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Analysis of oncological outcomes and renal function after laparoendoscopic single-site (LESS) partial nephrectomy: a multi-institutional outcome analysis

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Objective

- To report on a large multi-institutional series of laparoendoscopic single-site (LESS) partial nephrectomy (PN) and analyse renal function and short-term oncological outcomes.

Material and Methods

- We conducted a retrospective analysis of consecutive cases of LESS-PN performed between November 2007 and March 2012 at 11 participating institutions.
- Demographic data and data on the main peri-operative outcomes and complications were gathered and analysed.
- Kidney function was evaluated by measuring serum creatinine concentration and estimated glomerular filtration rate (eGFR).
- Chronic kidney disease was defined in stages for each patient according to the National Kidney Foundation, Kidney Disease Outcomes Quality Initiative.

Results

- A total of 190 cases were included in this analysis. The mean renal tumour size was 2.6 cm, and the mean PADUA score was 7.2.
- The median operating time was 170 min with a median estimated blood loss of 150 mL. A clampless technique was used in 70 cases (36.8%) and the median warm ischaemia time (WIT) was 16.5 min.
- PADUA score independently predicted the length of WIT (low vs high score: odds ratio 5.11, CI 1.50–17.41, $P = 0.009$; intermediate vs high score: odds ratio 5.13, CI 1.56–16.88, $P = 0.007$).
- The overall postoperative complication rate was 14.7%. Where a clamping technique was used, a significant increase in serum creatinine concentration and a significant decrease in eGFR were observed postoperatively and at 6 months. On multivariate analysis PADUA score was the only predicting factor.
- Overall survival rates were 99, 97 and 88% at 12-, 24- and 36-month follow-up, respectively, while disease-free survival rates were 98% at 12-month and 97% at 24- and 36-month follow-up.

Conclusion

- The study showed that LESS-PN is effective in terms of renal function preservation and oncological control at short- and intermediate-term follow-up.

Keywords

laparoendoscopic single-site surgery, LESS, partial nephrectomy, warm ischaemia time, complications

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Introduction

Over the past decade, nephron-sparing surgery (NSS) has become the standard of care for most renal tumours [1]. Renal function outcome is superior in patients undergoing partial nephrectomy (PN) when compared with those undergoing radical nephrectomy [2]. The long-term follow-up of patients who have undergone open PN has shown the technique to be safe and effective in terms of oncological and functional results [1,2]. Nevertheless, in recent years, laparoscopic PN (LPN) has also gained popularity, but it is currently performed in only a few high-volume referral centres and its diffusion has been limited by the steep learning curve involved [2]. Conversely, robot-assisted LPN is gaining momentum as a promising procedure that is able to bridge the technical difficulties of LPN, leading to a broader diffusion of minimally invasive NSS [3]. A crucial aspect of these new procedures remains warm ischaemia time (WIT), which can potentially affect short- and long-term renal function [4–7]. Over the last decade, the perception of 'safe' WIT has decreased from 55–40 min to 30–20 min [4,6,7]; however, more recent studies indicate that there may in fact be no safe WIT, suggesting that every minute might count [4]. Since its early use in urology, there has been a growing interest in laparoendoscopic single-site (LESS) surgery, which has proved to be applicable in the clinical field, being safe in the hands of experienced laparoscopic surgeons in well selected patients. The whole spectrum of extirpative and reconstructive urological procedures has by now been performed and described using LESS surgery [8,9]. LESS-PN intuitively represents a very challenging procedure, because of the potential need for hilar clamping, and extensive suturing, and because of the increased risk of peri-operative complications [10,11]. A collaborative multi-institutional project on LESS urological surgery was published 2 years ago with the aim of reporting the contemporary practice of LESS surgery at institutions pioneering the development of this technique in urology [9]. Following on from that collaborative effort, the objective of the present study was conceived and initiated to analyse the effect of LESS-PN specifically on renal function and short-term oncological outcomes.

Patients and Methods

Study Design

Our cohort consisted of 190 consecutive patients treated with LESS-PN at 11 participating institutions between November 2007 and March 2012 after a clinical diagnosis of enhancing renal mass. Each group performed the procedures according to its own protocols, entry criteria and techniques. All patients gave specific consent to undergo LESS surgery. Raw data with no identifiers were retrospectively collected and gathered into a standardized datasheet, which was specifically built for the purposes of the study.

Outcome

The following information was collected: age, gender, body mass index, pre- and postoperative renal function, previous abdominal surgery, specific comorbidities and American Society of Anesthesiologists (ASA) and Charlson comorbidity index (CCI) scores, tumour stage and grade, surgical margin status, operating time, WIT and estimated blood loss (EBL).

Additional collected data included type of surgery (robot-assisted vs conventional LESS–PN), surgical approach (trans- vs retroperitoneal), access site (umbilical vs extra-umbilical), use of ancillary needlescopic or minilaparoscopic ports, preoperative and postoperative serum haemoglobin levels, transfusion data, conversion to open surgery or to standard laparoscopy, length of hospital stay, postoperative pain evaluated based on a visual analogue scale score at time of discharge, and incision length.

Medical and surgical complications occurring at any time after surgery were captured for the inpatient stay as well as in the outpatient setting. They were classified as early (onset <30 days), intermediate (onset 31–90 days), or late (onset >90 days) complications. All complications were recorded with a grade assigned according to the modified Dindo–Clavien classification system [12]. The PADUA score [13] was used to assess the tumour characteristics.

Kidney function was evaluated by measuring serum creatinine concentration and estimated GFR (eGFR), calculated using the modification of diet renal disease (MDRD) equation, preoperatively and postoperatively and at 6-month follow-up. In addition, for each patient, chronic kidney disease (CKD) stage was defined according to National Kidney Foundation, Kidney Disease Outcomes Quality Initiative.

The length of follow-up was calculated from the date of surgery to the date of the most recent documented examination.

Statistical Analysis

Patients' baseline characteristics and surgical outcomes were reported as frequencies (percentages) for categorical variables, and median and interquartile ranges (IQRs) for continuous variables. The signed-rank test for dependent populations was used to compare median serum creatinine concentration and eGFR at different time points (preoperatively, at discharge and 6-month follow-up) and both groups (robot-assisted vs conventional LESS-PN) were matched for PADUA score in the evaluation of renal function. In addition, the number of patients with CKD stages 1–2 vs those with stages 3–5 were compared at the different time points (preoperative, postoperative and 6-month) using the McNemaer test for paired proportions. Calculated *P* values were adjusted using the Bonferroni method. Overall survival and disease-free-survival rates were calculated using the Kaplan–Meier method.

For all statistical analyses, a two-sided P value <0.05 was considered to indicate statistical significance. All analyses were performed using SAS Statistical Package Release 9.2 (SAS Institute, Cary, NC, USA).

Results

Study Population

The patient population was generally young (median [IQR] age 55 [48–64] years), non-obese (median [IQR] body mass index 25.76, [23.53–27.97] kg/m^2) and healthy (median [IQR] preoperative ASA and CCI scores 2 [1–3] and 2 [0–6], respectively). In all, 46 patients (24.2%) had previously undergone abdominal surgery (Table 1). The median (IQR) follow-up was 17.28 (6.43–25.18) months.

Intra- and Postoperative Outcomes

The median (IQR) operating time was 170 (130–209) min with a median (IQR) EBL of 150 (80–300) mL. A clampless technique was used in 70 cases (36.8%) and the median (IQR) WIT was 16.5 (0–26) min. In 117 cases (61.6%) the surgeons required additional ports, with standard laparoscopy and open surgery conversion rates of 5.8% (11/190) and 2.1% (4/190), respectively. The reasons for the conversion to standard laparoscopy were difficulties during dissection and exposure (four cases), demanding suture (five cases) and bleeding (two cases). There were no conversions to radical nephrectomy. The median (IQR) hospital stay was 4 (3–5) days and the median (IQR) visual analogue scale score at discharge was 1 (0–2). A total of 28 postoperative complications were recorded: 16 early, five intermediate and one late, for an overall complication rate of 14.7% (18 [64.3%] Clavien I–II and 10 [35.7%] Clavien III–IV complications [Tables 2,3]).

Table 1 Baseline characteristics.

Median (IQR) age, years	55 (48–64)
Median (IQR) body mass index, kg/m^2	25.7 (23.5–27.9)
Median (IQR) preoperative creatinine concentration, mg/dL	0.9 (0.74–1.03)
Median (IQR) preoperative eGFR, mL/min per 1.73 m^2	85.4 (72.9–96.9)
Male gender, *n* (%)	109 (57.4)
ASA score, *n* (%)	
1	84 (44.2)
2	79 (41.6)
3	27 (14.2)
Previous surgery, *n* (%)	46 (24.21)
Mean (SD) tumour size, cm	2.6 (0.9)
Tumour side, *n* (%)	
Left	89 (6.84)
Right	101 (53.16)
PADUA score, *n* (%)	
Low (6–7)	94 (49.47)
Intermediate (8–9)	62 (32.63)
High (≥10)	34 (17.9)

Renal Function

When a clamping technique was used and with increasing WIT duration, a significant increase in serum creatinine was observed postoperatively: the median (IQR) post- vs preoperative serum creatinine concentrations were 1.00 (0.82–1.18) vs 0.90 (0.74–1.03) mg/dL ($P < 0.001$) and the 6-month vs preoperative values were 0.93 (0.79–1.14) vs 0.90 (0.74–1.03) μmol/L ($P = 0.008$ [Table 4A, Fig. 1]). Similarly, a significant decrease in eGFR was observed postoperatively: median (IQR) post- vs preoperative eGFR: 74.69 (62.83–87.65) vs 85.39 (72.95–96.99) mL/min per 1.73 m^2, $P < 0.001$) and the 6-month vs preoperative eGFR values were 79.96 (67.37–97.34) vs 85.39 (72.95–96.99) mL/min per 1.73 m^2 ($P < 0.001$ [Table 4B, Fig. 2]). A significant increase in the percentage of patients with CKD stages 3–4 was also observed (preoperatively vs postoperatively: 11.58 vs 20.53% [$P = 0.002$] and preoperatively vs 6-month follow-up: 11.58 vs 17.37% [$P = 0.023$]). No patient was upstaged to CKD stage 5. WIT was <20 min in 45 of 120 clamped cases (37.5%). When

Table 2 Surgical outcomes.

Mean (SD) operating time, min	178 (70)
Mean (SD) EBL, mL	249 (259)
Clamping, *n* (%)	
No	70 (36.8)
Yes	120 (63.2)
Mean (SD) WIT, min	16 (14)
Mean (SD) length of skin incision, cm	2.9 (0.5)
Robot-assisted LESS technique, *n* (%)	71 (37.4)
Conversion to laparoscopy, *n* (%)	11 (5.8)
Conversion to open surgery, *n* (%)	4 (2.1)
Hospital stay, days	4 (3)
Complications, *n* (%)	
Overall	14.7
Clavien I/II	64.3
Clavien III/IV	35.7

Table 3 Complications according to the modified Dindo–Clavien classification.

Complication	Patients, *n*	Action
Clavien Grade I	**11**	
Flank pain	5	Analgesics
Fever	3	Antipyretics
Hypertension	2	Diuretics
Perinephritic haematoma	1	Conservative
Clavien Grade II	**7**	
Postoperative anaemia	5	Transfusion (unclamped LESS-PN = 1; clamped LESS-PN = 4)
Acute gastritis	2	Pharmacological treatment
Clavien Grade IIIb	**9**	
Postoperative ureter leakage	5	Placement of an ureteric stent
Lesion of the bowel	1	Surgical repair
Delayed gross haematuria	2	Selective angioembolization
Sepsis	1	CT-guided drainage, antibiotics
Clavien Grade IV	**1**	
Stroke	1	Antithrombotic drug, intensive unit, carotid endarterectomy

Table 4A Change in median serum creatinine concentration over time according to clamping technique, WIT >20 min and PADUA score.

		Median (IQR) serum creatinine concentration, mg/dL			*P* value for Wilcoxon signed-rank test*	
		Preoperative	Postoperative	6 months	Postoperative vs preoperative	6 months vs preoperative
Overall		0.90 (0.74–1.03)	1.00 (0.82–1.18)	0.93 (0.79–1.14)	**0.0002**	**0.0004**
Clamping	Yes	0.89 (0.73–1.01)	1.0 (0.82–1.20)	0.90 (0.76–1.10)	**0.0002**	**0.0084**
	No	0.91 (0.79–1.10)	0.98 (0.80–1.14)	1.0 (0.825–1.17)	0.3984	**0.034**
WIT >20 min	Yes	0.90 (0.74–1.02)	1.00 (0.83–1.24)	0.93 (0.75–1.15)	**0.0002**	**0.0076**
	No	0.90 (0.74–1.04)	0.97 (0.80–1.13)	0.92 (0.80–1.11)	**0.0012**	**0.0348**
PADUA score	Low (6–7)	0.90 (0.77–1.03)	0.98 (0.82–1.14)	0.97 (0.80–1.17)	**0.0022**	**0.0042**
	8–9	0.89 (0.72–1.00)	0.98 (0.80–1.20)	0.90 (0.75–1.01)	**0.0002**	1.00
	≥10	0.90 (0.73–1.06)	1.03 (0.88–1.21)	0.99 (0.80–1.14)	**0.0002**	**0.0032**

**Adjusted P value using Bonferroni method.*

Table 4B Change in median eGFR levels over time according to clamping technique, WIT >20 min, PADUA score.

		Median (IQR) eGFR, mL/min per 1.73 m^2			*P* value for Wilcoxon signed-rank test*	
		Preoperative	Postoperative	6 months	Postoperative vs preoperative	6 months vs preoperative
Overall		85.39 (72.95–96.99)	74.69 (62.83–87.65)	79.96 (67.37–97.34)	**0.0002**	**0.0002**
Clamping	Yes	87.59 (77.84–97.86)	73.75 (62.48–85.74)	84.37 (70.23–99.85)	**0.0002**	**0.0234**
	No	82.53 (62.90–96.99)	75.43 (63.85–88.90)	72.04 (62.21–90.52)	0.2772	**0.002**
WIT >20 min	Yes	85.40 (79.46–96.43)	71.82 (61.37–82.46)	79.79 (67.37–100.35)	**0.0002**	**0.0266**
	No	85.38 (68.11–99.63)	76.78 (63.85–89.72)	80.13 (66.35–96.13)	**0.0006**	**0.0054**
PADUA score	Low (6–7)	84.46 (71.63–100.77)	77.76 (63.26–91.58)	75.59 (64.38–97.74)	**0.002**	**0.002**
	8–9	89.07 (73.80–95.33)	74.74 (64.47–87.42)	84.81 (72.04–98.20)	**0.0002**	1.00
	≥10	83.72 (74.93–96.99)	72.31 (59.34–80.89)	78.32 (63.15–95.78)	**0.0002**	**0.0062**

**Adjusted P value using Bonferroni method.*

matched for PADUA score, a significant postoperative increase in serum creatinine concentration and decrease in eGFR was observed both after robot-assisted LESS-PN (both $P < 0.001$) and after conventional LESS-PN ($P = 0.006$ and 0.005). Nevertheless at 6-month follow-up, a decreased renal function was reported only for conventional LESS-PN ($P = 0.006$ and 0.042 [Table 5]).

Oncological Outcomes

The mean (SD) renal tumour size was 2.6 (0.9) cm, and PADUA score was 7.2. Of 190 lesions, 151 (79.47%) were malignant. Of these, 139 were RCCs and 12 were chromophobe renal cancers (Table 6). The remaining 39 lesions (20.53%) were benign and included 15 angiomyolipoma, 11 oncocytoma and 17 other benign diseases (adenomas, cysts, granulomas, lipomas). Positive surgical margins were found in eight cases (4.2%), including, at definitive pathology, two pT1a and one pT3 RCC, one pT1a chromophobe renal cancer, three angiomyolipoma and one oncocytoma. One patient developed liver metastasis 6 months after surgery and another one presented with a local recurrence 21 months after surgery. Three deaths occurred, two of those were not related to renal cancer and the third was the patient who developed liver metastasis. The overall survival rates were therefore 99, 97 and 88% at 12-, 24- and 36-month follow-up, respectively (Fig. 3), while the disease-free survival rates were 98% at 12-month and 97% at both 24- and 36-month follow-up (Fig. 4).

Discussion

Initially, NSS was reserved for patients at high risk of developing renal failure after kidney surgery to treat renal cancer. Van Poppel et al. [14], in a randomized, prospective, phase III trial reported equivalent oncological outcomes after NSS and radical nephrectomy, and suggested that NSS may be an acceptable approach for small asymptomatic RCC. LPN has been proposed as a valid alternative to open surgery, achieving equivalent functional and oncological outcomes but with less surgical trauma [15], and the evolution of minimally invasive techniques has furthered an impetus in the surgical community to reduce the invasiveness of laparoscopic surgery. In recent years, the introduction of advanced equipment and

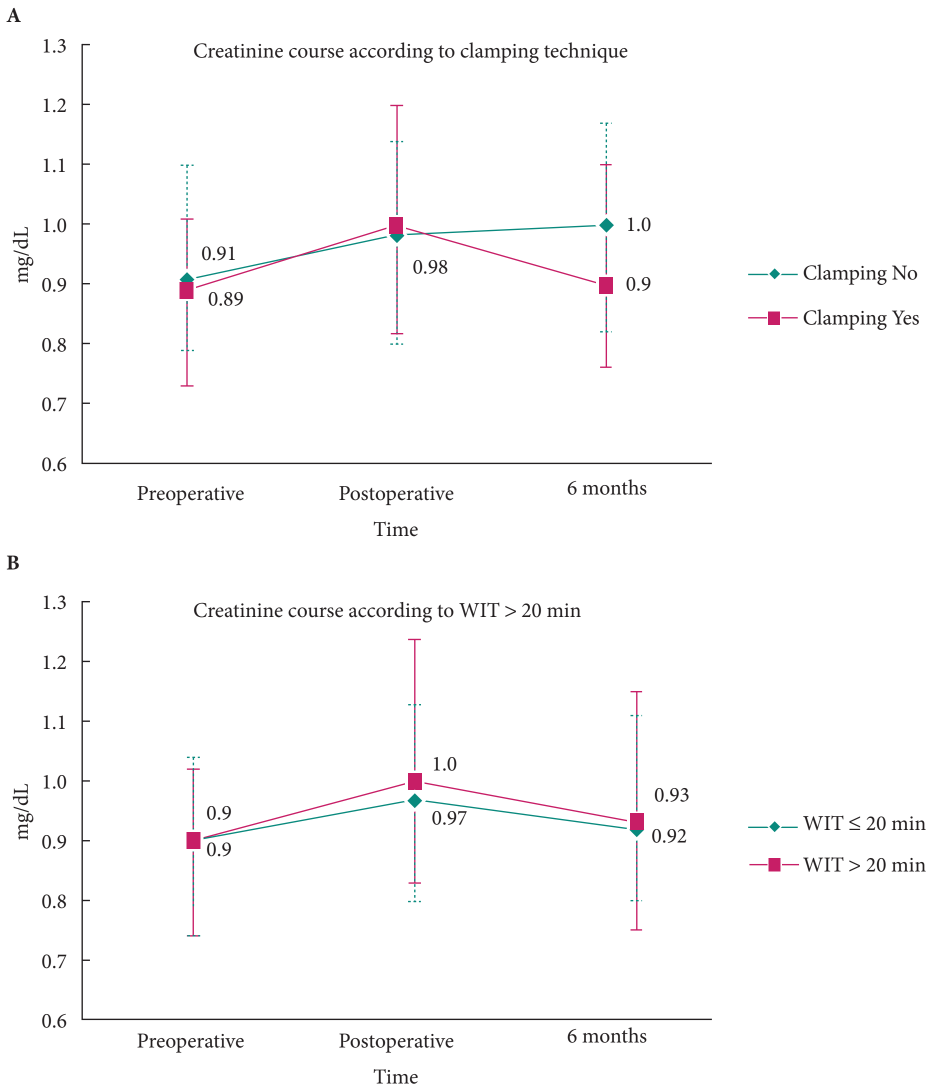


Fig. 1 Time course of creatinine levels by clamping technique (1A) and Wit duration (1B).

technical modifications put the concept of triangulation in the shade and shed light on LESS surgery as a new, alternative, laparoscopic approach [8,16]. The entire spectrum of urological procedures has now been performed and described using a LESS approach, including ablative and reconstructive surgery, as described in the first, worldwide, multi-institutional LESS surgery database [9,17,18]. Furthermore, recent studies have reported similar outcomes for LESS surgery and conventional laparoscopy in patients with several comorbidities and previous abdominal surgery [19,20]. After the first report by Aron et al. [21] on their initial experiences with ischaemic LESS-PN, several studies have reported on the problems and challenges encountered during LESS-PN [10,11,16,22–29]. Recently, a review of the literature that was focused on this kind of surgery [23] showed that it was exclusively performed by very skilled laparoscopic surgeons. Of the 110 cases described in the literature (62 robot-assisted), the authors noted that only very small masses (<3 cm) were approached (mean operating time: 179 min; mean EBL: 249 mL). Eighteen percent of the cases were performed without ischaemia; in the others, the mean WIT was ~21 min (transfusion rate: 7.5%). The occurrence of severe complications was generally low (5.4%) and, in a high percentage of the cases, additional trocars were added. More recently, a large multicentre analysis reported that patients presenting with low PADUA score tumours represented the best candidates for LESS-PN and that the application of a robotic platform was likely to reduce the overall risk of postoperative complications [10].

A technically modifiable risk factor during NSS that affects remnant renal function is the duration of renal ischaemia. The best WIT threshold to consider for a safe NSS procedure has been debated over the last years, and recently it has been suggested to be 20 min [7], but the concept that every minute of WIT may count is generally recognized [4]. Recently,

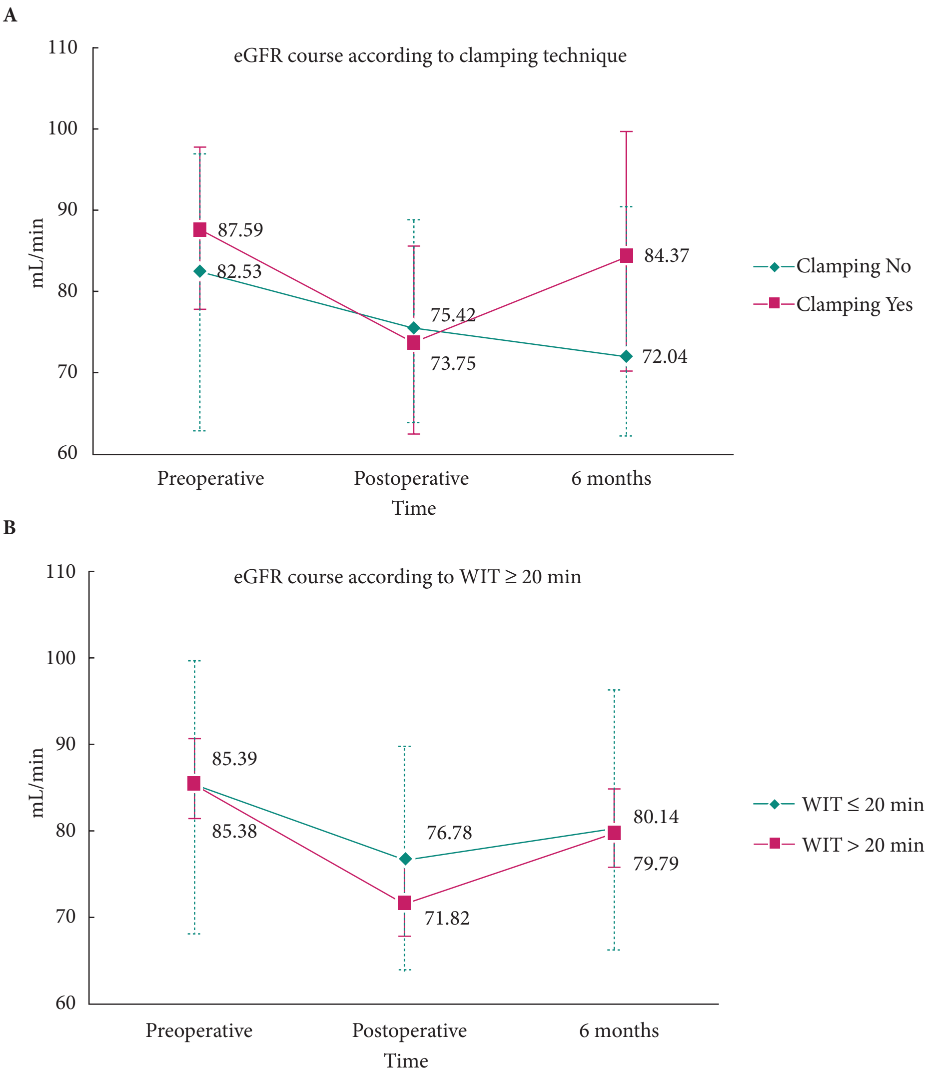


Fig. 2 Time course of decreasing eGFR levels by clamping technique (2A) and Wit duration (2B).

Table 5 Change in median eGFR and median serum creatinine concentration over time according to LESS technique, after matching for PADUA score.

	Median (IQR) eGFR, mL/min per 1.73 m^2			*P* value for Wilcoxon signed-rank test*	
	Preoperative	**Postoperative**	**6 months**	**Postoperative vs Preoperative**	**6 months vs preoperative**
Robot-assisted LESS-PN	85.40 (77.70–92.68)	73.91 (62.55–85.27)	84.77 (73.04–92.24)	**0.0004**	1.00
Conventional LESS-PN	92.00 (71.95–100.40)	78.92 (65.97–88.90)	79.37 (62.21–95.78)	**0.0058**	**0.006**
	Median (IQR) serum creatinine concentration, mg/dL				
Robot-assisted LESS-PN	0.96 (0.78–1.03)	1.01 (0.81–1.25)	0.93 (0.76–1.05)	**0.0002**	1.00
Conventional LESS-PN	0.88 (0.70–1.00)	1.00 (0.80–1.10)	0.91 (0.79–1.16)	**0.0052**	**0.0416**

however, the concept that it is the percent of parenchyma preserved rather than the actual WIT that may ultimately affect postoperative renal function has been put forward [6,30]. In the present study, the multivariable analysis showed PADUA score to be the only factor significantly predicting a short WIT; however, no assessment of residual renal parenchyma was performed.

When specifically assessing renal functional outcomes, a decline in eGFR and a higher percentage of patients with CKD stage >2 were noted, but a partial recovery of renal function was observed at the last available assessment at 6 months. Overall, the observed decreases in eGFR and CKD upstaging were similar to those reported for other PN techniques [31].

The oncological data showed a higher incidence of RCC; there were positive surgical margins in eight patients (4.2%). Nevertheless the overall survival rates were 99, 97 and 88% at 12-, 24- and 36-month follow-ups, respectively, and the disease-free survival rates were 98% at 12-month and 97% at 24- and 36-month follow-up, thus confirming LESS-PN to be a safe technique, at least with short- and medium-term follow-up.

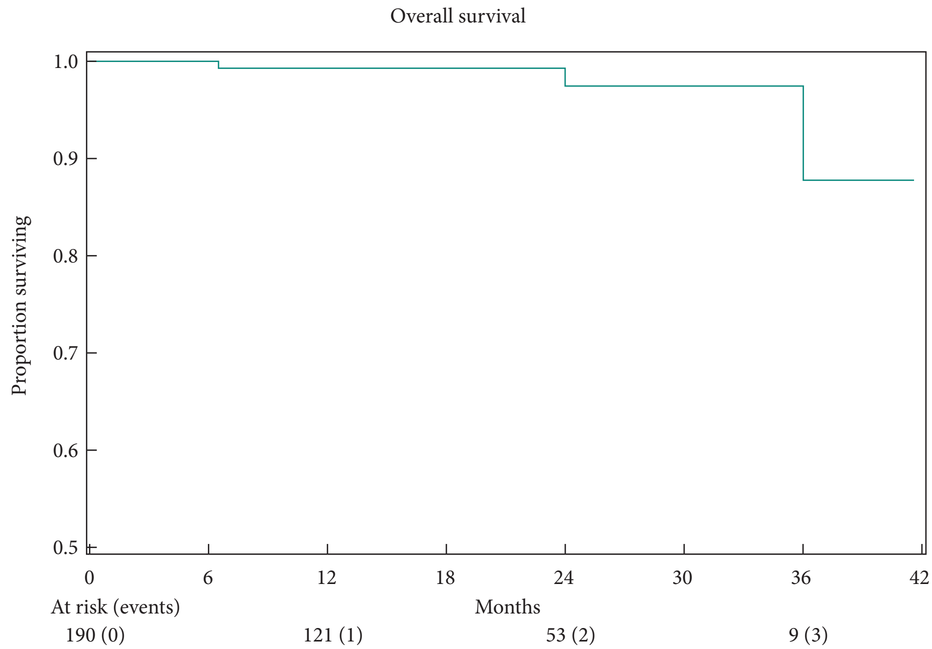
It should be noted that the use of one additional trocar was applied in 61.6% of cases in the present series, and one might argue that this represents a major bias. Nevertheless, according to the international and multidisciplinary consensus of the consortium for LESS surgery, the use of an additional 3-mm trocar should still be considered to be pure LESS surgery, whereas the use of an additional trocar >3 mm and of more than one additional trocar should be considered a conversion to 'reduced port' laparoscopy and standard laparoscopy, respectively [8–10,17,32,33]. Furthermore, the use of an additional trocar in LESS-PN could facilitate the procedure, reduce the risk of complication, and allow precise resection of the tumour [10].

Table 6 Pathological characteristics.

Pathological characteristic	*n* (%)
Malignant lesions	
Overall	151 (79.47)
RCC	139 (73.16)
Chromophobe renal cancers	12 (6.31)
Benign lesions	
Overall	39 (20.53)
Angiomyolipoma	15 (7.90)
Oncocytoma	11 (5.79)
Adenoms	2 (1.05)
Cysts	5 (2.64)
Granuloms	2 (1.05)
Lipoma	4 (2.10)
Positive surgical margins	8 (4.2)
Tumour recurrence	2 (1)

The present study has a few important limitations. Participating institutions were asked and agreed to provide their raw data to a principal investigator who collected these into a purpose-built datasheet. Thus, even if the data had been prospectively collected, biases related to the retrospective design would remain true. Moreover, a centralized review of CT images to score the tumours according to the PADUA system was not performed and this can arguably be regarded as an additional bias. In addition, these data reflect results from different surgeons, all of whom had substantial experience with laparoscopy and had previously completed multiple LESS operations. Patient selection criteria were not standardized, surgical expertise was not quantified, and different surgical techniques were applied. Ultimately, the reported figures over time do not reflect the learning curve of a single individual. Finally, one might argue that any new surgical technique needs to be compared with the standard technique before any conclusions can be drawn concerning its benefits. In this analysis no control group was considered as this was outside the scope of the study. Thus, the benefits of

Fig. 3 Overall survival after LESS-PN.



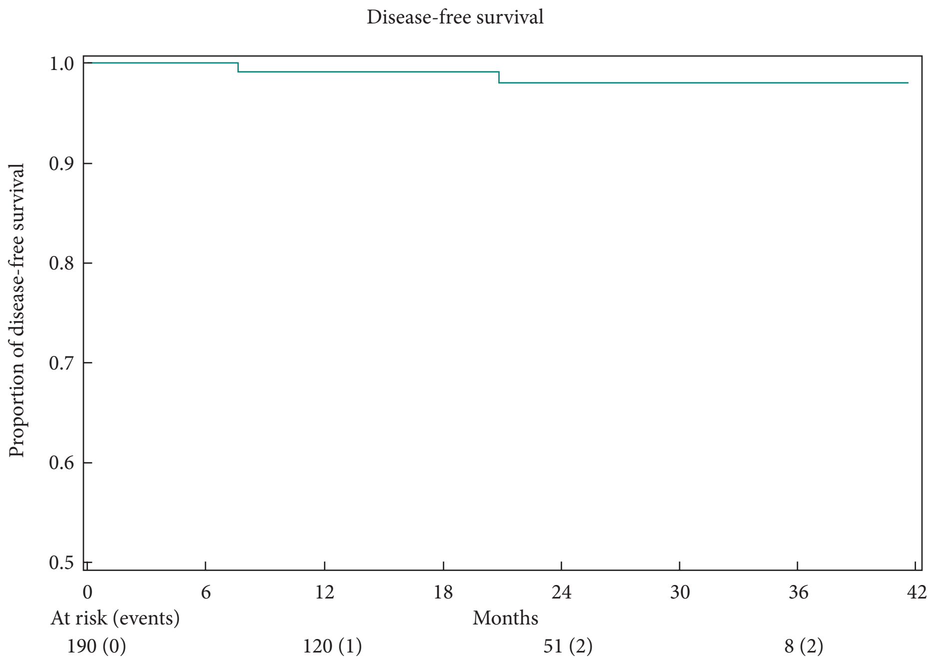


Fig. 4 Disease-free survival after LESS-PN.

LESS surgery compared with standard laparoscopy remain to be proven and long-term oncological outcomes are also required in order to demonstrate the oncological equivalence of LESS-PN to open or even standard laparoscopic surgery.

In conclusion, analysis of short- and intermediate-term oncological and renal function outcomes from the present large multicentre analysis confirms that LESS-PN represents a challenging procedure that can be safely and effectively performed in experienced hands. With regard to renal function, no damage to the kidney was found after LESS-PN, and there was complete normalization of renal function at follow-up. More prospective studies with long-term follow-up are needed to investigate the oncological safety of the LESS technique in the treatment of malignant urological tumours.

Conflict of Interest

None declared.

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Abbreviations: LESS, laparoendoscopic single-site; PN, partial nephrectomy; eGFR, estimated GFR; CKD, chronic kidney disease; EBL, estimated blood loss; WIT, warm ischaemia time; NSS, nephron-sparing surgery; LPN, laparoscopic partial nephrectomy; ASA, American Society of Anesthesiologists; CCI, Charlson comorbidity index; IQR, interquartile range.