrectomy (LPN).

Methods: This prospective randomized clinical study has been carried out at Urology department, Zagazig University from January 2017 till September 2020 on 35 patients candidates for partial nephrectomy, 17 patients in OPN and 18 patients in LPN.

Results: In total, 28 patients in both treatment groups complete the study. There was no statistical significant difference in age, gender, Body Mass Index (BMI), tumor size, tumor laterality and RENAL nephrometry score between both treatment groups. Significant differences were found between OPN and LPN regarding operative time (172.14±18.88 versus 148.93±31.88 min; *P*=0.027), estimate blood loss (252.86±70.32 versus 196.43±61.47 ml; *P*=0.032) and hospital stay (4.36±0.74 versus 3.14±1.1 days; *P*=0.002). Ischemia time was slightly higher in LPN (19.57±3.08 versus 17.79±2.15 min) without Significant difference (*P*=0.087). Positive safety margin was not significantly different between cases treated with OPN (1 case, 7%) and LPN (2 cases, 14%) (*P*=0.5). No cases developed local or distant recurrence during follow up period.

Conclusions: For cT1 renal tumors of low complexity, laparoscopic and open partial nephrectomy have comparable surgical and renal functional outcomes. LPN offers a strong alternative to OPN with shorter surgery time, less blood loss, and shorter hospital stay with quicker convalescence, with equivalent ischemia time compared to OPN.

Keywords: Renal tumors, laparoscopy, open partial nephrectomy, ischemia time.

INTRODUCTION

Renal cell carcinoma (RCC) accounts 2-3 % of all adult malignant neoplasms with higher incidence in Western countries. The incidence of RCC increased by about 2% both worldwide and in Europe over the last two decades. This is primarily a disease of older adults, with typical presentation between 50 and 70 years of age [1]. RCC is the most lethal of the common urologic cancers. Five-year relative survival rates for patients diagnosed in 2002 to 2008 were 71% for kidney cancer, 78% for bladder cancer (excluding carcinoma in situ), and 99% for prostate cancer [1]. Increased detection of renal tumors by ultrasound and computed tomography leads to increase the number of incidentally diagnosed RCCs which are usually smaller and of lower stage with improved survival rates of patients with these tumors [2]. Stage I renal tumors may be managed by radical nephrectomy, active surveillance or nephron sparing approaches, including partial nephrectomy and focal ablative procedure [3]. Nephron sparing surgery is the accepted treatment for most tumors < 4 cm (T1a), and it is a promising option for select tumors 4–7 cm (T1b), with equivalent oncological outcomes compared with radical nephrectomy [4]. Laparoscopic Partial Nephrectomy (LPN), since its

introduction in 1993, has become accepted alternative for the management of small sized renal tumors [5, 6]. LPN is associated with decreased pain and hospital stay postoperatively with maintained comparable oncologic outcomes in comparison with open partial nephrectomy (OPN) with preservation of healthy residual renal parenchyma [7]. LPN has a faster recovery profile, but in comparison with OPN, it was initially associated with more ischemia time and greater complications [8].

METHODS

Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans, this prospective randomized comparative clinical study was conducted at the department of Urology, Zagazig University Hospitals included 35 patients underwent partial nephrectomy by open and laparoscopic approaches from January 2017 till September 2020. Inclusion criteria were clinical T1N0M0 (< 7 cm), solitary, unilateral renal mass with low complex RENAL nephrometry score and normal contra lateral kidney; exclusion criteria were bilateral, multiple, large (> 7 cm), locally advanced, solitary kidney, tumor recurrence and contraindications of laparoscopy. Patients were assigned by computerized 1:1 randomization to one of two surgical treatment groups. OPN group included 17 patients and LPN group included 18 patients. Preoperative evaluation included clinical assessment, laboratory investigations included haemoglobin, and serum creatinines were performed preoperatively, 24h postoperatively and at 6th month follow up. abdominal ultrasonography, abdominal computed tomography angiography and chest x-ray.

Surgical technique:

Under general anesthesia, LPN was performed in the lateral decubitus position with transperitoneal approach and three to four ports were used. OPN was performed with variable of incisions between the 10th or 11th intercostal space with retroperitoneal approach. Once the hilum and mass were identified, IV mannitol was administered before the hilum was controlled renal artery and vein separately using a bulldog clamp. Tumor circumcision is carried out in warm ischem ia by using a cold scissor along with 0.5 cm margin. If required, collecting system reconstruction is done along with continuous 1st layer of renal parenchymal hemostasis which performed in two layers of absorbable anchoring sutures using hem-o-lok clips with absorbable hemostatic agents and, if possible, early unclamping after the 1st layer closure. In the pararenal space, the tube drain was positioned. In a laparoscopic approach, the en bloc renal mass with surrounding fat was retrieved with an endobag.

Perioperative analysis and follow up:

Parameters of surgical outcome collected were ischemia time / min defined as primary outcome, operative time / min and hospital stay / day defined as secondary outcomes, estimate blood loss / ml, blood transfusion rate, conversion rate and surgical complications. Renal functional outcome was assessed by eGFR using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [9] at baseline, 24h postoperative and 6th month eGFR with assessment of decline in eGFR from baseline. All patients were evaluated at 3rd and 6th month after surgery and then at least once per year for two years following surgery. Each visit included history taking, clinical examination, serum creatinine level, and check of recent abdominal CT and chest x-ray imaging for detection of tumor recurrence.

Statistical Analysis:

As a step of research ethical committee approval at our institution, department of community medicine calculate sample size -guided by study of Liu et al [10]- assuming that the mean difference of operative time 94.3±19.8 in laparoscopy group and 117.6±22.6 in open group and power 80% and confidence interval 95% by using Open Epi version 6, the calculated sample size is 28 patients 14 patients in each group with consideration of lost cases during follow up, sample size increased by about ≈ 20%.

Data about patients and tumor characteristics at baseline, surgical and functional outcomes were collected, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences software (SPSS version 20.0) for analysis. According to the type of data, the following tests were used to test differences for significance; Differences between frequencies (quantitative variables) in two groups were compared by Chi-square test. Differences between means (qualitative variables) in two groups were compared by Student's t-test. P value was set at <0.05 for significant results.

RESULTS

Twenty eight patients of both treatment groups complete two year follow up period of the study. OPN group (14 patients) included 6 men and 8 women with mean age 55.2±6.12 years; LPN group (14 patients) included 9 men and 5 women with mean age 57.3±5 years (*P*=0.33). According to tumor characteristics, mean tumor size was

3.75±0.93 versus 3.64±0.9 cm (*P*=0.76) and RENAL Score was 4.86±0.86 versus 4.79±0.89 (*P*=0.83) for OPN and LPN groups respectively without significant statistical difference. The data of patients' demographics and tumor characteristics of both groups were illustrated in table (1).

Operative time, started from induction of general anesthesia passing through patient positioning and surgical intervention till patient recovery, was shorter in LPN group 148.93±31.88 versus 172.14±18.88 min for OPN group (*P*=0.027). Ischemia time showed no significant difference between both groups. Estimate blood loss was significantly less in LPN group 196.43±61.47 versus 252.86±70.32 ml for OPN group (*P*=0.032). There was no significant statistical difference between both treatment groups according to transfusion, complications and conversion rates. Three cases in LPN group needed blood transfusion 2 of them intra-operative due to RT renal vein injury in one case, with failed trial of laparoscopic repair and hemodynamic instability, converted to laparoscopic radical nephrectomy, the other case due to uncontrolled tumor bed bleeding (unclamped supernumerary renal artery) converted to open partial nephrectomy while the 3rd case due to postoperative hematoma formation treated conservatively. Two cases of OPN group needed postoperative blood transfusion due to intraoperative renal surface bleeding associated with low hemoglobin level. No case conversion in OPN group. Surgical outcome parameters were illustrated in table (2).

The complications were presented as intraoperative and postoperative in table (3). The frequencies of total complications were comparable between both treatment groups. The LPN group developed 2 cases of intraoperative bleeding managed by blood transfusion with conversion of one case into laparoscopic radical nephrectomy and the other converted into OPN. The OPN group developed 2 cases of small pleural injury managed conservatively. Postoperative urine leakage was found in 2 cases of LPN group versus one case in OPN group; one case in each group treated by auxiliary endoscopic ureteral stenting with the other case of laparoscopic group treated conservatively with indwelling uretheral catheter for one week.

Pathological outcomes of our study showed a high incidence of RCC in both open (11 cases) and laparoscopic approach (12 cases) out of 14 cases in each group with fuhrman grade G2 in most cases. The incidence of positive safety margin was not significantly different between cases treated with OPN (1 case, 7%) and LPN (2 cases, 14%) (*P*=0.5). No cases developed local or distant recurrence during follow up period.

Renal function, 24hs postoperative and at 6 months after surgery, was not significantly different between both treatment groups. Mean eGFR decline from baseline at 6 months postoperatively was 4.57±3.88 ml/min per 1.73 m^2 and 7.36±6.57 ml/min per 1.73 m^2 for OPN and LPN respectively *(p=0.18)*. Renal functional outcome was illustrated in table (4).

Table (1): Patients and tumor characteristics

Variable	OPN N=14	LPN N=14	X^2 / t	P-value
Sex, *no.* **male / female**	**6 / 8**	**9 / 5**	**1.29**	**0.25**
Age *mean ±sd*	**55.2±6.12**	**57.3±5.00**	**0.98**	**0.33**
BMI *mean±sd*	**29.3±2.8**	**29.2±3.07**	**0.06**	**0.94**
Tumor Size, *cm* *mean±sd*	**3.75±0.93**	**3.64±0.9**	**0.30**	**0.76**
R.E.N.A.L Score *mean±sd*	**4.86±0.86**	**4.79±0.89**	**0.21**	**0.83**
Tumor Laterality, *no.* **Rt / Lt**	**9 / 5**	**10 / 4**	**0.16**	**0.68**

Table (2): Surgical outcomes

Variable	OPN N=14	LPN N=14	X^2 / t	P-value
Operative time, *min mean±sd*	**172.14±18.88**	**148.93±31.88**	**2.34**	**0.027**
Ischemia time, *min mean±sd*	**17.79±2.15**	**19.57±3.08**	**1.77**	**0.087**
EBL, *ml mean±sd*	**252.86±70.32**	**196.43±61.47**	**2.26**	**0.032**
Transfusion rate, *no.*	**2**	**3**	**0.24**	**0.62**
Complication rate, *no.*	**4**	**5**	**0.68**	**0.16**
Conversion rate, *no.*	**0**	**2**	**2.15**	**0.14**
to open	**-**	**1**	**1.037**	**0.30**
to radical	**0**	**1**	**3.42**	**0.002**
Hospital stay, *day mean±sd*	**4.36±0.74**	**3.14±1.10**		

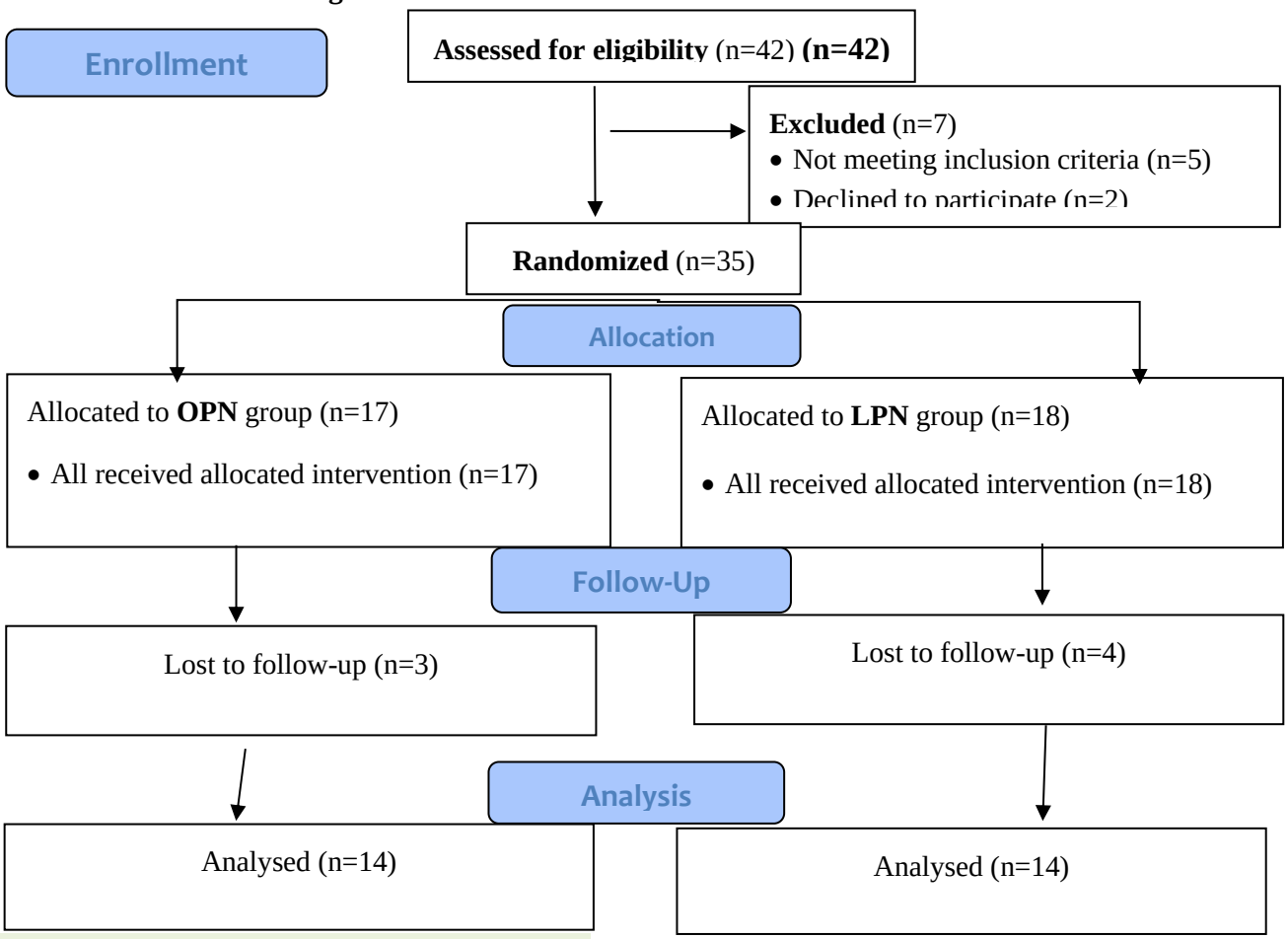
Table (3): Intra and postoperative complications

Complications	OPN N=14	LPN N=14	X^2	P-value
Intraoperative, *no.*	**2**	**2**	**0.00**	**1.00**
Pleural injury	**2**	**0**		
Bowel injury	**0**	**0**		
Bleeding	**0**	**2**		
Postoperative, *no.*	**2**	**3**	**0.24**	**0.62**
Wound infection	**1**	**0**		
Haematoma	**0**	**1**		
Urine leakage	**1**	**2**		
DVT	**0**	**0**		
Total, *no. (%)*	**4 (28.5)**	**5 (35.7)**	**0.68**	**0.16**

Table (4): Renal functional outcomes

eGFR *ml/min/1.73 m²* *mean±sd*	OPN N=14	LPN N=14	t	P-value
Baseline eGFR,	**67.00±10.92**	**70.71±11.57**	**0.87**	**0.39**
24h Postoperative eGFR	**63.64±10.62**	**66.57±10.81**	**0.72**	**0.47**
6 months eGFR,	**62.43±10.26**	**63.50±10.57**	**0.27**	**0.78**
Decline of eGFR from baseline	**4.57±3.88**	**7.36±6.57**	**1.36**	**0.18**

CONSORT Flowchart Diagram



DISCUSSION

Analysis of our study revealed that patients undergone LPN had decreased operative time with significant statistical difference compared with OPN (*P*=0.027) ; this result comes in agreement with two studies of Gill et al comparing open and laparoscopic partial nephrectomy in nearly 2000 cases [11,12], and with [10,13,14] and in contrast with Minervivi et al in a matched-pair comparison of 280 patients with TRIFECTA outcomes (RECORd Project) [15] and Becker et al [16] whose found no significant difference in operative time – even longer in LPN- between two approaches.

Mean estimate blood loss in our study was 196.4±61.4 for LPN and 252.8±70.3 ml for OPN with significant statistical difference (*P*=0.032); this is in line with [10, 11, 12, 17] and in contrast with [13, 14, 15]. There was significant statistical difference between both surgical approaches according to mean postoperative hospital stay/day 3.14±1.1 for LPN versus 4.36±0.7 days for OPN (*P*=0.002); this is consistent with most of studies like [10-14, 17].

The following advantages of laparoscopic surgery may be attributed to these different previously mentioned results of surgical outcomes: laparoscopic skill due to accumulated experience, especially during last cases; laparoscopic magnification allowing fine dissection of the renal artery and suturing of the surgical section and collection system; and continuous suture with Hemo-lok application for clamping the suture. OPN, on the other hand, can be associated with extensive muscle incisions, rib resection, further bleeding and more time required to close the wound and prolonged convalescence than laparoscopic surgery. Finally, different tumor sizes with different anatomical complexity in each study discussed.

According to ischemia time, our results show slight longer WIT (19.57±3.08 min) in laparoscopic surgery than in open surgery (17.79±2.15 min) without significant statistical difference (*P*=0.087). A number of prior studies compared ischemia time during laparoscopic and open surgery, with controversial results. Study of Italian REgistry of Conservative and Radical surgery for cortical renal tumor Disease (RECORd 2 project) comparing perioperative operative outcomes of open, laparoscopic and robotic PN noted that laparoscopic surgery had longer ischemia time than that of open surgery (*P*=0.006) [18] similar to other studies reported longer WIT with LPN [11,12,15,19,20] versus other studies reported shorter WIT [10,14,17,21].

These variations of results about WIT among previously mentioned including our study could be explained by usage of the early renal pedicle unclamping procedure, which was perceived to be an advantage of the laparoscopic procedure, in which the presence of pneumoperitoneum with an intra-abdominal pressure set at 15:20 mmHg prevents potential small vessel bleeding, allowing the tumor to be resected even by unclamped renal vessels. In addition, the high number of clampless procedures in open surgery group of multiple studies with surgeons may be less confident in performing a clampless procedure with a risk of compromised surgical field visualization by excessive bleeding, particularly with recent LPN experience.

Most reports show that, without a substantial statistical difference, perioperative complications are comparable between LPN and OPN, ranging from 5% to 33% for LPN and 4.1% to 38.6% for OPN [14, 22- 25]. In our study, no significant differences in intraoperative, postoperative and total complications were observed after OPN versus LPN (28.5% versus 35.7%, *P*=0.16) with major intraoperative bleeding in two cases (14.2%) of LPN group versus no cases of OPN due to uncontrolled vascular and parenchymal bleeding ended with blood transfusion in parallel with radical and open conversion respectively. Also with two cases of postoperative urine leakage one of them was in need of auxiliary endoscopic ureteral stenting.

These findings are compatible with study discussed the impact of surgical approach on perioperative complications and long term postoperative quality of life which revealed frequency of overall 30-day complications did not differ significantly between LPN and OPN (14.6 versus 16.1 %, *P*=0.8) patients. Moreover, major complications were significantly less frequent in LPN patients (2.4 versus 10.4 %, *P*=0.025) [16] and Minirvini et al, who reported that no significant difference in total complications between both approaches (*P*=0.34), whereas intraoperative surgical complications was significantly higher after OPN (*P*=0.03*)* [15].

These results come in contrast with two studies of Gill et al, [11, 12] whose reported higher rates of intraoperative (*P*=0.03), renal and urological complications (*P*=0.01) among LPN Which could be due to early worldwide experience with LPN and the extension of their LPN inclusion criteria to include, at the time of their research, cT1b, cT1c, central and more deeply infiltrating tumors.

Renal functional outcome of our study revealed no significant statistical difference between treatment groups according to postoperative (*P*=0.47) and 6 months follow up eGFR (*P*=0.78) even with slight increase of eGFR decline from baseline in LPN group (*P*=0.18). these results are consistent with a study discussed laparoscopic and open partial nephrectomy in matched-pair comparison of 200 patients reported that the decline in renal function was similar after PN and OPN and in multivariate analysis, The laparoscopic technique was an independent risk factor for GFR decline in the early postoperative period only, but there was no additional determinative impact on long-term GFR [14]. Also [15, 17, 26] reported the same results on effect of both surgical approaches on renal function. In conclusion, regardless of whether WIT was longer or shorter in LPN than in OPN, as shown in several studies, the mean long-term GFR was often comparable to open surgery [12, 14, 17, 22].

Some limitations of this study, such as limited sample size, may have decreased statistical power in subgroup analysis led to certain associations have not been established that could affect the results of this study. In addition, the CKD-EPI formula was used to assess postoperative renal function, not sequential scintigraphy, which may have allowed for a more detailed description of the function of each renal unit. Also, long term oncologic outcomes with incidence of local recurrence could be assessed with longer follow up periods.

CONCLUSION

For cT1 renal tumors of low complexity, laparoscopic and open partial nephrectomy have comparable surgical and renal functional outcomes. LPN offers a strong alternative to OPN with shorter surgery time, less blood loss, and shorter hospital stay with quicker convalescence, with equivalent ischemia time compared to OPN.

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