

Dynamic Characterization of Rubber O-Rings: Squeeze and Size Effects

Original

Dynamic Characterization of Rubber O-Rings: Squeeze and Size Effects / Al-Bender, F., Colombo, F., Reynaerts, D., Villavicencio, R., Waumans, T.. - In: ADVANCES IN TRIBOLOGY. - ISSN 1687-5915. - 2017:(2017), pp. 1-12. [10.1155/2017/2509879]

Availability:

This version is available at: 11583/2702000 since: 2018-02-27T18:25:56Z

Publisher:

Hindawi

Published

DOI:10.1155/2017/2509879

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Does tumour size really affect the safety of laparoscopic partial nephrectomy?

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Accepted for publication 2 July 2010

Study Type – Therapy (case series)
Level of Evidence 4

OBJECTIVE

- To investigate the perioperative safety of laparoscopic partial nephrectomy (LPN) for large renal masses (>4 cm).

PATIENTS AND METHODS

- After Institutional Review Board approval, data from 100 consecutive patients who had undergone transperitoneal or retroperitoneal LPN at our institution from January 2005 to June 2009 were obtained from our prospectively maintained database.
- The patients were divided into two groups according to radiological tumour size: group A (67 patients) with tumours ≤4 cm and group B (33 patients) with tumours >4 cm.
- Demographic, perioperative and pathological data were evaluated.

RESULTS

- The two groups were comparable in terms of demographic data. Mean tumour size was

What's known on the subject? and What does the study add?

Partial nephrectomy is the standard treatment for the management of small renal masses, and laparoscopy has been widely used in this setting as it has all the principles of open procedures combined with the advantages of minimal invasiveness.

Laparoscopic partial nephrectomy is feasible and has acceptable pathological results not only for small renal masses but also for large tumours, even if complication rate and ischemia time are still matters of debate.

2.4 and 5 cm ($P=0.0001$) for groups A and B, respectively. Group B tumours were more complex, as reflected by significantly more with a central location ($P=0.002$), and by significantly more transperitoneal LPNs, pelvicalyceal repairs and longer warm ischaemia time (WIT; 19 vs 28 min).

- Complications were recorded in nine group A patients (13.4%) and nine group B patients (27.2%) ($P=0.09$).
- There was no difference between preoperative and postoperative serum creatinine levels in either group, while a significant difference was found in postoperative estimated glomerular filtration rate between groups ($P=0.004$).
- The incidence of carcinoma was comparable between the two groups.

- The incidence of positive surgical margins (PSMs) was 3.9% in group A, whereas no PSM was recorded in group B ($P=0.3$).

CONCLUSIONS

- Laparoscopic partial nephrectomy for large tumours is feasible and has acceptable pathological results. However, the complication rate, in particular WIT, remains questionable.
- Further studies are required to better clarify the role of LPN in the management of tumours of this size.

KEYWORDS

partial nephrectomy, laparoscopy, large masses, renal cell carcinoma

INTRODUCTION

Partial nephrectomy (PN) is the standard treatment for the management of small renal masses (SRMs), and achieves similar results to those achieved by radical nephrectomy [1–5]. PN can preserve renal function, reduce the risk of chronic renal failure and have a positive impact on quality of life [4]. The role of PN for tumours >4 cm has traditionally been considered more controversial, however, recent reports from

tertiary centres have suggested that PN for renal tumours >4 cm may be feasible and safe [5–11].

In recent years, laparoscopic PN (LPN) has been widely used in the treatment of SRMs and, in some centres, it has become the standard treatment as it has all the principles of open PN (OPN) combined with the advantages of minimal invasiveness [12–14]. However, while the role of LPN for SRMs is well

documented, there are few reports regarding the use of LPN for large renal masses (>4 cm).

The aim of our study was to investigate the perioperative safety of LPN for large renal masses.

PATIENTS AND METHODS

After Institutional Review Board approval, data from 100 patients who had undergone

LPN by the same surgeon (F.P.) at our institution from January 2005 to June 2009 were obtained from our prospectively maintained database. We began to use LPN as a treatment method in May 2000, but we excluded the first 56 cases from our analysis and considered the entire data series from the first patient treated for a tumour >4 cm. Patients were consecutive. No OPNs were performed at our institution during the study period.

We included in the present study all patients who had been diagnosed with a single, organ-confined, contrast-enhancing renal mass suspected to be a malignant lesion. Indications for surgery for tumours suspected to be an angiomyolipoma included: tumour size >4 cm, chronic flank pain attributable to the renal mass, the requirement for pharmacological therapy and previous spontaneous haemorrhage. Patients were excluded if they had experienced preoperative extrarenal tumour extension, had radiological evidence of lymphadenopathy, or renal vein or collecting system involvement.

Patients were divided into two groups according to tumour size determined by CT. Group A included patients with tumours ≤4 cm and group B included patients with tumours >4 cm.

The preoperative and demographic variables studied were age, sex, radiological tumour size, side and location. Based on a previously reported classification, the tumour growth pattern was defined as 'central' when the tumour involved the central sinus fat or the collecting system on preoperative CT scans, 'cortical' when the lesion involved the cortex, and 'cortico-medullary' when it involved the medulla and the cortex of the kidney [15].

Laparoscopic partial nephrectomy was defined as 'elective' when the contralateral kidney was normal with normal overall renal function, and 'imperative' in cases of a solitary kidney, atrophic contralateral kidney, bilateral tumour or compromised renal function with a risk of end-stage renal disease in case of nephrectomy.

The same technique for LPN was performed in both groups and for lesions suspected of being benign or malignant [15]. Briefly, the procedure was performed using either a transperitoneal or a retroperitoneal approach

on the basis of the location of the tumour and surgeon preference. After opening the Gerota's fascia and identification of the ureter, the renal artery was isolated. A laparoscopic ultrasound probe was used to identify the lesion and its edges. The renal artery alone was then clamped with a vascular bulldog, and the resection was carried out with cold scissors. The renal parenchyma was reconstructed with 2-0 polyglactin 910 interrupted or running sutures secured with non-absorbable polymer locking clips, then a biological glue was used. The collecting system defects were repaired using a single stitch or by incorporating the collecting system in the running suture of the parenchymal reconstruction.

We considered surgical access, type of tumour resection, estimated blood loss (recorded from the suction device), warm ischaemia time (WIT), operative time, type of suture (running or interrupted), collecting system repair, use of biological glue and intraoperative complications. Intraoperative haemorrhage was defined as bleeding necessitating transfusion during the procedure, as ordered by the anaesthesiologists.

Complications, subsequent treatments and postoperative hospital stays were also recorded. Postoperative complications were classified according to the Clavien system [16]. Postoperative haemorrhage was defined as acute blood loss necessitating transfusion, angioembolization or reoperation. Urinary leakage was defined as biochemically confirmed persistent urine drainage. Data from outpatient visits 14 and 30 days after LPN were analysed in order to record complications.

Renal function was assessed using serum creatinine levels measured before LPN and on the 5th postoperative day (POD). Renal function was assessed by estimated GFR and kidney dysfunction was graded using the National Kidney Foundation Dialysis Outcomes Quality Initiative Clinical Practice Guidelines [17].

A single uro-pathologist reviewed all pathological analyses. Malignant masses were classified according to the WHO 2004 classification, and the tumours were graded according to Fuhrman grading. The tumour stage was determined according to the 2002 Union International Contre le Cancer revised TNM classification [18]. Margins were inked

and the specimen was sectioned at 2-mm intervals, perpendicularly on the inked base. Margins were classified as positive or negative, according to Minervini *et al.* [19]. When negative, the distance between the inked margins and the tumour was measured, noting the minimum and maximum thickness of peri-tumoural healthy tissue.

All data were evaluated using statistical software (Stat Soft 6.0®). Data presented a normal distribution. Descriptive analysis was used to evaluate all considered variables, qualitative analyses were compared using chi-squared analyses (Fisher exact tests) and quantitative analyses were compared using the Student's *t*-test. Multiple regression analysis was used to evaluate risk factors for complications and positive surgical margins. Statistical significance was considered for $\alpha \leq 5\%$. Data are presented as mean \pm SD.

The endpoint of the study was to evaluate the possible influence of tumour size on the safety of the procedure, i.e. if LPN outcomes and surgical margin status significantly differed between the two groups.

RESULTS

In all, 100 patients were evaluated: 67 patients were assigned to group A, and 33 patients to group B. The demographic data and tumour characteristics are shown in Table 1 and operative data are shown in Table 2. In group B, a significantly higher number of transperitoneal LPNs and pelvic/ureteral repairs, longer WIT and greater blood loss were recorded. No intraoperative complications were recorded in either group; most notably, no significant bleeding during the procedure or conversion to open surgery was observed. Postoperative complications are shown in Table 3. Overall, no differences were recorded between the groups in terms of the number and type of complication. No Clavien system grade IV or V complications were recorded.

Multiple regression analyses did not show any correlations between tumour size and overall complications or between overall complications and the side/location of the lesion. However, a significant statistical correlation was found between overall complications and growth pattern ($\beta = 0.43$, $P = 0.001$).

Measures of renal function according to tumour size are shown in Table 4. There was no difference between the preoperative and postoperative serum creatinine levels in the two groups. No difference in preoperative estimated GFR was observed, while a significant difference was found in postoperative estimated GFR between groups ($P = 0.004$).

Before LPN, no patients in group A vs four (12%) patients in group B presented with stage \geq III chronic kidney disease (CKD; $P = 0.003$). Stage progression was not recorded in group A, while four cases (12%) were reported in group B ($P = 0.003$). When considering the group B patients (four patients) in whom stage progression was observed vs patients in whom it was not (29 patients), no significant difference was recorded in terms of WIT ($P = 0.2$).

Pathological data are shown in Table 5. The incidence of carcinoma was comparable between the two groups. A significant difference was recorded between peritumoural healthy tissue excised from patients in the two groups; the amount of this tissue was higher in group B. The minimum mean measurement was 1.1 (± 1.1) mm in group A and 1.9 (± 1.9) mm in group 2 ($P = 0.04$). The maximum mean measurement was 5.5 (± 4.7) mm in group A and 7.9 (± 4.5) mm in group B ($P = 0.01$). The mean differential measurement of margin was 3.4 (± 3.2) mm in group A and 5.1 (± 3.2) mm in group B ($P = 0.001$).

The incidence of positive surgical margins (PSMs) was 3.9% in group A, whereas no PSM was recorded in group B ($P = 0.3$). Multiple regression analyses did not reveal correlations between surgical margin status and tumour size or between surgical margin status and the side/location of tumour, growth pattern or surgical access ($P = 0.1$).

DISCUSSION

Laparoscopy has been widely used in the last decade for many urological diseases, and LPN is safely performed for SRMs in many centres [12–15]. However, few data about LPN for large masses are available. Recently, Simmons *et al.* [20] suggested that LPN for large masses has similar operative efficacy and perioperative and pathological success rates to LPN for smaller tumours.

TABLE 1 Demographic data and tumour characteristics

Characteristics	Total	Tumour size		P
		Group A ≤ 4 cm	Group B > 4 cm	
Number of patients	100	67	33	–
Mean (SD) age, years	58.4 (14.9)	58.0 (15.9)	58.6 (14.8)	0.8
Mean (SD) body mass index	27.3 (3.9)	26.8 (4.5)	27.7 (3.4)	0.3
Male patients, %	63	60.5	64	0.9
ASA score ≥ 3 , %	46	45	50	0.7
Tumour in right kidney, %	51	54.5	49	0.7
Mean (SD) tumour size, cm	3.2 (1.5)	2.4 (0.8)	5.0 (1.0)	0.001
Tumour size range, cm	0.9–8.0	0.9–4.0	4.1–8.0	–
Patients with solitary kidney (%)	2 (2)	2 (3)	0 (0)	0.8
Location of tumour (%)				
Upper pole	37 (37)	26 (38.8)	11 (33.3)	0.7
Lower pole	35 (35)	22 (32.8)	13 (39.4)	0.6
Medium third	28 (28)	19 (28.4)	9 (27.3)	0.9
Location of the lesion (%)				
Anterior	45 (45)	32 (47)	14 (53)	0.6
Posterior	55 (55)	35 (53)	19 (47)	
Growth pattern (%)				
Cortical	10 (10)	8 (12)	2 (7)	0.3
Cortico-medullary	70 (70)	52 (77.5)	18 (54)	0.01
Central	20 (20)	7 (10.5)	13 (39)	0.002

ASA, American Society of Anaesthesiologists.

TABLE 2 Perioperative data classified by tumour size

Characteristics	Total	Tumour size		P
		Group A ≤ 4 cm	Group B > 4 cm	
Number of patients	100	67	33	–
Transperitoneal LPNs (%)	34 (34)	16 (24)	18 (54)	0.006
Conversions to OPN	0	0	0	–
Pelvic/lyceal repairs (%)	26 (26)	10 (15)	16 (50)	0.001
Mean (SD) WIT, min	22.8 (9.8)	19.7 (9.6)	28.4 (7.4)	0.001
WIT range, min	16–42	16–38	18–42	–
Mean (SD) blood loss, ml	156.1 (99.4)	132.2 (85.6)	203.9 (109.4)	0.006
Blood loss range, ml	50–800	50–750	50–800	–
Mean (SD) operative time, min	121.9 (33.3)	115.6 (27.1)	134.5 (40.7)	0.01
Use of running sutures (%)	44 (44)	35 (52.3)	11 (33.3)	0.1
Use of haemostatic sealant (%)	96 (96)	63 (94)	33 (100)	0.3
Mean (SD) hospital stay, days	6.1 (1.3)	6.0 (1.3)	6.2 (1.1)	0.3

To investigate this possibility, we reviewed our prospectively maintained database for LPN. To assess the technical feasibility and perioperative outcomes of LPN in patients with tumours > 4 cm, we compared this data with outcomes for tumours ≤ 4 cm.

Patients treated with LPN between January 2005 and June 2009 for single, organ-

confined, contrast-enhancing renal mass constituted the study population. Patients were consecutive and in the study period no patients were treated with OPN. We excluded the first 56 cases from our analysis and considered the entire data series from the first patient treated for a tumour > 4 cm to eliminate the bias of a learning curve. Thus all of the cases were performed in an era

TABLE 3 Postoperative complications classified according to tumour size, using the Clavien system

Group	Number of cases	Type of complication	Management of complications	Grade
A	4	Fever	Antipyretics, antibiotics	I
A	1	Pneumonia	Antipyretics, antibiotics	I
A	1	Retroperitoneal haematoma	Reoperation (on the 2nd POD, open suture of renal parenchyma)	IIIb
A	3	Acute Bleeding	Blood transfusion	II
			Embolization (two cases: on the 5th POD owing to pseudoaneurysm and 6th POD owing to arterovenous fistula)	IIIa
B	1	Fever	Antipyretics, antibiotics	I
B	2	Retroperitoneal haematoma	Antipyretics, antibiotics	I
B	5	Acute bleeding	Blood transfusion (1)	II
			Embolization (two cases: on the 7th POD owing to pseudoaneurysm, and 6th POD owing to pseudoaneurysm)	IIIa
			Reoperation (two cases: on the 1st POD open suture of renal parenchyma; on the 1st POD open nephrectomy owing to uncontrolled bleeding from the resection bed)	IIIb
B	1	Urinary Fistula	Endoscopic double J stent placement (on the 2nd POD)	IIIa

No statistically significant differences were recorded between the two groups in terms of complication rate (13.4% vs 27.2% for groups A and B respectively, $P = 0.09$). Grade III complications did not differ significantly between the two groups (4.5% vs 15% for groups A and B respectively, $P = 0.06$).

TABLE 4 Renal function classified according to tumour size

Characteristics	Tumour size		P
	Group A ≤4 cm	Group B >4 cm	
Number of patients	67	33	-
Mean (SD) preoperative serum creatine, mg/dL	0.9 (0.2)	1.0 (0.5)	0.1
Mean (SD) postoperative serum creatine, mg/dL	1.1 (0.1)	1.0 (0.4)	0.06
Mean (SD) preoperative estimated GFR, mL/min	91.8 (15.9)	80.8 (23.8)	0.1
Mean (SD) postoperative estimated GFR, mL/min	87.2(20.9)	78.2(23.8)	0.004
CKD stage ≥ III, n (%)			
Before LPN	0	4 (12.5)	0.003
After LPN	0	8 (25.0)	<0.001
Mean (SD) WIT of patients without CKD stage progression, min	-	28.06 (8.3)	0.2
Mean (SD) WIT of patients with CKD stage progression, min	-	31.25 (5.7)	

Estimated GFR was based on the Modification of Diet in Renal Disease study definition and kidney dysfunction was classified as follows: Stage I, GFR ≥90; stage II, GFR 60–89; stage III, GFR 30–59; stage IV, GFR 15–29; and stage V, GFR <15 [17].

where LPN was being offered for tumours >4 cm. In our opinion, these aspects make the study population somewhat homogeneous. The present study focuses specifically on perioperative outcomes within 30 days of LPN, presenting data on short-term renal functional outcomes and complications.

The two groups were comparable in terms of demographic data but, not surprisingly, differed as far as lesion size was concerned

($P = 0.001$). The tumours in group B were more complex, as reflected by the higher incidence of central location ($P = 0.002$). This resulted in a higher rate of transperitoneal LPNs ($P = 0.006$), which allows for easier mass manipulation, particularly when the mass is large. We also found an higher rate of pelvicalyceal system repair in group B. No differences were recorded between the two groups regarding the type of suture and use of sealants.

In group B, statistically significantly greater blood loss and longer operative times were recorded; however, one should note that both of these, ≈70 mL of blood loss and 20 min longer operative time, were clinically negligible. WIT was longer in the patients in group B by only 8 min despite increased tumour complexity; this measurement was comparable with previous reports [20–22], but it is still higher than that reported for OPN [10]. An early unclamping technique was proposed in order to reduce WIT [23] but this approach could increase the complication rate and cause significant blood loss. Even if the WIT values in the present study could seem discouraging, it is important to emphasize that the data used also reflect our initial experiences with large masses. No significant intraoperative complications were recorded in either group.

As far as postoperative complications are concerned, no significant differences were noted in the two groups, even if an increase in complication rate was observed in group B. A significant correlation was found between a central growth pattern of the lesions and complications, and this could be easily explained by the fact that tumour resection and suture are more difficult in these cases. The grade ≥ III complication rate was 4.5% and 15% in group A and B respectively, with a trend toward a statistical difference between the two groups, but we think that these rates

are acceptable considering the complexity of this kind of surgery.

The preoperative and postoperative creatinine serum levels (measured on the 5th POD) were comparable, but a significant 'early' impairment of postoperative renal function, evaluated using estimated GFR, was recorded for group B. We confirmed that the estimated GFR measurement, rather than the serum creatinine level, is clinically more relevant and, arguably, should be adopted as the standard measurement in preoperative assessment for LPN. We observed a nonsignificant trend toward longest duration of WIT in patients with stage migration and this could suggest that prolonged WIT is associated with an increased incidence of postoperative kidney dysfunction.

As far as pathological data are concerned, one should note that a single, experienced uro-pathologist reviewed all the specimens. No significant differences were observed between the two groups. Even though the number of patients is very low, our data suggest that increased tumour size did not correlate with a higher incidence of stage pT3 disease.

Overall, the PSM rate was 2.5%, and this is comparable with that found in the literature for LPN and OPN [3,6,7,11,12,20]. Interestingly, no PSM was found in group B, and this rate was lower than that reported by other studies [20]. We consider our data highly interesting because one of the most important criticisms of LPN is the high rate of PSM with respect to OPN. Our data provide evidence against this assertion, which we believe is the strength of our study. The mean amount of excised peri-tumoural healthy tissue was higher in group B ($P = 0.001$). One should note that in patients with a large renal mass a small amount of tissue should be removed in order to reduce the risk of renal function impairment, but this is not always possible because of the limited angulation of instruments during laparoscopy, which causes the surgeon to work in a limited direction.

The present study has some limitations. It is a retrospective study, and a limited number of patients, including patients with RCC, were enrolled in group B, and this could increase chances of a statistical error with regard to type II. Although these limitations could

TABLE 5 Pathological data classified according to tumour size

	Group A, N = 67 (%)	Group B, N = 33 (%)	P
Histological subtypes in benign tumours (n = 22)			
Angiomyolipoma	8	4	0.1
Oncocytoma	2	0	0.08
Other	6	2	0.8
Total	16 (24)	6 (18)	
Histological subtypes in malignant tumours (n = 78)			
Clear cell carcinomas	30 (58.8)	15 (55.6)	0.9
Papillary carcinomas	12 (23.5)	10 (37.0)	0.2
Chromophobe carcinomas	5 (9.8)	2 (7.4)	0.9
Other	4 (7.9)	0	0.2
Total	51 (76)	27 (82)	
Fuhrman Grade in malignant tumours			
Grade 1	19 (32.3)	10 (37.0)	0.8
Grade 2	20 (39.2)	13 (48.2)	0.5
Grade 3	12 (23.5)	4 (14.8)	0.4
Grade 4	0	0	-
Total	51	27	
T stage, according to UICC classification, in malignant tumour,			
T1a	49 (96)	0	n.a.
T1b	0	23 (85.2)	n.a.
T2	0	2 (7.4)	n.a.
T3a	2 (4)	1 (3.7)	n.a.
T3b	0	1 (3.7)	n.a.
Surgical margin status, n = 78			
Positive	2 (3.9)	0	0.8

UICC, Union International Contre le Cancer. n.a., not applicable.

affect our results, we believe that our study provides useful information to the urological community. LPN is an emerging treatment method for large tumours and further improvements are likely in the future with the development of new techniques or extended indications.

In our opinion, it is essential that the surgeon has significant laparoscopic experience before embarking on LPN procedures, especially for large renal masses, and these data may not be immediately transferable to the practising urologist. We strongly advise that surgical techniques should always be chosen in relation to the surgeon's experience. Therefore, when a large renal mass has to be treated and the surgeon is not skilled in LPN, we believe that a well performed OPN is better than a poor LPN or a well performed laparoscopic radical nephrectomy.

In conclusion, our data demonstrate that LPN for large tumours is feasible and has acceptable pathological results. However,

the complication rate and WIT remain questionable. Further studies are required to better clarify the role of LPN in the management of tumours of this size.

ACKNOWLEDGEMENTS

The authors would like to thank Cosimo De Nunzio, MD, for his collaboration and his critical review.

CONFLICT OF INTEREST

None declared.

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Abbreviations: PN, partial nephrectomy; SRM, small renal mass; LPN, laparoscopic partial nephrectomy; OPN, open partial nephrectomy; WIT, warm ischaemia time; POD, postoperative day; PSM, positive surgical margin; CKD, chronic kidney disease.

EDITORIAL COMMENT

DOES TUMOUR SIZE REALLY AFFECT THE SAFETY OF LAPAROSCOPIC PARTIAL NEPHRECTOMY?

The study by Porphiglia *et al.* is a well written article on the feasibility of laparoscopic partial nephrectomy (LPN) for renal masses >4cm. The evolution of LPN for the management of renal masses of increasing size has mirrored the historical evolution of open partial nephrectomy (OPN). Masses of increasing size and complexity are tackled by surgeons with significant laparoscopic experience. However, it is crucial to point out that LPN for the large renal mass is a challenging operation. It should not be attempted by surgeons who are not adept at intracorporeal suturing and reconstruction. The issue of warm ischaemia continues to be a factor in LPN, making experience and speed even more crucial. The question then arises, in this era of extreme enthusiasm for robot-assisted surgery, whether robotic assistance can help in complex renal mass resections and reconstructions. There are certain intuitive concerns. The beauty of pure LPN is that the surgeon is in total control, whereas the robot-assisted surgeon has to heavily rely on the bedside assistant(s). The margin of error in renal surgery is much smaller than in prostatectomy. The dissection is in close proximity to large vital blood vessels and the risk of massive haemorrhage is greater. The dissection and mobilization of the kidney and the mass plus the renal hilum is faster and more efficient. The resection and reconstruction portion, given certain angles and certainly the size of the lesion, can be more challenging for the not-so-proficient laparoscopic surgeon. The opposite is true for robotic assistance. The initial