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Laparoendoscopic single-site surgery for the treatment of different urological pathologies: Defining the learning curve of an experienced laparoscopist



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Laparo-endoscopic single-site surgery;
Learning curve;
LESS;
Single port;
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ABBREVIATIONS

ASA, American Society of Anesthesiologists;
BMI, body mass index;
EBL, estimated blood

Abstract Objectives: To define the learning curve of laparoendoscopic single-site surgery (LESS) of an experienced laparoscopist.

Patients and methods: Patients who had LESS, since its implementation in December 2009 until December 2014, were retrospectively analysed. Procedures were divided into groups of 10 and scored according to the European Scoring System for Laparoscopic Operations in Urology. Different LESS indications were done by one experienced laparoscopist. Technical feasibility, surgical safety, outcome, as well as the number of patients required to achieve professional competence were assessed.

Results: In all, 179 patients were included, with mean (SD) age of 36.3 (17.5) years and 25.4% of the patients had had previous surgeries. Upper urinary tract procedures were done in 65.9% of patients and 54.7% of the procedures were extirpative. Both transperitoneal and retroperitoneal LESS were performed in 92.8% and 7.2% of the patients, respectively. The intraoperative and postoperative complication rates were 2.2% and 5.6% (Clavien–Dindo Grade II 3.9% and IIIa 1.7%),

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loss;
LESS, laparoendo-
scopic single-site sur-
gery;
VAS, visual analogue
scale

respectively. In all, 75% of intraoperative complications and all conversions were reported during the first 30 LESS procedures; despite the significantly higher difficulty score in the subsequent LESS procedures. One 5-mm extra port, conversion to conventional laparoscopy and open surgery was reported in 14%, 1.7%, and 1.1% of the cases, respectively. At mean (SD) follow-up of 39.7 (11.4) months, all the patients that underwent reconstructive LESS procedures but one were successful.

Conclusion: In experienced hands, at least 30 LESS procedures are required to achieve professional competence. Although difficult, both conversion and complication rates of LESS are low in experienced hands.

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Introduction

Laparoendoscopic single-site surgery (LESS) was recently introduced in the field of minimally invasive urological surgery, aiming to further reduce postoperative pain, shorten hospital stay, and improve cosmesis [1–3]. Despite its technical difficulty, which limits its applications to experienced laparoscopists, LESS may be regarded as an emerging trend in minimally invasive urological surgery that has significantly evolved and became widely applicable in a relatively short time [3].

Attempting to share experiences of LESS and to outline its technical feasibility, difficulties, complications and outcomes, multi-institutional studies were recently reported including most of the centres that pioneered LESS worldwide [3–6]. These studies proved that LESS is at least comparable to well-established conventional laparoscopy. However, to date no single published report has highlighted the learning curve of LESS for an experienced laparoscopist to achieve professional competence. Therefore, we present for the first time a learning curve for LESS for an experienced laparoscopist for the treatment of different urological pathologies in different age groups.

Patients and methods

This retrospective study included 179 consecutive patients, with different urological pathologies, who were indicated for laparoscopy and were treated with LESS since its implementation at our institute in December 2009 until December 2014. All patients gave an informed consent for LESS. Exclusion criteria included absolute contraindications to laparoscopy and children aged <3 years. Procedures were scored according to the European Scoring System for Laparoscopic Operations in Urology [7]. Data were collected in a standard data sheet and all procedures were approved by our Ethical Care Committee. All LESS procedures were done by one experienced laparoscopist (A.M.A.) with an advanced laparoscopic background. To outline the

learning curve for the laparoscopist, consecutive procedures were divided into groups of 10 and each group was analysed and the different groups were compared.

Outcome measures

Demographic data of patients included age, gender, body mass index (BMI), past history of (abdominal/pelvic) surgery, American Society of Anesthesiologists (ASA) score, associated comorbidities, and indication for LESS. Procedures were divided as either ablative or reconstructive, and either upper urinary tract or pelvic. The operative data analysed were: operative time, estimated blood loss (EBL), intraoperative complications, and blood transfusion. Data of the surgical procedure included: type of single-port device, type of instruments, access technique (single-port or single-incision/single-site), port-insertion site (umbilical or extra-umbilical) and approach (transperitoneal or retroperitoneal). Adding an extra ≥ 5 mm trocar was regarded as conversion to reduced-port laparoscopy [8]. Also, conversion to conventional laparoscopy or open surgery was recorded. Postoperative data included: hospital stay, visual analogue scale (VAS) pain score at discharge and postoperative complications during the hospital stay and within the first 3 months postoperatively. Postoperative complications were graded according to the Clavien–Dindo system [9]. Finally, the functional and oncological outcomes were recorded during the follow-up period.

Statistical analysis

Data were analysed using the IBM Statistical Package for the Social Sciences (SPSS®) software package version 20.0 (SPSS Inc., IBM Corp., Armonk, NY, USA) [10]. Comparisons between groups for categorical (qualitative) variables were assessed using the chi-squared test. The Mann–Whitney test was used to compare groups for abnormally distributed (non-parametric) quantitative variables. A $P \leq 0.05$ was considered to indicate statistical significance.

Results

Patient demographics, procedures and instrumentation

Included were 179 patients with a mean (SD) age of 36.3 (17.5) years and a mean (SD) BMI of 28.65 (6.76) kg/m²; of them 44% had a BMI of > 30 kg/m². All demographic data are presented in Table 1. Different indications of LESS are shown in Table 2. Of the procedures, 54.7% were extirpative and 65.9% targeted the upper urinary tract. In all, 38 patients (21.2%) were children, with mean (SD) age of 6.2 (4.2) years. Indications for LESS in the children included: undescended testes (18), varicocele (eight), PUJ obstruction (six), and simple nephrectomy (six).

Trans-umbilical transperitoneal access using a multichannel-port technique was used in 92.8% of the patients, whilst retroperitoneal access was used in 7.2%. The most commonly used access device was the TriPort (44.1%; Olympus, NY, USA and Advance Surgical Concept, Wicklow, Ireland) followed by the Covedien SILS port (31.8%; Covedien, Chicopee, MA, USA). The QuadPort was used in 22.9% of the procedures (Olympus, and Advance Surgical Concept), whilst X-Cone (Karl Storz, Tuttlingen, Germany) and Ethicon ports (Endosurgery, Cincinnati, OH, USA) were used only once (0.6%). Pre-bent and articulating instruments were used according to port type.

Table 1 The patients' demographic data.

| Variable | Value |
|--|---------------|
| Age, years, mean (SD) | 36.34 (17.50) |
| <i>n</i> (%): | |
| < 18 | 38 (21.2) |
| 18–40 | 61 (34.1) |
| 40–60 | 62 (34.6) |
| > 60 | 18 (10.1) |
| Sex, <i>n</i> (%): | |
| Male | 108 (60.3) |
| Female | 71 (39.7) |
| BMI, kg/m ² , mean (SD) | 28.65 (6.76) |
| <i>n</i> (%): | |
| 16–18.5 | 20 (11.2) |
| 18.5–25 | 24 (13.4) |
| 25–30 | 56 (31.3) |
| 30–35 | 58 (32.4) |
| 35–40 | 15 (8.4) |
| > 40 | 6 (3.3) |
| Smoking, <i>n</i> (%) | 48 (26.8) |
| Comorbidity, <i>n</i> (%) | |
| Renal insufficiency | 5 (2.8) |
| Hypertension | 23 (12.8) |
| Diabetes | 22 (12.3) |
| ASA score, <i>n</i> (%): | |
| 1 | 154 (86.0) |
| 2 | 20 (11.2) |
| 3 | 5 (2.8) |
| Prior abdominal/pelvic surgery, <i>n</i> (%) | 29 (25.4) |

Table 2 Diagnosis and procedures of LESS included.

| Variable | <i>N</i> (%) |
|--|--------------|
| <i>Diagnosis</i> | |
| Non-functioning kidney | 32 (17.9) |
| PUJ obstruction | 25 (14.0) |
| Renal parenchymal tumour | 20 (11.2) |
| Unilateral simple renal cyst | 16 (8.9) |
| Unilateral undescended testicle | 12 (6.7) |
| Bilateral undescended testicle | 10 (5.6) |
| Ureteric stone | 10 (5.6) |
| Vesico-vaginal fistula | 14 (7.8) |
| Vesico-uterine fistula | 8 (4.5) |
| Unilateral varicocele | 6 (3.3) |
| Bilateral varicocele | 4 (2.2) |
| Refluxing ureter after simple nephrectomy | 3 (1.7) |
| Upper urothelial tumour | 5 (2.8) |
| Non-functioning kidney + ureteric stone | 3 (1.7) |
| Non-functioning kidney + VUR | 3 (1.7) |
| Bilateral simple renal cyst | 2 (1.1) |
| Pelvic organ prolapse | 2 (1.1) |
| Adrenal tumour | 2 (1.1) |
| Bladder diverticulum | 2 (1.1) |
| <i>Procedure</i> | |
| Simple nephrectomy | 32 (17.9) |
| Renal cyst excision | 18 (10) |
| Fistula repair (vesico-vaginal fistula and vesico-uterine fistula) | 22 (12.3) |
| Radical nephrectomy | 20 (11.2) |
| Dismembered pyeloplasty | 22 (12.3) |
| Ureterolithotomy | 10 (5.6) |
| Varicolectomy | 10 (5.6) |
| Nephroureterectomy | 11 (6.1) |
| Second-stage Fowler-Stephens procedure | 8 (4.5) |
| First-stage Fowler-Stephens procedure | 7 (3.9) |
| Primary orchidopexy | 5 (2.8) |
| Orchidectomy | 2 (1.1) |
| Ureterectomy | 3 (1.7) |
| Y-V pyeloplasty | 3 (1.7) |
| Sacrocolpopexy | 2 (1.1) |
| Adrenalectomy | 2 (1.1) |
| Bladder diverticulectomy | 2 (1.1) |

Perioperative outcomes, complications and conversions

Intraoperative complications occurred in four cases (2.2%), in two cases there was intraoperative bleeding, one case of left gonadal vein injury, and one case of respiratory hypoventilation. Of the 10 postoperative complications (5.6%), seven and three were Clavien–Dindo Grade II and IIIa, respectively. One patient developed retroperitoneal abscess, two had urinary leakages, two had wound infection, two had UTI, one had anaemia, and two developed umbilical hernia (Table 3). The overall conversion rate was 16.8%; including conversion to reduced-port laparoscopy in 14%, conventional laparoscopy in 1.7% and open surgery in 1.1%.

Perioperative outcomes predictors

Univariate analysis to evaluate predictors of perioperative outcomes identified age, BMI, female gender, high

Table 3 Perioperative outcomes and postoperative complications of all LESS procedures.

| Variable | Value |
|--------------------------------|----------------------------|
| Mean (SD, range): | |
| Operative time, min | 120.48 (60.59, 40.0–420.0) |
| EBL, mL | 69.47 (60.84, 0.0–140.0) |
| Incision length at closure, cm | 2.71 (1.21, 1.5–7.0) |
| Hospital stay length, days | 1.44 (1.01, 0.0–5.0) |
| Postoperative VAS pain score | 1.24 (0.79, 0.0–3.0) |
| N (%): | |
| Intraoperative complications | 4 (2.2) |
| Bleeding | 2 (1.1) |
| Injury of left gonadal vein | 1 (0.55) |
| Respiratory hypoventilation | 1 (0.55) |
| Postoperative complications | 10 (5.6) |
| Retroperitoneal abscess | 1 (0.55) |
| Urinary leakage | 2 (1.1) |
| Wound infection | 2 (1.1) |
| UTI | 2 (1.1) |
| Anaemia | 1 (0.55) |
| Umbilical hernia | 2 (1.1) |
| Clavien–Dindo grade: | |
| II | 7 (3.9) |
| IIIa | 3 (1.7) |

ASA score, oncological surgical indication, upper urinary tract surgeries, and high procedure's score as significant. Patient's comorbidities significantly increased EBL and length of hospital stay, whilst previous abdominal or pelvic surgery only significantly extended the operative time. Ablative procedures increased intraoperative EBL. Multivariate analysis identified increased BMI as a significant risk factor for all inferior perioperative outcomes.

Predictors of conversion and complications

Univariate analysis identified female gender, previous abdominal or pelvic surgeries, reconstructive surgeries, pelvic procedures, and procedures of high difficulty score as significant risk factors for additional port insertion, whilst high ASA score significantly increased the rate of conversion to conventional laparoscopy. Meanwhile, high BMI significantly increased the risk of conversion to open surgery (Table 4). Despite being statistically non-significant ($P = 0.60$), all intraoperative complications occurred in female patients. For postoperative complications, univariate analysis identified female gender and increased BMI as significant risk factors. However, multivariate analysis showed that none of the perioperative factors were significant predictors of conversion and complications.

Analysis of learning and training of LESS

In all, 75% of all intraoperative complications (sequential cases number 5, 18 and 29) and all conversions were reported during the first 30 LESS procedures, therefore

Table 4 Univariate analysis for two groups of patients (those who did not develop complications and/or conversion and those who developed complications and/or conversion).

| Variable | Overall complications and conversions | | P |
|---------------------------------|---------------------------------------|-----------------|---------|
| | No (n = 135) | Yes (n = 44) | |
| N (%): | | | |
| Sex: | | | |
| Male | 99 (73.3) | 6 (13.6) | <0.001* |
| Female | 36 (26.7) | 38 (88.6) | |
| Prior abdominal/pelvic surgery | 26 (19.3) | 22 (50) | 0.001* |
| Other comorbidities | 21 (15.6) | 7 (15.97) | 0.955 |
| ASA score: | | | |
| I | 116 (85.69) | 20 (45.5) | 0.001* |
| II | 16 (11.9) | 22 (50.0) | |
| III | 3 (2.2) | 2 (4.5) | |
| Oncological pathology (outcome) | | | |
| No recurrence | 18 (100) | 9 (100) | – |
| Type of procedure: | | | |
| Ablative | 85 (63.0) | 9 (20.5) | <0.001* |
| Reconstructive | 50 (37.0) | 35 (79.5) | |
| Site: | | | |
| Upper | 90 (66.7) | 17 (38.6) | 0.006* |
| Pelvic | 45 (33.3) | 27 (54.5) | |
| Approach: | | | |
| Retroperitoneal | 11 (8.1) | 2 (4.5) | 0.423 |
| Transperitoneal | 124 (91.9) | 42 (95.5) | |
| Type of instruments: | | | |
| Pre-bent | 87 (64.4) | 33 (75.0) | 0.321 |
| Articulation | 48 (35.6) | 11 (25.0) | |
| Level of difficulty: | | | |
| Easy | 55 (40.7) | 0 | <0.001* |
| Slightly difficult | 9 (6.7) | 4 (9.1) | |
| Fairly difficult | 30 (22.2) | 2 (4.5) | |
| Difficult | 26 (19.3) | 10 (22.7) | |
| Very difficult | 15 (11.1) | 4 (9.1) | |
| Extremely difficult | 0 | 24 (54.5) | |
| Mean (range): | | | |
| Age at surgery, years | 36.5 (3–73) | 34 (21–67) | 0.320 |
| BMI, kg/m ² | 29 (15–40) | 30.5 (22–48) | 0.036* |

* Statistically significant.

patients were subsequently divided into two groups where the first group included the first 30 procedures and the second group included the subsequent 149 procedures. Comparisons between the two groups for perioperative outcomes, complications, conversion rates, and procedure difficulty scores are shown in Table 5.

Follow-up

At a mean (SD) follow-up of 39.7 (11.4) months, all reconstructive LESS procedures but one complex vesico-vaginal fistula were successful (98.1% success rate), whilst patients with renal parenchymal and pelvic tumours showed no recurrence. Three patients were lost

Table 5 Comparison between the two groups regarding the perioperative outcomes, complications, conversion rates and level of difficulty.

| Variable | Group I (n = 30) | Group II (n = 149) | P |
|-------------------------------------|---------------------|-----------------------|---------|
| Mean (SD): | | | |
| Operation time, min | 104.33 (59.05) | 126.25 (60.42) | 0.013* |
| EBL, mL | 50.50 (60.90) | 76.25 (59.73) | 0.001* |
| Hospital stay length, days | 1.27 (1.11) | 1.50 (0.68) | 0.201 |
| Postoperative VAS pain score | 1.23 (1.0) | 1.24 (0.71) | 0.88 |
| N (%): | | | |
| Intraoperative complications | | | 0.015* |
| No | 27 (90.0) | 148 (99.3) | |
| Yes | 3 (10.0) | 1 (0.7) | |
| Postoperative complications | 4 (13.3) | 6 (4) | 0.043* |
| Additional port insertion | 6 (20) | 19 (12.8) | 0.29 |
| Conversion to open surgery | 2 (6.7) | 0 | 0.026* |
| Conversion to standard laparoscopy | 3 (10) | 0 | 0.0018* |
| Level of difficulty | | | 0.06 |
| Easy | 14 (46.7) | 29 (19.5) | |
| Slightly difficult | 4 (13.3) | 24 (16.1) | |
| Fairly difficult | 3 (10) | 25 (16.8) | |
| Difficult | 2 (6.7) | 26 (17.4) | |
| Very difficult | 4 (13.3) | 25 (16.8) | |
| Extremely difficult | 3 (10) | 20 (13.4) | |

* Statistically significant.

during the follow-up, whilst one patient with T1bN0M0 renal parenchymal tumour died from a cause other than the original pathology after 27 months.

Discussion

LESS has been proposed as an evolutionary step beyond conventional laparoscopy and it has been increasingly adopted by urologists worldwide since its introduction in 2007 [1,11]. Although, the recently reported multi-institutional studies included large number of patients, in all of these studies there were strict patients' selection criteria with a variety of experienced laparoscopist who did LESS at different institutions of variable settings and in different healthcare systems [2–5,12]. Even studies that reported single-centre experiences, the LESS procedures were probably performed by more than a laparoscopist [2,13].

In the present study, we report a detailed analysis of the learning curve of an experienced laparoscopist who performed 179 consecutive LESS procedures at a single centre. Only absolute contraindications of laparoscopy and children aged <3 years were excluded, as in younger children it is difficult to use the commercially available LESS instruments that are designed for adults and also objective evaluation of postoperative pain is

inaccurate. However, paediatrics represented 21.1% of the total number of patients. In our present study, 44% of the patients had a BMI > 30 kg/m², 27.9% had associated comorbidities, and 25.4% had had previous surgeries. In most reported series of LESS, patients were not obese and of low-grade surgical risk [2–4,13].

Autorino et al. [4] reported the largest multi-institutional study that included 1163 patients who had LESS at 21 institutions worldwide. In their study, 85.6% of the procedures targeted the upper urinary tract and 83.4% were extirpative. This trend might reflect the technical difficulty for the lower urinary tract, as well as of reconstructive LESS procedures, due to the unfavourable ergonomics of LESS. In our present series, upper urinary tract LESS procedures represented 65.9% of the cases, whilst 45.3% had reconstructive LESS procedures. Because of the current technical limitations of LESS, a good laparoscopic background is necessary before practicing LESS. With more training LESS can be widely adopted and applied even to the most complex urological procedures [11,14]. In our present study, all cases were done by one surgeon with an advanced laparoscopic background of > 10 years (A.M.A.). Data analysis showed that 75% of intraoperative complications, as well as conversion to conventional laparoscopy and open surgery, occurred during the first 30 LESS procedures. In the first 30 LESS procedures, 60% were considered 'easy' and 'slightly difficult', whilst the subsequent procedures were considered as 'fairly difficult', 'difficult', 'very difficult' and 'extremely difficult' in 64.4%. Furthermore, despite the higher technical difficulty in the subsequent group of patients, the incidence of adding an extra port was significantly higher in the first 30 LESS procedures. This may reflect the fact that with increasing experience of the operating surgeon, professional competence can be achieved and this probably requires ~30 LESS procedures.

Attempting to overcome current limitations of LESS, the da Vinci® Robot System (Intuitive Surgical, Sunnyvale, CA, USA) was used and it facilitated, to some extent, these limitations [15]. However, as it was not originally developed for LESS the current da Vinci system has some limitations. Recently, a novel robotic system has been specifically developed for single-port surgery [16]. Although it has been safely used for major urological LESS procedures, the problem of assistant access to the surgical field has not been solved and remains a challenge.

Like most of the reported LESS series [1–4], transperitoneal trans-umbilical access was commonly used in our present patients. Ryu et al. [17] described urological retroperitoneal LESS and their results are comparable to ours for complication and conversion rates but are inferior for perioperative outcomes. However, their report represented one of the early experiences with single-port retroperitoneal laparoscopy,

where LESS was still in its infancy. Overall, like conventional laparoscopy, transperitoneal and retroperitoneal approaches were used for LESS; however, retroperitoneal LESS is less favourable.

A wide variety of access devices have been developed for LESS, aiming for simultaneous use of at least three instruments during the surgery [18]. However, each device has its own advantages and disadvantages and still the ideal port is not yet available [19]. Five types of multichannel access devices were used in our present study. The use of these different access devices was mainly due to their commercial availability; however, the frequently used ones were the most convenient. Both articulating and pre-bent instruments were developed for use with different access devices in order to overcome the problem of triangulation and to facilitate surgery during the single-port approach [1]. In our present study, both articulating and pre-bent instruments were used. Data analysis showed that neither the access device nor the instrument was a predictor for preoperative outcomes, conversions or complications.

The perioperative outcomes of the present study were favourable compared with those of the two largest multi-institutional studies [3,4]. This may be because the present study included a larger proportion of 'easy', 'slightly difficult', and 'fairly difficult' procedures (55.3%). Also, all the procedures in the present study were done by one experienced laparoscopist. On the other hand, the previously mentioned multi-institutional studies included a larger proportion of 'difficult' procedures, where LESS was performed by different surgeons with variable levels of experience and surgical skills.

Our present data analysis to evaluate predictors of perioperative outcomes correlated with the literature except for pelvic LESS procedures that had significantly better perioperative outcomes compared to upper urinary tract LESS procedures [4,20]. This could be explained by the higher proportion of 'easy' procedures, namely varicocelelectomy and undescended testis, which are categorised as pelvic surgeries. Moreover, no pelvic oncological indications were included in our present series.

To consider LESS as a safe alternative to the well-established conventional laparoscopy, potential risk of conversion and complications must be relatively low and clearly defined [13]. Two case series have specifically evaluated LESS for upper tract procedures. In 125 upper urinary tract LESS procedures, Irwin et al. [13] reported conversion to conventional laparoscopy and complication rates of 5.6% and 15.2%, respectively. Also, Greco et al. [20] reported a 17% complication rate in 192 upper urinary tract LESS procedures. Increasing experience and the proven feasibility of LESS have allowed for reporting of larger LESS series, from which more information has accrued. Autorino et al. [4] reported intraoperative and postoperative complication

rates of 3.3% and 9.4%, respectively. Their overall conversion rate was 19.6%, where conversion to reduced-port laparoscopy, conventional laparoscopy and open surgery was 14.6%, 4% and 1.1% of LESS procedures, respectively. Compared with what has been published, our present study showed a lower complication rate. Again, this may be related to the fact that all cases were done by one laparoscopist and also the other reported studies might have included a larger proportion of technically difficult procedures. However, the conversion rate in our present study was comparable with that reported by Autorino et al. [4], although almost half of our present cases were reconstructive LESS procedures compared with 16.6% of their cases. Furthermore, analysis identified female gender, previous abdominal or pelvic surgeries, reconstructive surgeries, pelvic procedures, and procedures of high difficulty score as significant risk factors for additional port insertion, which correlates with the literature [4]. Despite being statistically non-significant, all intraoperative complications in the present series occurred in females, which might have been related to the high BMI of the females, which was 31.29 kg/m² compared to 26.93 kg/m² in males. For the postoperative complication predictors, analysis identified female gender and increased BMI as significant risk factors, which is in accordance with the literature [4].

The present study is unique for three main reasons. Firstly, it included a relatively large LESS series with different genitourinary pathologies in different age groups who were operated upon by one skilled laparoscopist. Secondly, the present study is both descriptive and analytical, providing information on the perioperative outcomes and risk factors for complications and conversions in LESS. Finally, the present study is the first to analyse the progression of the learning curve of LESS of an experienced laparoscopist. On the other hand, limitations include the retrospective design of the study, as although the data were prospectively collected bias would have remained. Also, our present series represents the outcomes of a surgeon with an extensive laparoscopic background; therefore results may not be representative of those achieved by less experienced urologists. Moreover, a comparative analysis with standard laparoscopy and potentially other available 'scarless' options was not performed.

Conclusions

The present study defines the learning curve of an experienced laparoscopist to achieve professional competence of LESS for the treatment of different urological pathologies in different age groups. In experienced hands, at least 30 LESS procedures appear to be required to achieve professional competence. Although it can be safely applied in urology with low conversion

and complication rates, good training and good laparoscopic experience are prerequisites for satisfactory results of LESS.

Conflict of interest

None.

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