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Laparoendoscopic Single-site Surgery in Urology: Worldwide Multi-institutional Analysis of 1076 Cases

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Abstract

Background: Laparoendoscopic single-site surgery (LESS) has gained popularity in urology over the last few years.

Objective: To report a large multi-institutional worldwide series of LESS in urology. **Design, setting, and participants:** Consecutive cases of LESS done between August 2007 and November 2010 at 18 participating institutions were included in this retrospective analysis.

Intervention: Each group performed a variety of LESS procedures according to its own protocols, entry criteria, and techniques.

Measurements: Demographic data, main perioperative outcome parameters, and information related to the surgical technique were gathered and analyzed. Conversions to *reduced-port* laparoscopy, conventional laparoscopy, or open surgery were evaluated, as were intraoperative and postoperative complications.

Results and limitations: Overall, 1076 patients were included in the analysis. The most common procedures were extirpative or ablative operations in the upper urinary tract. The da Vinci robot was used to operate on 143 patients (13%). A single-port technique was most commonly used and the umbilicus represented the most common access site. Overall, operative time was 160 ± 93 min and estimated blood loss was 148 ± 234 ml. Skin incision length at closure was 3.5 ± 1.5 cm. Mean hospital stay was 3.6 ± 2.7 d with a visual

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analog pain score at discharge of 1.5 ± 1.4 . An additional port was used in 23% of cases. The overall conversion rate was 20.8%; 15.8% of patients were converted to reduced-port laparoscopy, 4% to conventional laparoscopy/robotic surgery, and 1% to open surgery. The intraoperative complication rate was 3.3%. Postoperative complications, mostly low grade, were encountered in 9.5% of cases.

Conclusions: This study provides a global view of the evolution of LESS in the field of minimally invasive urologic surgery. A broad range of procedures have been effectively performed, primarily in the academic setting, within diverse health care systems around the world. Since LESS is performed by experienced laparoscopic surgeons, the risk of complications remains low when stringent patient-selection criteria are applied. © 2011 European Association of Urology. Published by Elsevier B.V. All rights reserved.

1. Introduction

Laparoendoscopic single-site surgery (LESS) has been proposed as an evolutionary step beyond standard laparoscopy and has been increasingly adopted by urologists worldwide since its introduction [1,2]. Conceptually, it is driven by the hypothesis that minimization of skin incision to gain access to the abdominal or pelvic cavities may benefit patients in terms of port-related complications, recovery time, pain, and cosmesis [3,4].

Over the last few years, many standard laparoscopic operations in urology have been successfully performed using LESS. However, the actual role of LESS in the field of minimally invasive urologic surgery remains to be determined [5,6].

Evidence supporting LESS has been limited to small case series or case-control studies from selected centers [5]. One multi-institutional study including >100 patients was recently reported [7]. Comparative studies have shown that LESS is at least comparable to standard laparoscopy [8,9]. Thus, more robust analyses of larger samples are desirable to corroborate positive findings from early series.

This study was initiated as a collaborative effort with the purpose of reporting the contemporary practice of LESS at institutions pioneering the development of this technique in urology. The aim was to provide an analytical overview of indications, techniques, and outcomes of urologic LESS in various hospital settings worldwide.

2. Methods

2.1. Study design

Our cohort consisted of consecutive patients treated with LESS between August 2007 and December 2010 at 18 participating institutions. Groups at medical centers worldwide with reported experience in urologic LESS were identified by searching available literature and invited to participate in the study. Each group performed the procedures according to its own protocols, entry criteria, and techniques. All patients consented specifically for LESS. Raw data without any identifier were retrospectively collected and gathered into a standardized datasheet, which was specifically built for study purpose.

2.2. Outcomes

Demographic data included age, gender, race, body mass index (BMI), past history of previous abdominal/pelvic surgery, American Society of Anesthesiologists (ASA) score, comorbidities, and indication for LESS. Procedures were categorized as *extirpative/ablative* or *reconstructive* and as *upper urinary tract* or *pelvic*. Moreover, they were scored based on a Likert-type scale (1, slightly difficult; 5, extremely difficult) [10].

The following outcome parameters were analyzed: operative time, estimated blood loss, intraoperative adverse events, transfusions, length of stay, and visual analog pain score (VAS).

Relevant operative data related to the surgical procedure were recorded, including access technique (single-port or single-incision/ single-site), access site (umbilical or extraumbilical), approach (transperitoneal or retroperitoneal), use of articulating or prebent laparoscopic instruments, use of the da Vinci robot, type of single-port device, and use of ancillary needlescopic or minilaparoscopic ports [11].

Addition of one extra trocar was considered as conversion to reducedport laparoscopy [12], whereas conversion from LESS to laparoscopic surgery was defined as unplanned installation of more than one trocar to complete the procedure. Conversion to open surgery was defined as an unplanned abdominal incision to perform the operation.

Postoperative complications were scored according to the standardized Clavien-Dindo system [13].

Two periods were arbitrarily defined: one including years 2007–2008 and the other including years 2009–2010. A comparative analysis between these periods was conducted.

2.3. Statistical analysis

All patient data were collected in an Excel spreadsheet (Microsoft Corp., Redmond, WA, USA). Data of continuous variables are expressed as mean plus or minus standard deviation. Binary and categorical variables are reported as counts and percentages. Standard statistical tests were applied for comparison as appropriate. Values of p < 0.05 were considered statistically significant.

3. Results

3.1. Patient demographics

Overall, 1076 patients underwent urologic LESS during the study period (Table 1), comprising, on average, 15% (range: 4–59%) of the overall laparoscopic or robotic procedures performed at the participating institutions during the same time frame.

3.2. Procedures, techniques, and instrumentation

Most procedures (86%) were done in the upper urinary tract, with most of these being extirpative or ablative (84%). A transperitoneal access was preferentially adopted in 92% of cases. The da Vinci robot was used in 143 cases (13%).

Table 1 – Demographic data: cumulative analysis*

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Patients, no.	1076
Mean age, yr	52.1 ± 16.9
Male/female	559/517
Race, no. (%)	
Asian	506 (47)
Caucasian	485 (45)
African American	34 (3.2)
Others	51 (4.8)
BMI, kg/m ²	25 ± 4.2
ASA score	1.7 ± 0.7
Past medical and surgical history, no. (%)	
Previous abdominal or pelvic surgery	283 (26.3)
Renal insufficiency	59 (5.4)
Hypertension	368 (34.2)
Diabetes	111 (10.3)
Most frequent indication for LESS, no, (%)	
Renal tumor or mass $^{\Delta}$	417 (38.7)
Renal cyst	117 (10.9)
Nonfunctioning kidney	111 (10.3)
Upper tract obstruction [¶]	98 (8.4)
Adrenal mass/tumor/cyst [§]	56 (5.2)
Urinary stone°	53 (4.9)
Living donor	46 (4.3)
Varicocele	45 (4.2)
BPH	42 (3.9)
Prostate cancer	25 (2.3)
Vaginal prolapse	13 (1.2)
Bladder cancer	5 (0.4)

BMI = body mass index; ASA = American Society of Anesthesiologists; BPH = benign prostatic hyperplasia.

* Binary and categorical variables are reported as counts and percentages. ^AIncluding kidney cancer, kidney benign mass, upper tract transitional cell carcinoma.

¹Including ureteropelvic junction obstruction, ureteral stricture, retrocaval ureter.

[§]Including adenomas, pheochromocytomas, schwannomas.

°Including renal and ureteral calculi

There was a significant increase in the number of cases per month during 2009–2010; the rate of some procedures (ie, pyeloplasty, donor nephrectomy, simple prostatectomy, cryoablation, and sacrocolpopexy) was lower, whereas some other procedures were performed more frequently (ie, radical nephrectomy, partial nephrectomy, renal cyst decortication, adrenalectomy, varicocelectomy, and ureterolithotomy). There was a significant increase in use of the da Vinci robot over time (Table 2 and Fig. 1).

A single-port technique was chosen in 77% of cases and the umbilicus was the predominant site of access (71% of cases). In cases in which a single-port platform was used, 46% involved a homemade device and 54% used a commercially available device. Among these, Triport/ Quadport (Advanced Surgical Concepts, Bray, Co. Wicklow, Ireland) was used in 29% of cases, SILSport (Covidien, Dublin, Ireland) in 8%, Gelport/Gelpoint (Applied Medical, Rancho Santa Margarita, CA, USA) in 7%, and XCone/ Endocone (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) and Uni-X (Pnavel Systems, Brooklyn, NY, USA) in 5%. When a single-incision technique was chosen, a variable combination of multiple trocars or multichannel port with trocars was used. Articulating instruments were used in 73% of cases.

3.3. Perioperative outcomes

Overall operative time was 160 ± 93 min and estimated blood loss was 148 ± 234 ml. Skin incision length at closure was 3.5 ± 1.5 cm. Mean hospital stay was 3.6 ± 2.7 d with a pain VAS at discharge of 1.5 ± 1.4 . Perioperative outcomes for the most commonly performed procedures are presented in Table 3.

3.4. Complications and conversions

An additional port was used in 23% of cases. In 34% of these, a 2- to 3-mm extra port was used, whereas in the remaining 66% of cases, an extra 5- to 12-mm additional port was required.

The overall conversion rate was 20.8%, with 15.8% of cases converting to reduced-port laparoscopy, 4% to conventional laparoscopy or robotic surgery, and 1% to open surgery. Reasons for conversion were difficult dissection (37% of converted cases), failure to progress (21%), bleeding (25%), difficult suturing (11%), difficult retraction (3%), and difficult access (3%).

The intraoperative complication rate was 3.3%, with need for conversion to open surgery occurring in three cases and laparoscopy in five cases (Table 4).

Postoperative complications were encountered in 9.5% of cases, most being low grade according to Dindo-Clavien [13] (Table 5). The overall transfusion rate was 6.1%.

There was no difference in terms of conversion to laparoscopic or open surgery and in complication rates when comparing the two study periods. Use of additional instruments or ports, needlescopic or minilaparoscopic, or standard (reduced-port laparoscopy) approach occurred more frequently during the 2009–2010 period (Table 2).

4. Discussion

The first two large series of urologic LESS were published in 2009 [14,15]. Since then, other early single-center experiences have been reported, as have early comparative studies, albeit limited by small numbers, nonrandomized design, and lack of standardization in the assessment of postoperative outcomes [5]. Overall, these series suggested that LESS was not inferior to conventional laparoscopy in terms of perioperative outcomes, and revealed an encouraging trend toward less postoperative pain and better cosmesis.

Recently, two prospective trials comparing LESS versus laparoscopy have been reported. Tugcu et al compared LESS simple nephrectomy and conventional laparoscopic simple nephrectomy [16]. Time to return to normal activities was reduced in the LESS group and all patients undergoing LESS were very pleased with cosmetic outcome. Kurien et al conducted a randomized comparison of clinical outcomes following standard laparoscopic and LESS donor nephrectomies [17]. LESS donor nephrectomy gave early pain relief with shorter hospital stay and comparable graft function than standard laparoscopy.

Although they represent the highest level of evidence currently available in medicine, randomized controlled trial

	Overall (<i>n</i> = 1076)	Period 2007–2008 (<i>n</i> = 234)	Period 2009–2010 (<i>n</i> = 842)	p value
Mean cases per mo, no.	27.3 ± 14.5	13.9 ± 5.1	37.1 ± 11.4	<0.001
High-score [*] procedures, %	24	33.3	21.5	< 0.001
Robotic LESS procedures, %	13	5.5	15.4	< 0.001
Type of procedures, no.				
Pyeloplasty	89	42	47	< 0.001
Simple nephrectomy	130	34**	96 [†]	0.193
Donor nephrectomy	51	27	24	< 0.001
Radical nephrectomy	172	24	186 [‡]	0.002
Simple prostatectomy	42	21	21	< 0.001
Partial nephrectomy	127	19	108	0.048
Cryoablation	37	17	20	< 0.001
Sacrocolpopexy	13	13	0	< 0.001
Nephroureterectomy	39	8	31	0.849
Renal cyst decortication	115	7	108	< 0.001
Radical prostatectomy	25	5	20	0.830
Radical cystectomy	6	3	3	0.092
Adrenalectomy	55	2	53	< 0.001
Varicocelectomy	44	2	42	0.004
Ureterolithotomy	51	1	50 [§]	< 0.001
Others	43	9	34	0.894
Use of additional 2–3 mm instruments only, no,	82	32	50	< 0.001
Conversions, no,				
To reduced-port laparoscopy	170	18	152	< 0.001
To conventional laparoscopy	43	11	32	0.533
To open surgery	11	2	9	0.270
Complications, no.				
Intraoperative	34	4	30	0.151
Postoperative	101	29	72	0.074

Table 2 -	 Temporal tren 	ds in urologi	c laparoendos	copic single-site	surgery (LESS) surgery

* Score: 4–5, according to the classification adopted from Autorino et al [5] and Guilloneau et al [10].

** Including one bilateral case.

[†] Including three bilateral cases.

[‡] Including one bilateral case and seven cases with a renal vein thrombus.

[§] Including one case done in conjunction with a simple nephrectomy and one case done with a varicocelectomy.

results are not linearly generalizable. Even if more prone to be biased, real-life-practice studies might enjoy higher external validity [18].

The present analysis provides an overview of practice patterns and surgical techniques and outcomes in urologic LESS worldwide. The use of a central reporting system allowed standardized reporting from different institutions embracing this technique in a variety of settings and health care systems.

As a general principle, all eligible laparoscopic-surgery patients may be considered for LESS. On the other hand, although performed by experienced laparoscopic surgeons, patient selection with LESS is more rigorous than with conventional laparoscopy and the threshold for conversion is low [11]. Disease features, as well as patients' features, are to be considered.

When looking at the overall population of our study, patients were relatively young, nonobese, and of low surgical risk. Almost one fourth of cases patients elected LESS, even if they had had previous abdominal or pelvic surgery.

The most frequent surgical indication (almost 60% of cases) was represented by renal diseases, and upper urinary

Table 3 – Outcomes for most commonly	norformed urolog	ric lanaroondocconic cin	rla_cita curgary procedures
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Procedure	Cases, no.	ORT, min	EBL, ml	WIT, min	LOS, d	VAS
Radical nephrectomy	210	158 ± 47.5	168.3 ± 217.6	-	4.1 ± 2.6	1.5 ± 1.1
Simple nephrectomy	130**	160.7 ± 71.5	165.9 ± 313.9	-	$\textbf{3.7} \pm \textbf{2.6}$	2 ± 1.4
Partial nephrectomy	127	$\textbf{208.3} \pm \textbf{165.3}$	$\textbf{276.9} \pm \textbf{294.3}$	$18.4 \pm 15.5^\ddagger$	1.6 ± 1.7	1 ± 0.2
Renal cyst decortication	115	90.9 ± 35.5	29.5 ± 41.5	-	$\textbf{2.6} \pm \textbf{1.2}$	1.2 ± 1
Pyeloplasty	89	223.7 ± 72.4	69.7 ± 70	-	$\textbf{3.8}\pm\textbf{4}$	1.9 ± 1.5
Adrenalectomy	55	153.5 ± 65.1	123.3 ± 118.6	-	3.6 ± 1.5	1.9 ± 1.5
Donor nephrectomy	51	175.2 ± 53	118.3 ± 96	5.1 ± 1.8	2.5 ± 1.1	1.4 ± 1.6
Ureterolithotomy	51†	138 ± 62	63.8 ± 60.3	-	$\textbf{3.2}\pm\textbf{1.6}$	1.8 ± 1.5

ORT = operative room time; EBL = estimated blood loss; WIT = warm ischemia time; LOS = length of stay; VAS = visual analog score at discharge. * >50 cases.

** Including four bilateral cases.

[†] Including one case done in conjunction with a simple nephrectomy and one case done with a varicocelectomy.

[‡] Including cases with off-clamp technique.

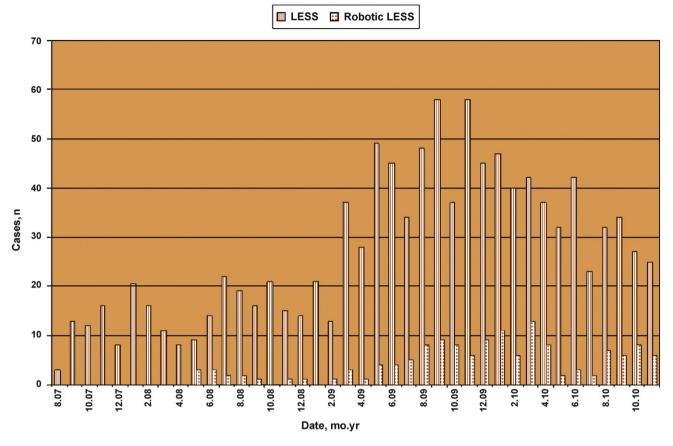


Fig. 1 – Trends in robotic laparoendoscopic single-site surgery (LESS): number of LESS and robotic LESS cases over the study period.

	Cases, no. (%)	Case requiring conversion to open surgery, no.	Cases requiring conversion to laparoscopy, no.	Comment
Vascular injury	19 (1.7)	3	4	Including injury to IVC (two cases), renal vein (two cases), adrenal vein (two cases), portal vein (one case)
Bowel injury	6 (0.5)	-	-	Including minor serosal tears (five cases)
Splenic injury	2 (0.2)	-	1	Including one minor and major injury
Diaphragmatic injury	2 (0.2)	-	-	Minor injuries
Others	7 (0.6)	-	-	Including bleeding during transvesical enucleation of prostate (three cases), minor liver injury (one case), rectal injury (one case), ureteral injury (one case), pleural injury (one case)
Total	36 (3.3)	3 (0.3)	5 (0.4)	
IVC = inferior vena cav	a.			

Table 4 –	Intraoperative	complications
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Table 5 – Postoperative complications according to Dindo-Clavien[13]

Grade	Cases, no.	Overall cohort, %
1	36	3.3
2	41	3.8
2 3a	14	1.3
3b	7	0.6
4a	5	0.4
Total	103	9.5

tract surgery was performed much more frequently. One might argue that the adoption of nephron-sparing techniques might be slowed by LESS, similar to what has happened with standard laparoscopy [19]. However, it should be emphasized that, whenever feasible, nephronsparing surgery should be the main treatment option for patients with renal masses, regardless of the surgical approach.

Not surprisingly, extirpative or ablative procedures were more commonly performed than reconstructive ones. This can be related to the recognized unfavorable ergonomics with LESS. A solid laparoscopic background is desirable before embarking in LESS. Peculiar features of this technique (ie, crossing or collision of instruments, lack of triangulation, and in-line vision) represent additional challenges for the surgeon compared with standard laparoscopy. These tasks become even more demanding reconstructive procedures when suturing is needed. An effective strategy can be the use of needlescopic or minilaparoscopic instruments in the nondominant hand to aid in triangulation. These are introduced through a small puncture requiring no formal closure and their use is still regarded as part of LESS [11].

To overcome current constraints, da Vinci robotic technology has been applied to LESS. Some robotic features are likely to be effective in pursuing this aim [20]. In 2008, Kaouk et al reported the first successful series of single-port robotic procedures in humans and noted an improved facility for intracorporeal dissecting and suturing due to robotic instrument articulation [21]. Encouraging outcomes for robotic LESS have been reported by the same group [22–24]. Overall, robotic LESS represented 13% of this entire series, with an expected increase in the period 2009–2010.

Although addition of the da Vinci system to LESS has improved limitations experienced with conventional LESS, we are still in the infancy of robotic single-site surgery [20]. Currently available robotic platforms remain bulky, as they have not been specifically designed for LESS. Robotic innovations are in development [20,25]. As robotic surgery has aided the spread of laparoscopy, it is likely that robotics will play a major role in the development of LESS.

According to current endorsed nomenclature [3,4,11], LESS access can be obtained either by performing a single skin and fascial incision, through which a single multichannel access platform is placed (*single port*) or by placing several low-profile ports through separate fascial incisions (*single site*).

Several access devices have been developed for singleport surgery to allow simultaneous use of multiple instruments and their clinical application has been shown [22,23,26,27]. Each device presents specific features aiming to facilitate LESS. However, the ideal platform is yet to be defined [28].

In the present series, a single-port access was used most commonly, and the umbilicus was the most frequently chosen access site. All commercially available ports have been adopted and among them, the TriPort (R-port)/ Quadport has been more frequently used. This platform was among the first to appear on the market; thus, it is likely that the use of one port over others has been dictated in each center primarily by availability. Interestingly, in one third of the procedures, homemade single-port devices were used.

Access was preferably through the umbilicus, which can obviously offer the desirable cosmetic outcome of a virtually scarless surgery. The choice of an extraumbilical site can be related to the approach (eg, tip of the 12th rib for retroperitoneal access) or specific indications, such as adrenalectomy (pararectal or subcostal site), donor nephrectomy (Pfannenstiel incision), or simple prostatectomy (above pubic symphysis). Bucher et al recently assessed the perception and preference of women regarding conventional laparoscopy, umbilical LESS, and transvaginal natural orifice transluminal endoscopic surgery (NOTES). An anonymous questionnaire was given to female medical and paramedical staff, patients, and the general population. With similar operative risk, 87% preferred LESS, 4% preferred NOTES, and 8% preferred laparoscopy [29].

With the increasing number of centers performing LESS, there was an expected increase in the number of cases per month; however, the rate of more advanced procedures significantly declined. This can be explained by the fact that centers starting LESS in the period 2009-2010 have opted for less challenging procedures in their early experience. An exception can be represented by adrenalectomy, almost exclusively performed by LESS in the 2009-2010 period. Because of the anatomical topography of the adrenal gland, the distance from the entry port to the target organ in a transumbilical LESS approach is suboptimal and this ultimately translates into a more demanding procedure. A retroperitoneal approach has been proposed [30] or a subcostal incision [31], which is cosmetically less appealing. A Pfannenstiel incision might represent an option when performing a donor nephrectomy [32].

In general, as for conventional laparoscopy, both transperitoneal and retroperitoneal routes have been described for LESS with variable strategies in terms of patient positioning, incision site, and port placement. Experience with retroperitoneal urologic LESS remains limited [30,33]. The retroperitoneal approach can limit working space, which, in LESS, can be even more problematic. In the present series, a transperitoneal approach was used most often.

Several reports have described the use of fixed-shaft bent, as well as actively articulating, instruments to facilitate single-port surgery [2,5]. Although these instruments are helpful in resolving the problems of triangulation, the lack of sufficient strength to provide robust retraction and dissection persists. The use of articulating or prebent instruments was adopted by the majority of surgeons in our series.

When considering main perioperative outcomes, it can be grossly estimated that some of the most commonly performed LESS procedures (eg, radical or partial nephrectomy, pyeloplasty, adrenalectomy, and renal cyst decortication) compare favorably with reported series of their laparoscopic counterparts [34–38]. Some concerns remain for some other procedures, such as donor nephrectomy, where the warm ischemia times tend to be longer than in mature laparoscopic series [39], or ureterolithotomy and simple nephrectomy, where operating time tends to be longer [40,41].

It has been wisely stated that sensitivity to the potential for complications is critical and the threshold for conversion must be appropriately low [5–11]. Irwin et al first reported a study looking at complications and rates of conversion from LESS to conventional laparoscopy during upper tract urologic procedures [7]. Overall, 125 patients were included

in the analysis. Conversion to conventional laparoscopy was necessary in 5.6% of cases and complications occurred in 15.2% of patients undergoing LESS surgery.

The overall conversion rate in our series was 20.8% (15.8%, reduced-port laparoscopy; 4%, conventional laparoscopy or robot-assisted surgery; and 1%, open surgery). In 21% of cases, surgeons decided to convert because limitations of LESS prevented them from progressing or, more specifically, to proceed with suturing (11%); to have adequate counter traction (3%); or to gain adequate access (3%). In 25% of cases, conversion to laparoscopy or open surgery was made necessary by safe management of complications.

Overall, the intraoperative complication rate in our series was 3.3%. Most complications were managed conservatively, with conversions to open or laparoscopic surgery occurring only in 0.7% of cases. Postoperative complications were detected in 9.5% of cases, with most being low grade. When comparing these figures to reported rates of complications for urologic laparoscopy [42–44], there seems to be no significant difference, suggesting a duplication of outcomes, even if LESS can be still considered in its infancy and improvements are likely.

The strength of the present study is represented by the large number of patients, which probably mimics what is seen in real-life practice. Nevertheless, some limitations of this project are to be recognized. First, it represents a retrospective analysis. Centers were asked by and agreed to provide their raw data to a principal investigator who collected them into a purpose-built datasheet. Thus, even if data had been prospectively collected by each center, biases related to the retrospective design remain. For the same reason, the analysis was necessarily limited to variables that were available and of sufficient quality to allow a reliable assessment. Second, almost all invited centers had separately reported part of these data in the past 3 yr. Third, as no control group has been considered in the current analysis, the actual benefits of LESS compared to standard laparoscopy and the recently *rediscovered* scarless options, such as minilaparoscopy, remain to be definitively proven [45]. As with any new surgical technique, LESS requires further clinical validation. Data from longer clinical followup are awaited. Prospective comparative studies are beginning to appear [16,17] or are under way.

5. Conclusions

This study reports the largest multi-institutional experience with urologic LESS to date. It provides a real-life-practice picture of what has been done so far in this field worldwide. Despite unsolved challenges, LESS can be regarded as an emerging trend in minimally invasive urologic surgery and it has significantly evolved, becoming a widely applicable technique in a relatively short time. Outcomes demonstrate that a broad range of procedures can be effectively and safely done by applying different LESS techniques in a variety of hospital settings. Undeniably, a solid laparoscopic surgical background and stringent patient-selection criteria are critical for successful LESS. Application of robotic technology may further facilitate LESS. Author contributions: Riccardo Autorino had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Autorino, Kaouk.

Acquisition of data: D. Han, Lee, Branco, Greco, Allaf, Sotelo, Liatsikos, Stolzenburg, Rane, White, W. Han, Haber, Molina, Jeong, Lee, Linhui, Best, Stroup, Rais-Bahrami, Schips, Fornara, Pierorazio, Giedelman, White. Analysis and interpretation of data: Autorino, Kaouk, Kim, Rha. Drafting of the manuscript: Autorino, Kaouk. Critical revision of the manuscript for important intellectual content: Kim, Cadeddu, Derweesh, Yinghao, Richstone, Cindolo, Stein. Statistical analysis: Autorino, White. Obtaining funding: None. Administrative, technical, or material support: None. Supervision: Kaouk. Other (specify): None.

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