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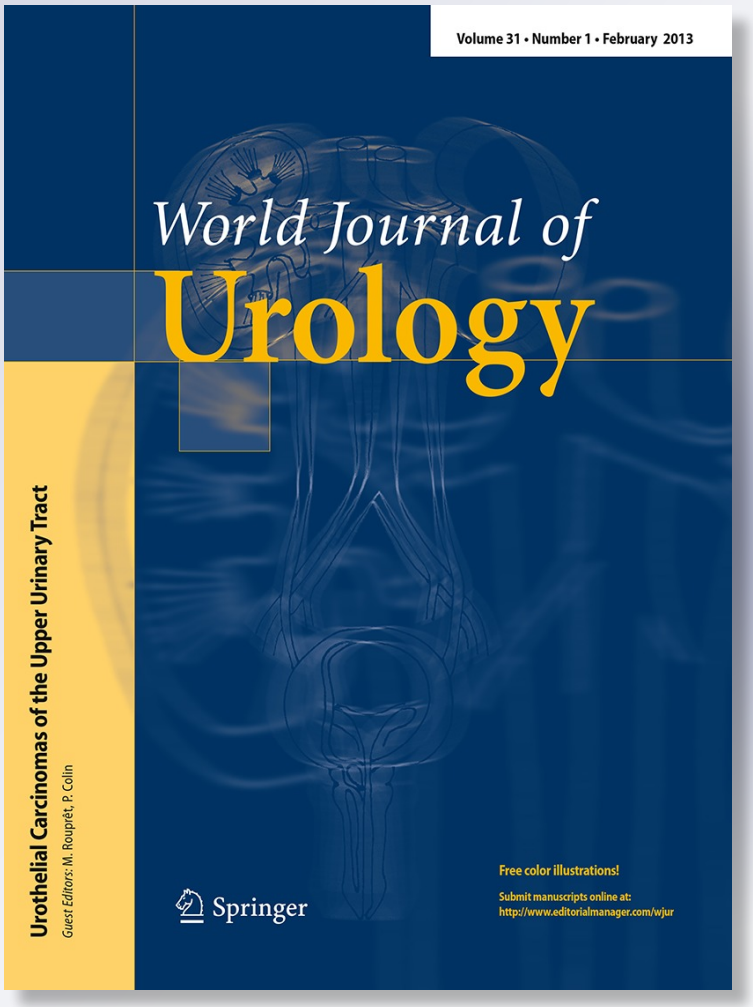

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ORIGINAL ARTICLE

Laparoendoscopic single-site versus conventional laparoscopic radical nephrectomy for renal cell cancer in patients with increased comorbidities and previous abdominal surgery: preliminary results of a single-centre retrospective study

Christopher Springer · Antonino Inferrera · Felix Kawan · André Schumann · Paolo Fornara · Francesco Greco

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Abstract
Objective Laparoendoscopic single-site surgery (LESS) represents an evolution of laparoscopy for the treatment for urologic diseases. The aim of this study is to investigate the feasibility of LESS in patients with increased comorbidities and previous abdominal surgery undergoing radical nephrectomy (LESS-RN) for renal cell carcinoma.
Materials and methods A total of 25 patients with increased comorbidities and previous abdominal surgery who underwent LESS-RN were compared to 31 patients with the same characteristics after conventional laparoscopic radical nephrectomy (LRN). LRN was performed between January 2009 and May 2010, and LESS-RNs were performed between June 2010 and November 2011. Demographic data and perioperative and postoperative variables were recorded and analysed.
Results

- The mean ASA score in the LESS-RN and LRN groups was 3.2 ± 0.4, and the mean BMI was 32.7 ± 2.1 and 34.2 ± 0.8 kg/m^2, respectively.
- The mean operative time in the LESS-RN and LRN groups was 143.7 ± 24.3 and 130.6 ± 26.5 min, ($p = 0.11$), and the mean hospital stay was 3.8 ± 0.8 versus 4.2 ± 1.4 days in the two groups ($p = 0.06$), respectively.
- Three and four complications were recorded in the LESS-RN and in the LRN groups, for a mean complication rate of 12 and 12.9 % ($p = 0.12$), respectively
- All tumours were organ-confined with negative surgical margins, and the mean R.E.N.A.L nephrometry score for LESS-RN and LRN was 9.78 ± 1.7 and 9.82 ± 1.3 ($p = 0.14$), respectively.

Conclusions LESS-RN in patients with increased comorbidities and previous abdominal surgery is equally effective as LRN without compromising on surgical, oncologic short-term and postoperative outcomes.

Keywords Laparoendoscopic single-site surgery · Laparoscopy · Outcomes · Renal cell carcinoma · Risk factors

Introduction

The advent of laparoscopic surgery has all greatly influenced urologic surgery, resulting in smaller incisions, reduction in tissue injury and less blood loss. Decreased perioperative stress is particularly important when performing oncologic surgery as exacerbated activation or reactive suppression of the immune system might affect tumour growth and dissemination [1, 2].

Recent developments in laparoscopy have been aimed at further reducing morbidity and improving the cosmetic outcome. These developments include the use of mini-laparoscopic 2-mm needle ports [3], use of natural orifices [4] and, more recently, use of transumbilical access for surgery [5–7]. Laparoendoscopic single-site surgery (LESS) utilizes bent and conventional laparoscopic (straight) instruments introduced through a specialized multilumen port. Case selection during initial experience

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and precise definition of indications and contraindications for LESS are considered to be important for a successful outcome [8].

Actually, there are no available studies about the safety of LESS surgery in patients with increased comorbidities and previous abdominal surgery affected by oncologic urologic diseases.

Due to reduced surgical trauma and the minimally invasive nature of laparoscopic procedures, these patients may benefit more from the advantages associated with this procedure.

The aim of this study was to determine whether highly evolved laparoscopic procedures such as LESS radical nephrectomy (LESS-RN) for renal cell carcinoma are as equally efficacious as conventional laparoscopy in patients with increased risk either because of increased surgical difficulty or because of associated comorbidities.

Patients and methods

This was a retrospective single-centre study including 56 patients with increased comorbidities and previous abdominal surgery recruited between January 2009 and November 2011, with 25 consecutive patients undergoing LESS-RN and 31 historical control patients with LRN. LRN was performed between January 2009 and May 2010, and LESS-RNs were performed between June 2010 and November 2011. During the same period, 33 patients without comorbidities underwent a LESS-RN for renal cancer.

A prospective institutional review board–approved datasheet was constructed for this study. The following information was collected: age, gender, body mass index (BMI), renal function, prior abdominal surgery, specific comorbidities as well as American Society of Anaesthesiologists (ASA) score, tumour stage and grade, surgical margin status, specimen weight, operative time and estimated blood loss (EBL). 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 stay (LOS), postoperative pain evaluated based on a visual analogue scale score (VAS) at the discharge, incision length and subjective scar satisfaction.

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, depending on the date of onset. For late complications, those deemed to be related or possibly related to LESS were captured, regardless of how long after surgery the onset occurred.

All complications were recorded according to the modified Dindo–Clavien classification [9].

Patients were assigned a score (American Society of Anaesthesiology [ASA] score) that described the patients' physical status and comorbidities [10].

Preoperatively, all the patients underwent a sonography and a computed tomography with contrast medium or a magnetic resonance imaging if deemed necessary. The indications to perform LESS-RN and the surgical technique were previously described [11].

The R.E.N.A.L (tumour size-[R]adius, location and depth-[E]xophytic or endophytic; nearness to the renal sinus fat or collecting system [N]; anterior or posterior position [A]; and polar vs. non-polar location [L]) nephrometry score was used to assess the characteristics of the tumours in both groups [12].

The follow-up period was calculated from the date of surgery to the date of the most recent documented examination. No patient was lost during follow-up.

The data were recorded in a Microsoft Excel database (Microsoft Inc., Redmond, WA, USA), and statistical analysis was performed using SigmaPlot® software version 11.0 (SPSS Inc., Chicago, IL, USA). Data are expressed as mean ± SD. Between-group analyses were performed by Student's t test. Fisher's exact test was applied to evaluate statistical between-group differences in pathological stages. A p value of < 0.05 was considered statistically significant.

Results

Baseline characteristics

Preoperative results are summarized in Table 1. All patients underwent a radical nephrectomy for enhancing renal masses with a median preoperative tumour size of 6.1 ± 1.4 cm for LESS-RN and of 6.4 ± 1.9 cm for LRN

Table 1 Preoperative data of the LESS-RN versus LRN

	LESS-RN	LRN
N	25	31
Age (years)	67.4 ± 11.2	66.1 ± 8.4
Gender (female/male ratio)	1.5	1.8
Mean BMI (kg/m^2)	32.7 ± 2.1	34.2 ± 0.8
Left/right kidney	15/10	18/13
Mean preoperative tumour size (cm)	6.1 ± 1.4	6.4 ± 1.9
Mean R.E.N.A.L. nephrometry score	9.78 ± 1.7	9.82 ± 1.3
Mean ASA score	3.2 ± 0.4	3.2 ± 0.4

($p = 0.09$). The mean ASA score was 3.2 ± 0.4 in both groups.

The LESS cohort included 19 patients with obesity, 2 patients with aplastic anaemia, 1 patient with obesity and von Willebrand disease, 1 patient with chronic obstructive pulmonary disease, non-insulin-dependent diabetes mellitus, chronic renal insufficiency, obesity, deep vein thrombosis and coronary syndrome and two elderly (>70 years old) patients with coronary syndrome, previous myocardial infarction and obesity. Fifteen patients had undergone prior abdominal surgery (3 patients laparoscopic hysterectomy, 3 patients a laparoscopic and 2 patients an open cholecystectomy, 1 patient an open transperitoneal pyeloplasty, 2 patients a splenectomy and 4 patients had undergone a renal transplantation).

The LRN cohort included 20 patients with obesity, 1 patient with aplastic anaemia, 1 patient with von Willebrand disease, 6 patients with coronary syndrome, previous myocardial infarction and obesity, and three elderly patients (72 years old) with obesity, non-insulin-dependent diabetes mellitus and previous myocardial infarction. Sixteen patients had undergone prior abdominal surgery (5 patients laparoscopic hysterectomy, 6 patients a laparoscopic, 4 patients an open cholecystectomy and one patient an open transperitoneal pyeloplasty).

Intra- and postoperative outcomes

The mean operative time in the LESS-RN and LRN groups was 143.7 ± 24.3 and 130.6 ± 26.5 min, ($p = 0.11$), with a mean EBL of 131.2 ± 31.7 and 130 ± 62.7 ml ($p = 0.08$), respectively. The mean LOS resulted to be 3.8 ± 0.8 versus 4.2 ± 1.4 days in the two groups ($p = 0.06$), respectively.

There was no difference between LESS-RN and LRN in postoperative haemoglobin decrease (1.4 ± 0.8 vs. 1.6 ± 0.8 mmol/L, $p = 0.09$) and postoperative creatinine increase (15.7 ± 8.8 vs. 14.7 ± 6.9 μmol/L, $p = 0.10$) (Table 2).

The mean VAS and the mean analgesic requirement resulted to be lower in the patients who underwent LESS-RN when comparing with the group who underwent LRN. After discharge, patients undergoing LESS-RN returned quickly to work (17.3 ± 9.6 days after LESS-RN and 26.8 ± 10.1 after LRN ($p = 0.03$) (Table 2).

Three and four complications were recorded in the LESS-RN and in the LRN groups, respectively: 1 early, five intermediate and one late, for a mean complication rate of 12 and 12.9 % ($p = 0.12$), respectively. A detailed description is provided in Table 3.

The mean length of skin incision was 4.1 ± 0.6 cm after LESS-RN and 6.5 ± 2.2 after LRN ($p = 0.04$).

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 (100 %) who underwent LESS-RN were enthusiastic with the appearance of the scars, whereas only 21 patients of the LRN group (67.7 %) were enthusiastic with the appearance of the scars ($p = 0.03$).

Oncologic outcomes

In the LESS group, the definitive pathologic results revealed a renal cell carcinoma in all cases with a stage distribution of two T1a (in the native kidneys of 2 transplant patients), 12 T1b and 11 T2 tumours. Fourteen tumours were centrally localized, 8 were located on the lower upper pole, and 3 were located on the upper pole of the kidney, requiring an adjunctive adrenalectomy.

Also, in the LRN group, all cases were pathologically renal cell carcinoma, with a stage distribution of 19 T1b and 12 T2 tumours (Table 2). Twenty tumours were centrally localized, 9 were located on the lower upper pole, and 2 were located on the upper pole of the kidney, requiring an adjunctive adrenalectomy.

All tumours were organ-confined with negative surgical margins, and the mean R.E.N.A.L nephrometry score for LESS-RN and LRN was 9.78 ± 1.7 and 9.82 ± 1.3 ($p = 0.14$), respectively.

At a median follow-up of 14.1 ± 2.4 months for the LESS-RN group and of 21.3 ± 2.1 months for the LRN group, all patients were alive with no evidence of tumour recurrence or port-site metastasis.

Discussion

In recent decades, renal surgery has changed in ways never before imagined, with the increasing incorporation of minimally invasive laparoscopic/robotic procedures.

Minimally invasive surgery aims to provide effective treatment for surgical diseases inside a body cavity while decreasing access-related morbidity with a reduced postoperative pain, shorter hospital stay, faster recovery, improved cosmesis and early return to their occupation [2]. Evolution of minimally invasive techniques has furthered an impetus in the surgical community to reduce the invasiveness of laparoscopic surgery. LESS has been developed in an attempt to further reduce the morbidity and scarring associated with surgical intervention. Comparative series between conventional laparoscopy and LESS have recently become available.

Raman et al. [6] were the first to report a case–control study comparing LESS with conventional laparoscopy. They compared 11 LESS with 22 laparoscopic nephrectomies.

Table 2 Intraoperative and postoperative data of the LESS-RN versus LRN

	LESS-RN	LRN	*p* value
N	25	31	
Operating time (min)	143.7 ± 24.3	130.6 ± 26.5	0.11
Blood loss (ml)	131.2 ± 31.7	130 ± 62.71	0.08
Haemoglobin decrease (mmol/L)	1.4 ± 0.8	1.6 ± 0.8	0.09
Creatinine increase (μmol/L)	15.7 ± 8.8	14.7 ± 6.9	0.10
Postoperative day of oral intake	1.0	1.3 ± 0.3	0.10
Mean VAS (1–10)	2.2 ± 1.2	4.3 ± 2.6	0.04
Mean analgesic requirement (mg)	9.8 ± 6.2	16.9 ± 5.1	0.02
Length of stay (days)	3.8 ± 0.8	4.2 ± 1.4	0.06
Skin incision (cm)	4.1 ± 0.6	6.5 ± 2.2	0.04
Mean convalescence (days)	17.3 ± 9.6	26.8 ± 10.1	0.03
Conversion rate to conventional laparoscopy (patients)	1	–	
Conversion rate to open surgery (patients)	1	2	0.16
Tumour stage			
pT1a	2	0	NA
pT1b	12	19	0.07
pT2	11	12	0.01
Tumour grade (Fuhrman classification)			
Grade 1	2	3	0.15
Grade 2	7	9	0.19
Grade 3	16	19	0.11
Tumour size (cm)	6.6 ± 1.1	6.4 ± 1.0	0.12
Surgical margins	Negative	Negative	NA
Tumour recurrence and port-site metastasis (patients)	0	0	NA

NA not applicable

Table 3 Complications after LESS-RN and LRN

Complication	LESS-RN ($n = 25$)	LRN ($n = 31$)	Action
Clavien grade I	–	1	
Flank pain	–	1	Analgesics
Clavien grade II	2	1	
Postoperative anaemia	2	1	Transfusion
Clavien grade III B	1	2	
Postoperative incisional hernia	–	1	Surgical repair
Lesion of the bowel	1	1	Surgical repair
Mean complication rate	3/25 (12 %)	4/31 (12.9 %)	

According to the authors, the superiority of LESS over standard laparoscopic nephrectomy was "limited" to a mere subjective cosmetic advantage, even if this advantage was not specifically measured or quantified.

Autorino et al. [13] reported in a recent review of the literature that the outcomes after single-site surgery in non-high-risk patients seem to be comparable to conventional laparoscopy. Nevertheless, only series of LESS in well-selected patients are reported in the literature [4–8, 13–20].

Moreover, Gettman et al. [18] in a recent editorial offering the update recommendations for LESS and NOTES in urology pointed out that LESS is suitable in appropriately selected patients, including thinner patients (BMI < 30) with limited prior abdominal surgery.

In general, patients with higher ASA scores have a higher risk for complications, often leading to longer hospitalization [21, 22]. This is true for both open and laparoscopic cases. However, laparoscopy as a surgical technique, because of the creation of the pneumoperitoneum and the use of CO2 as gas insufflator, leads to pathophysiologic changes that may not be well tolerated by patients with medical comorbidities and thus high ASA scores [23].

Obesity is a medical condition in which excess body fat (BMI of 30 or greater) has accumulated to the extent that it may have an adverse effect on health, leading to reduced life expectancy and/or increased health problems [24]. Obese or older patients frequently have associated medical conditions (e.g. diabetes, heart failure, hypertension and renal failure), which are not prone to further improvement. Such patients have diminished reserves and tolerance to complications, and they are usually assigned a higher ASA score. The above-mentioned comorbidities increase the risk for postoperative complications and make anaesthesia riskier [24, 25].

Nevertheless, it is well known that these patients can extremely benefit of a minimally invasive surgical approach, which, through a minor surgical trauma, decrease the postoperative morbidity.

This has represented the initial point of our study: if laparoscopy can be applied to patients with increased comorbidities and previous abdominal surgery, can a new surgical approach which theoretically further reduces the trauma associated with wound scar incision as LESS be also performed safely in these patients?

In a recent multi-institutional study, Greco et al. [8] demonstrated that malignant disease at pathology and high ASA score represent a predictive factor for complications after LESS for upper urinary tract surgery. Thus, surgeons approaching LESS should start with benign diseases in low

surgical risk patients to minimize the likelihood of post-operative complications. Furthermore, LESS is still representing a demanding surgical procedure, requiring a prior great experience with conventional laparoscopy.

Given the several advantages offered by the current da Vinci system, it is likely that its adoption for LESS will increase. However, we are still far from the ideal robotic platform, as the currently available robot is bulky and not specific for what is necessary in single-site surgery [26].

In our experience, 25 patients with increased comorbidities and previous abdominal surgery underwent LESS-RN for renal cell carcinomas. These patients were then compared to 31 historical control patients with LRN with the same increased risks. To our knowledge, this is the first study investigating the feasibility of LESS in these patients. The overall complication rate was 12 % for LESS-RN, and this result is comparable with the literature [8, 27]. Interestingly, despite this series representing our initial LESS experience in patients with increased risks, we noted no differences in complication rates compared to conventional laparoscopy. This is likely attributable to all cases being performed by an experienced surgeon who had previously completed multiple LESS operations in selected non-high-risk patients.

In 2008, Canes et al. [17] reported that using the umbilicus as the portal of entry limits the appropriate candidates for LESS approach and that obese patients are not suitable for natural orifice translumenal endoscopic surgery.

In our experience, there was no problem to perform LESS in obese patients too. Generally, muscle relaxation is essential in these patients, and this requires a continuous collaboration between surgical and anaesthesiologic team.

There are a several limitations to the present study that must be acknowledged, however. Firstly, this was a retrospective study, hence imparting an inherent selection bias that cannot be overcome. Another limitation of the present study includes the small cohort of the patients and the short follow-up. The main issue which has to be investigated: Is the LESS surgery oncologically safe?

At 14-month follow-up, no tumour recurrences nor progressions nor port-site metastasis was recorded.

If the first studies about LESS are concentrated to report surgical outcomes, we are expecting in the future studies reporting long-term follow-up after LESS in order to evaluate its oncologic safety.

Conclusion

LESS-RN in patients with increased comorbidities and previous abdominal surgery, performed by a skilled laparoscopic surgeon, is equally effective as LRN without compromising on surgical, oncologic short-term and post-operative outcomes.

Conflict of interest All authors have nothing to declare and affirm that the results presented in this paper have not been published previously in whole or part, except in abstract format. Dr. Christopher Springer is a fellow at the Department of Urology and Renal Transplantation, the Martin-Luther University, Halle/Saale.

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