Clampless laparoendoscopic single-site partial nephrectomy for renal cancer with low PADUA score: technique and surgical outcomes

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

- Laparoendoscopic single-site (LESS) surgery has proved to be immediately applicable in the clinical field, being safe and feasible in the hands of experienced laparoscopic surgeons in well-selected patients. All extirpative and reconstructive urological procedures have been described in the literature, but LESS partial nephrectomy (PN) is one of the most complex procedures and few studies have been published on this subject.

- The study describes a clampless technique for LESS PN, by reducing the blood pressure and increasing the intra-abdominal pressure of the pneumoperitoneum to 20 mmHg, timed to precisely coincide with excision of the tumour. This technique was found to be safe and feasible in the treatment of low-risk T1a RCC.

Objective

- To describe the technique and report the surgical outcomes of clampless laparoendoscopic single-site (LESS) partial nephrectomy (PN) in the treatment of renal cell carcinoma (RCC) with low PADUA score.

Patients and Methods

- Clampless LESS PN was performed in 14 patients with cT1a renal tumours. Indications to perform a clampless LESS PN were low-risk, laterally based renal tumours, located away from the renal hilum, with a PADUA score ≤7.
- Demographic data and peri-operative and postoperative variables were recorded and analysed.
- Kidney function was evaluated by measuring serum creatinine concentration and estimated glomerular filtration rate (eGFR) pre- and postoperatively and at 6-month follow-up.

Results

- The median operating time was 120 min and warm ischaemia time was zero in all cases. Only one early complication (Clavien grade 1) was recorded: one patient developed a flank haematoma which it was possible to treat by conservative therapy.
- Serum creatinine and modification of diet renal disease eGFR were not found to be significantly different pre- and postoperatively and at 6-month follow-up.
- Definitive pathological results showed 12 pT1a RCCs and two pT1a-chromophobe RCCs. All tumours were removed with negative surgical margins.
- All patients were satisfied with the cosmetic results.
- At a median (range) follow-up period of 12 (8–15) months, all patients were alive without evidence of tumour recurrence or port-site metastasis.

Conclusion

- Clampless LESS PN is a safe and feasible surgical procedure in the treatment of low-risk T1a RCC, with excellent cosmetic results.

Keywords

laparoendoscopic single-site surgery, LESS, partial nephrectomy, renal cell carcinoma, surgical technique, outcomes

Introduction

The widespread use of modern imaging methods has led to the earlier diagnosis and improved staging of RCC and resulted in a marked increase in the number of renal tumours detected incidentally in patients with no urological symptoms [1]. These tumours are often of lower grade and stage, and nephron-sparing surgery (NSS) is a

good treatment option for small (<4 cm) renal lesions [1,2]. Although open partial nephrectomy (PN) is considered to be the 'gold standard' in the surgical therapy of T1 renal tumours, advances in laparoscopic surgery, the refinement of intracorporeal suturing and the availability of haemosealant substances, have led to increasing use of laparoscopic PN (LPN) for NSS [1]. LPN is currently performed in only a few high-volume reference centres, however, and its diffusion has been limited by its steep learning curve. Recently, robot-assisted LPN has emerged as a promising procedure, able to bridge the technical difficulties of standard LPN in favour of a broader diffusion of minimally invasive treatment of small renal masses [3].

A crucial variable in surgery for RCC is warm ischaemia time (WIT), which can potentially affect short- and long-term renal function [4–9]. Over the last decade, the perception of 'safe' WIT has decreased from 55–40 min to 30–20 min [4–10], but more recent studies indicate that there may in fact be no safe WIT, suggesting that every minute counts [4].

Since its initial clinical use in urology, there has been an increasing enthusiasm and a growing interest for laparoendoscopic single-site (LESS) surgery. LESS surgery has proved to be immediately applicable in the clinical field, being safe and feasible in the hands of experienced laparoscopic surgeons in well-selected patients. All extirpative and reconstructive urological procedures have been described in the literature [11–13], but LESS PN is one of the most complex procedures. Autorino et al. [11] judged LESS PN to have a 'medium potential role in the future' because it may require extra-umbilical insertion of a multichannel, challenging sutures, and an increased risk of bleeding with prolonged WIT. In a recent case report, Cindolo et al. [14] reported their first experience with LESS PN without WIT, with favourable short-term outcomes and high patient satisfaction at 12-month follow-up. Nevertheless, the worldwide experience with this technique is still limited. In the current report, we present our technique and our preliminary experience with 14 patients who underwent clampless LESS PN.

Patients and Methods

Between April and December 2011, 14 patients underwent a clampless LESS PN for RCC. All patients gave written consent after being informed that the procedure would be attempted via a single incision and after being counselled that additional incisions might be necessary.

A prospective institutional-review-board-approved datasheet was constructed for the present study. The following data were collected: age, gender, body mass index (BMI), pre- and postoperative renal function, information on previous abdominal surgery, specific comorbidities according to the Charlson comorbidity index, tumour stage and grade, surgical margin status, operating time, WIT and estimated blood loss. Additional collected data included intraoperative variables (number of additional 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 (VAS) at discharge, incision length and subjective scar satisfaction. All analgesic drugs administered were analysed and recorded on the patients' charts during the hospital stay.

Both medical and surgical complications occurring at any time after surgery were captured including 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 (I, II, IIIa, IIIb, IVa, IVb, or V) assigned according to the modified Dindo–Clavien classification [15].

One laparoscopic surgeon (F.G.), with an experience of >150 conventional laparoscopic PNs and 60 LESS operations, performed all procedures.

Before surgery, all patients underwent renal ultrasonography and CT to give detailed information on tumour size, location, extent of parenchymal infiltration and proximity to the pelvi-calyceal system. Patients with severe heart failure (New York Heart Association Functional Classification III–IV), chronic renal insufficiency and/or with an American Society of Anesthesiology (ASA) score of ≥3 were excluded from the study. The PADUA score was used to assess the characteristics of the tumours [16].

Indications to perform a clampless LESS-PN were low-risk, laterally based renal tumours, located away from the renal hilum, with a PADUA score ≤7 (Fig. 1). All operations were performed for localized incidentally discovered renal masses of <4 cm (cT1a); all indications were elective.

Follow-up was calculated from the date of surgery to the date of the most recent documented examination. In all patients a physical examination and ultrasonography were performed every 3 months and CT or MRI was performed every 6 months in the first year after surgery.

Kidney function was evaluated by measuring serum creatinine concentration and estimated GFR (eGFR) pre- and postoperatively and at 6-month follow up. eGFR was calculated using the modification of diet renal disease (MDRD) equation.
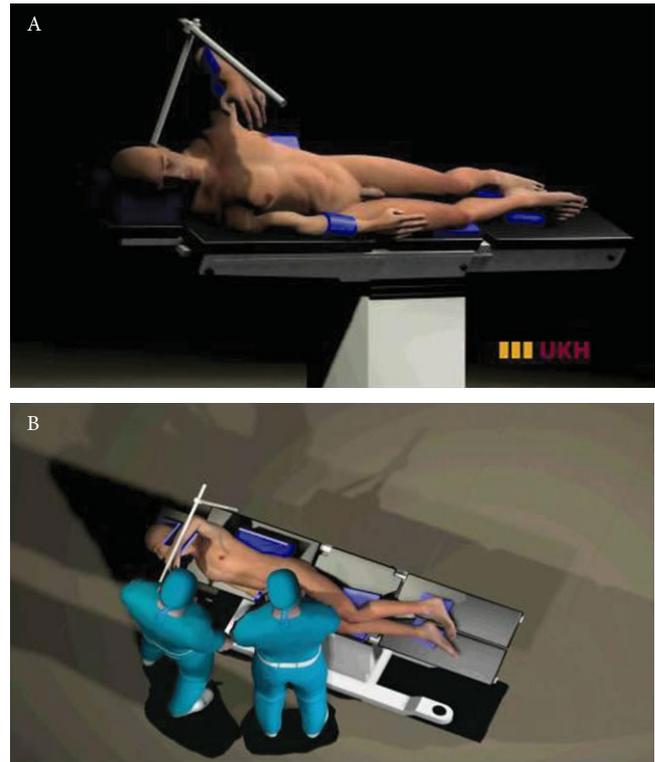
Fig. 1 Left-sided RCC, PADUA score 6.

Fig. 2 A and B: Placement of the patient and of the surgical team.

Surgical technique

The sequence of steps in clampless LESS PN is similar to that used in standard LPN. Mechanical bowel preparation is not necessary. In contrast to open surgery, the motility of the intestine remains virtually unaffected in laparoscopic procedures, as evidenced by a constant serotonin level during and after surgery [17]. Prevention of thrombosis (low-molecular-weight heparin) is mandatory. Single-shot i.v. antibiotics using a cephalosporin should be administered at the beginning of the procedure.

Clampless LESS PN is performed under general anaesthesia. Intra-operative invasive monitoring involves an intra-arterial line, central venous pressure monitoring, electrocardiogram and urine output. A recommended regimen is induction using i.v. thiopental and isoflurane as the inhalation agent. After the induction of general anaesthesia, a nasogastric tube and transurethral catheter are placed to decompress the stomach and bladder.

Total i.v. anaesthesia was used to get a transient, controlled, pharmacologically induced reduction of blood pressure (with a median value of 90/60 mmHg), timed to precisely coincide with excision of the tumour.

The patient is placed in the semilateral decubitus position with the side with the lesion elevated at 60°. The ipsilateral arm is secured using an arm board and the contralateral arm is fixed beside the trunk and well padded to avoid lesions of neural structures. Additional fixation is done using cloth tapes across the hips and the legs. Great care should be taken to generously pad all rests and cloth tapes.

When the patient is positioned securely, the table is rolled to a classic flank position to verify the stability of the system (Fig. 2A). The surgeon and the assistant stand at the contralateral side of the relevant kidney (i.e. renal tumour left, surgeon at the right side [Fig. 2B]).

The Endocone trocar (Karl Storz, Tuttlingen, Germany) is a specialized multilumen with six 5-mm working-channel, one 12-mm channel and one 15-mm channel, which is essential to introduce instruments with bigger dimensions. A 30° lens high-definition laparoscopic camera (Karl Storz) with 5-mm diameter and 50 cm in length was used in all cases. The laparoscope is inserted through one of the 5-mm channels and frees the 12-mm channel for insertion of instruments with diameter >5 mm, such as vascular bulldog clamps.

In all cases a combination of bent (curved) and conventional laparoscopic (straight) instruments were used to perform all procedures. The instruments were inserted through one of the 5-mm channels and the 12-mm channel of the trocar.

The operating table is moved back into dorsal supine position and a mini laparotomy is performed for the insertion of the trocar. The fascia is fixed with a 2/0 polyglactin 910 suture. An 'Alexis' small wound retractor is inserted and the trocar is placed. Then the table is rolled at 60° (Fig. 3).

Fig. 3 Placement of the Endocone trocar.
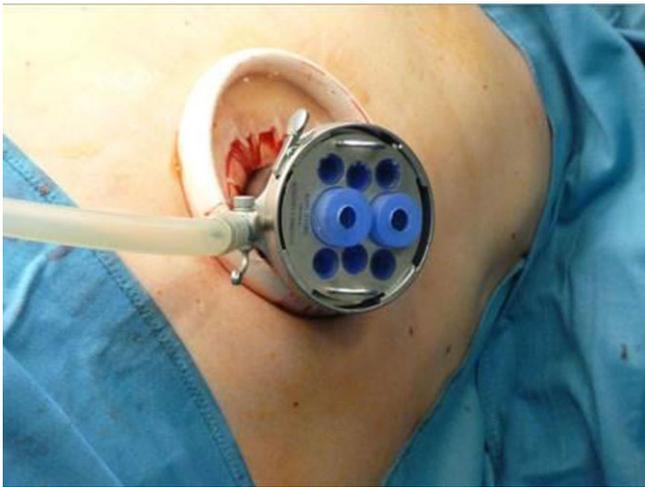
Fig. 4 Identification of the ureter.

During the performance of left-sided clampless LESS PN, the line of Toldt was incised from above the spleen to the level of the iliac vessels. Then the muscle psoas was identified and the colon was reflected medially. Incision of the splenocolic ligament follows in order to mobilize the spleen along with the colon and pancreas. Curved forceps, held in the left hand, are used to expose the tissue and curved monopolar scissors in the right hand are used to dissect the tissue and to cut along the line of Toldt.

Right-sided clampless LESS PN starts with peritoneal incision carried cephalad above the hepatic flexure. The dissection of the line of Toldt is performed. Colon retraction and division of all lateral ligaments follows. Gerota's fascia and the psoas muscle are identified.

The middle portion of the ureter is identified medially to the psoas muscle (Fig. 4). The curved forceps are used to grasp the ureter, and the curved scissors are used for dissection.

The Gerota's fasciae is now opened and the lower pole of the kidney is mobilized. The lower pole is lifted laterally

Fig. 5 Preparation of the renal pedicle.

Fig. 6 Resection of the tumour without ischemia.

and the hilum is under gentle tension to prepare the vessels. The renal vein at the first and the renal artery are identified (Fig. 5). The preparation of the renal vessels is mandatory, in order to proceed to clamping of the artery in the presence of serious bleeding during the resection of the tumour. An additional 3-mm trocar can occasionally be inserted directly through the skin to facilitate haemostatic stitches. The systolic blood pressure of the patient is maintained at <110 mmHg and the intra-abdominal pressure of the pneumoperitoneum is increased to 20 mmHg, to avoid possible bleeding from small vessels, allowing a precise resection of the tumour even with unclamped renal vessels. The kidney is mobilized within Gerota's fascia and defatted; the tumour is localized and excised with cold shears (Fig. 6).

Renal parenchymal repair is performed with running sutures. A Hem-o-Lok clip is secured on the suture to prevent it from pulling through. Another Hem-o-Lok clip is applied to the suture flush with the opposite renal surface, compressing the kidney (Fig. 7). The intra-abdominal pressure of the pneumoperitoneum is then decreased to 12 mmHg to check for adequate haemostasis. Fibrin glue is then applied to the cut renal parenchymal surface (Fig. 8) and the *en bloc* specimen is extracted in a

Fig. 7 Renal parenchymal repair performed with running sutures.

Fig. 8 Fibrin glue is applied to the cut renal parenchymal surface.

Table 1 Preoperative data on 14 patients who underwent clampless LESS PN.

Preoperative variable	Value
Median (range) age, years	52.5 (46–61)
Gender (female/male ratio)	0.75
Median (range) BMI, kg/m^2	26.2 (25–27.9)
Left/right kidney, n	11/3
Median (range) ASA score	2 (1–2)
Median (range) Charlson comorbidity index score	2 (1–2)
Median (range) tumour size, cm	2 (1.5–2.5)
Median PADUA score	6
Median preoperative haemoglobin, g/dL	16.5 (15.5–18)

10-mm Endocath II bag (Covidien, Dublin, Ireland). A flat suction drain is placed and the trocar is then removed. The fascia is then closed with interrupted 2/0 polyglactin 910 sutures and skin is approximated with an intracutaneous suture.

Results

Preoperative results are shown in Table 1. The patient population was generally young (median [range] age 52.5 [46–61] years), non-obese (median [range] BMI 26.2 [25–27.9] kg/m^2) and had a median (range) preoperative ASA score and Charlson comorbidity index of 2 (1–2).

Table 2 Intra-operative and postoperative data on 14 patients who underwent clampless LESS PN.

Intra-operative and postoperative variable	Value
Median (range) operating time, min	120 (110–145)
Median (range) blood loss, mL	165 (130–250)
Transfusions	0
Median (range) haemoglobin at discharge, g/dL	14.5 (13.5–16.5)
Postoperative day of oral intake	1
Median (range) VAS score* at discharge	1 (1–2)
Median (range) analgesic requirement, mg metamizol	9.25 (6–18)
Median (range) length of stay, days	4 (3.5–4.5)
Use of one additional 3-mm port, n	11
Median (range) skin incision, cm	4 (3.5–5)
Conversions to conventional laparoscopy	0
Conversions to open surgery	0
Tumour recurrence and port-site metastasis at the follow-up (patients)	0

Scale: 1–10.

The median (range) operating time was 120 (110–145) min, with a median (range) estimated blood loss of 165 (130–250) mL; WIT was zero in all cases and no patient required even momentary clamping of the main renal artery or vein, or pelvicalyceal repair (Table 2).

Median (range) times for tumour excision and suturing were 1.6 (1–2.5) and 3 (2–5) min, respectively.

The median length of hospital stay was 4 days and the median length of skin incision was 4 cm; all patients were discharged from hospital with minimal discomfort, as demonstrated by their pain assessment scores (median VAS = 1; Table 2). Only one early complication (Clavien grade 1) was recorded: one patient developed a flank haematoma which was treated successfully by conservative therapy. Serum creatinine concentration and MDRD eGFR were not significantly different pre- and postoperatively and at follow-up [Table 3]).

The definitive pathological results showed pT1a RCC in 12 patients and pT1a-chromophobe RCC in two patients. All tumours were removed with negative surgical margins (Table 4).

At the first postoperative visit, all patients completed an arbitrary questionnaire rating the cosmetic results (1: unsatisfied; 2: satisfied; 3: very satisfied; 4: enthusiastic). All patients were very satisfied with the cosmetic results (Fig. 9).

At a median (range) follow-up period of 12 (8–15) months, all patients were alive without evidence of tumour recurrence or port-site metastasis.

Discussion

Nephron-sparing surgery was initially reserved for patients at high risk of developing renal failure after kidney surgery

Table 3 Renal function in the 14 patients who underwent clampless LESS PN.

	Preoperative renal function	Postoperative renal function	Renal function at 6-month follow-up	P
Median (range) serum creatinine, mg/dL	0.71 (0.62–0.82)	0.86 (0.75–0.98)	0.78 (0.68–0.88)	NS
Median (range) eGFR, mL/min/1.72m^2	106.5 (81–141)	93.1 (68–128)	103.1 (73–127)	NS

NS, nonsignificant.

Table 4 Postoperative histopathological results of the 14 patients who underwent clampless LESS PN.

Histopathological variable	Value
Median (range) tumour size, cm	2.1 (1.5–2.5)
Tumour stage pT1a, *n*	14
Tumour grade: Fuhrman classification, *n*	
Grade 1	5
Grade 2	9
Negative surgical margins, *n*	14

Fig. 9 Postoperative appearance of surgical scar at 1 month follow-up.

to treat RCC. Van Poppel et al. [2], in a randomized prospective phase III trial, reported equivalent oncological outcome after NSS and RN, and suggested that NSS may be considered an acceptable approach for small asymptomatic RCC. Evolution of minimally invasive techniques has furthered an impetus in the surgical community to reduce the invasiveness of laparoscopic surgery.

Over the last 4 years, LESS techniques in urology have been popularized worldwide. In a recent literature review it was reported that the outcomes after single-site surgery in patients with non-high-risk disease seem to be similar to those after conventional laparoscopy [11]. It should be noted LESS series reported in the urological literature comprise well-selected patients [11,18,19], although experience with LESS radical nephrectomy in transplant patients has been also described [20].

As a general principle, all eligible laparoscopic surgery patients may be considered for LESS, depending on surgeons' own experience. The updated recommendations from the Endourological Society NOTES and LESS Working Group and European Society of Urotechnology NOTES and LESS Working Group, have recently pointed out that LESS surgery is suitable in appropriately selected patients, including patients with low BMI with limited previous abdominal surgery [21]. In fact, many institutions have made a safe stepwise transition from standard laparoscopy to LESS surgery for selected indications, but LESS surgery has not replaced standard laparoscopy even at high-volume institutions performing the technique [12]. LESS PN has been reported so far by few groups [14,22–26]. Aron et al. [22] reported five selected cases (inclusion criteria: BMI <30 kg/m^2; tumour size <7 cm; anterior exophytic tumour at the interpolar or lower pole

location; and no previous abdominal surgery). In all cases, an additional trocar was used to assist in suture closure of the renal defect. Median WIT was 20 min and one patient had postoperative bleeding and pulmonary embolism.

A limitation of the study of Aron et al. [22] is the lack of complete data on renal function. The primary technically modifiable risk factor during NSS that affects remnant kidney function is the duration of WIT. The traditionally accepted time limit has been 30 min [5], although recent investigators suggest that every minute may count [4].

Laparoscopic and robot-assisted NSS without ischaemia has been recently proposed as an innovative approach to NSS to reduce or eliminate the risk of renal damage associated with WIT [27].

In the present study, we report a novel technique of clampless LESS PN. Our technique has two fundamental aspects: (i) increasing the pressure of the pneumoperitoneum to 20 mmHg and (ii) transient, controlled, pharmacologically induced reduction of blood pressure, timed to precisely coincide with excision of the tumour. Clampless LESS PN was feasible and safe with the latter combination and WIT was zero in all cases with only one early complication (Clavien grade 1) which we were able to treat with conservative therapy.

Limitations of the present study are its small cohort of patients and short follow-up. The key question that needs to be investigated is whether LESS surgery is oncologically safe. Although the first studies on LESS surgery focus on surgical outcomes, we expect studies in the future to report long-term follow-up after LESS surgery so as to better evaluate its oncological feasibility.

It should be noted that the use of one additional trocar was applied in 11/14 cases in the present series and one might argue that this represents a major bias, but we embrace the concept that patient safety comes first. According to current terminology [21,28,29], the use of an extra 3-mm trocar is still considered to be LESS surgery, but when more than one additional trocar is used, this represents a conversion to standard laparoscopy. In a recent multi-institutional study, co-authored by the present authors [12], the use of additional port occurred in 23% of cases, with an overall conversion rate of 20.8%. Nevertheless the use of an additional trocar in clampless LESS PN could facilitate the procedure, reducing the risk of complications and allowing a precise resection of the tumour.

It could be argued that, as with drug evaluation, any new surgical technique should be compared with the original technique before any conclusions can be drawn concerning its benefits. In the present analysis no control group (i.e. standard laparoscopy) was considered; this was outside the scope of the present manuscript. The benefits of LESS surgery compared with standard laparoscopy remain to be proven and further clinical validation is required.

Clampless LESS PN remains a demanding surgical procedure, requiring much previous experience with conventional laparoscopy. Its combination of bent and conventional instruments reduces instrument collision and reproduces, albeit in a limited way, their triangulation as occurs in conventional laparoscopy. In addition, as stated in a recent multi-institutional study led by our group [13], malignant disease at pathology represents a predictive

factor for complications after LESS for upper urinary tract surgery; therefore, surgeons approaching LESS surgery should start with benign diseases in low surgical risk patients to minimize the likelihood of postoperative complications.

In conclusion, clampless LESS PN is a safe and feasible surgical procedure in the treatment of low-risk T1a RCC, with excellent cosmetic results. Further prospective studies with longer follow-up are needed to investigate the oncological safety of the LESS technique in the treatment of urological malignant tumours.

Acknowledgements

Conflict of Interest

None declared.

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Abbreviations: LESS, laparoendoscopic single-site; PN, partial nephrectomy; eGFR, estimated GFR; NSS, nephron-sparing surgery; LPN, laparoscopic partial nephrectomy; WIT, warm ischaemia time; BMI, body mass index; VAS, visual analogue scale; MDRD, modification of diet renal disease; ASA, American Society of Anaesthesiology.