Urological Laparoendoscopic Single Site Surgery: Multi-Institutional Analysis of Risk Factors for Conversion and Postoperative Complications

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Purpose: We analyzed the incidence of and risk factors for complications and conversions in a large contemporary series of patients treated with urological laparoendoscopic single site surgery.

Materials and Methods: The study cohort consisted of consecutive patients treated with laparoendoscopic single site surgery between August 2007 and December 2010 at a total of 21 institutions. A logistic regression model was used to analyze the risks of conversion, and of any grade and only high grade postoperative complications.

Abbreviations and Acronyms

ASA = American Society of Anesthesiologists

BMI = body mass index

EBL = estimated blood loss

LESS = laparoendoscopic single site surgery

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Results: Included in analysis were 1,163 cases. Intraoperatively complications occurred in 3.3% of cases. The overall conversion rate was 19.6% with 14.6%, 4% and 1.1% of procedures converted to reduced port laparoscopy, conventional laparoscopic/robotic surgery and open surgery, respectively. On multivariable analysis the factors significantly associated with the risk of conversion were oncological surgical indication ($p = 0.02$), pelvic surgery ($p < 0.001$), robotic approach ($p < 0.001$), high difficulty score ($p = 0.004$), extended operative time ($p = 0.03$) and an intraoperative complication ($p = 0.001$). A total of 120 postoperative complications occurred in 109 patients (9.4%) with major complications in only 2.4% of the entire cohort. Reconstructive procedure ($p = 0.03$), high difficulty score ($p = 0.002$) and extended operative time ($p = 0.02$) predicted high grade complications.

Conclusions: Urological laparoendoscopic single site surgery can be done with a low complication rate, resembling that in laparoscopic series. The conversion rate suggests that early adopters of the technique have adhered to the principles of careful patient selection and safety. Besides facilitating future comparisons across institutions, this analysis can be useful to counsel patients on the current risks of urological laparoendoscopic single site surgery.

Key Words: urinary tract, laparoscopy, endoscopy, intraoperative complications, ablation techniques

LESS has been increasingly reported in the urological literature in the last few years.[1] Comparative studies suggest that LESS is at least comparable to standard laparoscopy.[2] However, despite steady adoption worldwide for a wide range of surgical indications[3] the actual role of LESS remains to be determined.[4]

Similar to what has been done for laparoscopy,[5] LESS must be scrutinized for the risk of complications. This becomes even more imperative since LESS is technically more challenging due to its inherent ergonomic limitations. Although conversion itself cannot be considered a complication, it is nevertheless an important factor when fully counseling patients on the potential risks/benefits of any given procedure.[6] Generally the potential for complications and the risk of conversion should be appropriately low for LESS to be offered as a reasonable alternative to more established techniques.[7] To date limited data have been reported that specifically analyze the occurrence of complications and the need for conversion during LESS.[8–11]

This multi-institutional project was initiated as a collaborative effort to report the contemporary practice of LESS at centers where the development of this technique is being pioneered for urology worldwide.[3] We analyzed the incidence of and risk factors for complications and conversion in a large contemporary series of patients treated with urological LESS.

METHODS

Study Design

The study cohort consisted of consecutive patients treated with LESS between August 2007 and December 2010 at a total of 21 participating institutions. Groups at medical centers worldwide with reported experience with urological LESS were identified by searching the available literature and invited to participate in the study. Each group performed the procedures according to its protocols, entry criteria and techniques. All patients provided consent specifically for LESS. Raw data without an identifier were retrospectively collected and gathered in a standardized data sheet.

Outcomes

Demographic data were accrued, including patient age, gender, race, BMI, history of abdominal/pelvic surgery, ASA score, comorbidities and indication for LESS. Procedures were categorized as extirpative/ablative or reconstructive, and as upper urinary tract or pelvic. They were scored by the degree of technical difficulty according to a scale adapted from the European Scoring System for laparoscopic urological surgery.[3,12] The outcome parameters analyzed were operative time, EBL, intraoperative adverse events, transfusion, length of stay and visual analog pain score at discharge home.

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), da Vinci® robot use, type of single port device and the use of ancillary needlescopic/mini-laparoscopic ports, which is still considered LESS.[7] Adding an extra 5 mm or greater trocar was considered conversion to reduced port laparoscopy. Conversion from LESS to laparoscopic surgery was defined as unplanned installation of more than 1 trocar. Conversion to open surgery was defined as creation of an unplanned abdominal incision.

Postoperative complications were graded according to the standardized Clavien-Dindo system.[13] Medical and surgical complications that developed within 90 days after surgery were captured, including during the inpatient stay and in the outpatient setting.

Statistical Analysis

Continuous variables are shown as the mean ± SD. Categorical variables are shown as the frequency and percent. A logistic regression model was used for univariable and multivariable analysis. Three risk analyses were done, including the risk of 1) conversion to any of reduced port laparoscopy, standard laparoscopy or open surgery, 2) postoperative complications of any grade and 3) high grade (Clavien 3 to 5) complications only. Variables at

$p < 0.2$ on univariable analysis were selected for multivariable analysis. For high grade complications only univariable analysis was done due to the few events.

Analyzed variables included patient gender, age at surgery (less than 60 vs 60 years or greater), BMI (less than 30 vs 30 kg/m^2 or greater), prior abdominal or pelvic surgery, ASA score (0 to 2 vs greater than 2), any comorbidity, indication, surgical site (upper tract vs pelvic), access site (umbilical vs extraumbilical), surgical approach (transperitoneal vs retroperitoneal/extraperitoneal), surgery type (extirpative vs reconstructive), robotic approach, procedure difficulty score (2 or less vs 3 or greater), operative time (less than 3 vs 3 hours or greater), EBL (less than 100 vs 100 ml or greater) and intraoperative complications. For statistical analysis of risk factors in cases with more than a single complication only the highest grade was considered.

Two-sided $p < 0.05$ was considered statistically significant. All statistical analysis was done using standard statistical software.

RESULTS

Patients and Procedures

Overall 1,163 patients with a mean ± SD age of 51.5 ± 16.6 years and a mean BMI of 25.4 ± 6.6 kg/m^2 were included in analysis (table 1). Of the procedures 83.4% were extirpative while 85.6% targeted the upper urinary tract. A single port technique applied via transperitoneal access was preferentially adopted and the umbilicus was the most common site of access. In 12.3% of cases the da Vinci robotic platform was used.

Outcomes

Overall mean operative time was 155.8 ± 75.8 minutes and mean estimated blood loss was 141 ± 271.5 ml. Intraoperative complications occurred in 30 cases (3.3%) while there were none in 1,125 (96.7%). Overall 230 cases (19.6%) were converted, including 170 (14.6%), 47 (4%) and 13 (1.1%) to reduced port laparoscopy, conventional laparoscopic/robotic surgery and open surgery, respectively. Of the 109 postoperative complications 37 (33.9%), 44 (40.4%), 23 (21.2%) and 5 (4.6%) were grade 1 to 4, respectively, when considering the highest grade in patients with more than 1 complication. Mean hospital stay was 3.49 ± 2.6 days with a mean visual analog pain score at discharge home of 1.5 ± 1.4 on a scale of 1 to 10. Table 2 lists conversions and complications for the most commonly performed (greater than 50) procedures.

Conversion Predictors

Univariable analysis revealed that female gender ($p = 0.01$), oncological surgical indication ($p < 0.001$), pelvic surgery ($p < 0.001$), extraperitoneal/retroperitoneal approach ($p = 0.01$), reconstructive procedure ($p = 0.003$), robotic approach ($p < 0.001$), high procedure score ($p < 0.001$), extended operative time ($p < 0.001$), higher EBL ($p < 0.001$) and an intraoperative complication ($p = 0.001$) were potential risk factors for conversion.

On multivariable analysis the only factors still significantly associated with the risk of conversion were oncological indication ($p = 0.02$), pelvic surgery ($p < 0.001$), robotic approach ($p < 0.001$), high procedure score ($p = 0.004$), extended operative time ($p = 0.03$) and an intraoperative complication ($p = 0.001$).

Table 1. *Study population, procedures and techniques*

	No. Pts (%)
BMI (kg/m^2):	
Less than 30	981 (86)
30 or Greater	160 (14)
ASA score:	
1 or 2	994 (86)
3 or 4	162 (14)
Comorbidity:	
Absent	573 (49.6)
Present	583 (50.4)
Prior abdominopelvic surgery:	
Absent	856 (73.3)
Present	307 (26.4)
Surgical indication:	
Nononcological	648 (55.7)
Oncological	515 (44.3)
Surgery type:	
Extirpative/ablative	970 (83.4)
Reconstructive	193 (16.6)
Procedure score:	
1 or 2	655 (56.5)
3 or Greater	508 (43.5)
Surgery site:	
Pelvic	168 (14.4)
Upper	995 (85.6)
Robotic approach:	
No	1,020 (87.7)
Yes	143 (12.3)
LESS technique:	
Single port	902 (77.7)
Single site	258 (22.3)
Surgical approach:	
Transperitoneal	1,082 (93)
Retroperitoneal/extraperitoneal	81 (7)
Access site:	
Umbilical	1,044 (90.5)
Extraumbilical	109 (9.5)

Data not available on entire study population.

Postoperative Complications

Analysis. A total of 120 complications occurred in 109 patients (9.4% overall). Most patients experienced minor (grade 1 and 2) complications with major (grade 3 and 4) complications noted only in 2.4% of the entire cohort (28 of 1,163 patients). There was no multiple organ dysfunction (grade 4b) or death (grade 5). A total of 38 types of complications were recorded and grouped into 10 categories. The most common complication categories were infectious in 1.9% of cases, hemorrhagic in 1.9%, gastrointestinal

Table 2. *Conversions and complications for most commonly performed LESS procedures*

Procedure	No. Pts	No. Conversions (%)				No. Intraop Complications (%)	No. Postop Complications (%)	
		Reduced Port	Laparoscopy	Open	Overall		All Grades	Grade 3–4
Nephrectomy:								
Radical	220	17 (7.7)	6 (2.7)	1 (0.5)	24 (10.9)	7 (3.2)	20 (9.1)	4 (1.8)
Simple	147	13 (8.8)	8 (5.4)	2 (1.4)	23 (15.6)	5 (3.4)	14 (9.5)	3 (2)
Partial	133	70 (52.6)	9 (6.8)	2 (1.5)	81 (60.9)	6 (4.5)	13 (9.8)	4 (3)
Donor	61	8 (13.1)	5 (8.2)	0	13 (21.3)	1 (1.6)	5 (8.2)	2 (2)
Renal cyst decortication	128	0	2 (1.6)	0	2 (1.6)	2 (1.6)	9 (7.1)	0
Pyeloplasty	95	4 (4.2)	9 (9.5)	0	13 (13.7)	2 (2.1)	17 (17.9)	9 (9.5)
Adrenalectomy	55	7 (12.7)	6 (10.9)	0	13 (23.6)	7 (12.7)	2 (3.6)	0
Ureterolithotomy	55	0	0	3 (5.5)	3 (5.5)	1 (1.8)	5 (9.1)	0
Varicocelectomy	54	1 (1.9)	0	0	1 (1.9)	0	5 (9.3)	0

in 1.8% and genitourinary in 1.7%. The most common events were ileus and transfusion due to bleeding.

Predictors. Univariable analysis to evaluate predictors of any grade of complication identified female gender ($p = 0.04$), extended operative time ($p = 0.04$) and an intraoperative complication ($p = 0.003$) as significant. On multivariable analysis female gender ($p = 0.03$) and an intraoperative complication ($p = 0.002$) remained statistically significant but higher ASA score ($p = 0.11$), reconstructive procedure ($p = 0.17$) and extended operative time trended toward significance.

For high grade complications alone univariable analysis identified reconstructive procedures ($p = 0.03$), high procedure score ($p = 0.002$) and extended operative time ($p = 0.02$) as significant predictors. The robotic approach ($p = 0.14$) and higher EBL ($p = 0.12$) trended toward significance.

DISCUSSION

Until recently only 3 large series of urological LESS were reported.[14–16] In 2009 White et al described a single institution experience with the first 100 LESS urological procedures.[14] Six patients required conversion to standard laparoscopy and none required conversion to open surgery. The overall complication rate was 11%.

A 2-center experience with a total of 100 LESS procedures was reported by Desai et al.[15] The addition of 1 or more ports was needed in 6 cases and conversion to open surgery was necessary in 4. The overall conversion rate was 10% with 1 death after simple prostatectomy. The overall complication rate was 14%.

Choi et al reported a cumulative experience with 171 patients treated with LESS.[16] Intraoperative complications occurred in 7 cases (4.1%) and postoperative complications occurred in 9 (5.3%). Seven cases (4.1%) were converted to mini-incision open surgery.

Our group recently reported a detailed analysis of the initial series of more than 1,000 LESS cases from urological institutions worldwide.[3] The current report represents another analysis by the same investigators, focusing on urological LESS complications and conversions.

The complication rate is broadly considered a surrogate of surgical competence. Accurate reporting of complications is important for preoperative counseling, for identifying modifiable risk factors to decrease the complication rate and for designing clinical trials. Although complications and conversions were reported in several series of specific LESS procedures,[1] few studies have specifically addressed the issue with LESS overall as a technique.

Irwin et al reported a study of complication and conversion rates in 125 upper tract urological LESS procedures from a total of 6 institutions.[8] Conversion to laparoscopy was necessary in 7 patients (5.6%) and none required open conversion. Complications occurred in 15.2% of cases. Irwin et al concluded that LESS appeared to be associated with a higher complication rate than in mature laparoscopic series but conversion was rare, reflecting stringent patient selection. The limitations of that study included the inability to standardize LESS patient selection criteria, instrumentation and surgical technique as well as the lack of available complete data on a control group for comparison. These limitations were also noted in our analysis and are directly linked to its retrospective nature.

Besides describing the events in their series, Irwin et al did not provide a risk analysis.[8] This was more recently done by Greco et al, who looked at risk factors for complications in a multi-institutional series of LESS done for upper urinary tract disease.[11] The overall complication rate in this series was 17% with conversion to open surgery considered a complication. Multivariable analysis revealed that a higher ASA score and malignant disease on pathological evaluation were risk factors for complications. Greco et al concluded that surgeons who ap-

proach LESS should start with benign diseases in patients at low surgical risk.

Best et al reviewed their initial series of LESS pyeloplasty, focusing on the 30-day complication rate.[9] Seven patients (25%) experienced complications with 71% of complications in the initial 10 patients. Best et al concluded that LESS pyeloplasty is a technically challenging procedure even for an experienced laparoscopic surgeon.

Ramasamy et al compared the postoperative complications of LESS and standard laparoscopic living donor nephrectomy using a standardized complication reporting system.[10] At 30 days there was no difference in the overall complication rate between the 2 groups (7.1% vs 7.9%, $p > 0.05$). Multivariable binary logistic regression analysis revealed that estimated blood loss was the only predictor of fewer complications.

The current study is unique for 2 main reasons. 1) It was done using the largest LESS series ever reported to our knowledge, including upper tract and pelvic surgical procedures. 2) For the first time to our knowledge this study provides an analysis of risk factors for complications and conversions.

We found an overall conversion rate of 19.7%, including 14.6%, 4% and 1.1% rates of conversion to reduced port laparoscopy, conventional laparoscopy and open surgery, respectively. On multivariable analysis significant factors that increased the likelihood of any type of conversion were oncological surgical indication, pelvic surgery, robotic assistance, high procedure difficulty score, extended operative time and intraoperative complications.

Arguably these factors are somehow associated. Procedures with a higher degree of difficulty naturally require more operative time. Likewise the robotic operating platform is often used in inherently more challenging cases.[17] LESS pelvic surgery is already recognized as highly challenging, which is likely related to ergonomic considerations. As expected, an intraoperative complication was associated with an increased risk of conversion. This indirectly suggests that surgeons have embraced the concept that patient safety comes first.

This becomes clearer when looking at conversions for the most commonly performed procedures (table 2). Partial nephrectomy is by far the procedure most likely not to be completed as LESS. Others, each for different specific issues, still represent a challenge for the surgeon who performs LESS, including donor nephrectomy due to donor safety,[18] pyeloplasty due to the need for precise suturing[19] and adrenalectomy due to the anatomical topography of the adrenal gland.[20]

Postoperative complications were detected in 9.4% of cases overall and most of them were low grade. As previously mentioned,[21] the spectrum of LESS complications would be expected to be identical to those of laparoscopic surgery, in addition to LESS specific issues related to access, instruments, and limited dexterity and triangulation. The specific complications in our series seem to resemble those in reported laparoscopic series.[5,22–26] Statistically significant associations with a complication of any grade were noted on multivariable analysis only for female gender and an intraoperative complication while higher ASA score, a reconstructive procedure and extended operative time trended toward but did not attain statistical significance.

Significant factors partially differed when considering only high grade complications, representing those with a more significant clinical impact on the postoperative course. In this regard univariable analysis identified reconstructive procedure, high procedure difficulty score and extended operative time as significant predictors. Again, the more challenging the procedure (and this especially applies for those requiring suturing), the more a certain LESS technique is likely to deviate from the regular postoperative course.

Martin et al established a list of 10 critical elements that should be included when reporting surgical complications.[27] The aim was to provide a more accurate, comprehensive representation of surgical morbidity and allow for reliable comparisons of outcomes among different institutions, surgeons or surgical techniques. Despite the availability of such a standardized reporting methodology it remains underused in the urological literature.[28] Notably the criteria of Martin et al were applied in our analysis, including a grading system to objectively measure the severity of each complication.

The current study has a few limitations. 1) It is a retrospective study and, as such, may not thoroughly capture all conversions/complications. Even if data had been prospectively collected at most centers, biases related to the retrospective design would have remained. Moreover, the data presented do not reflect total complications but rather complications that occurred within a defined period after surgery. Besides the quality of the data collection, the retrospective design intrinsically affected other aspects of the study methodology, including the difficulty scale used to score procedures.

2) Our series represents the outcomes of surgeons with an extensive laparoscopic background. As such, results may not be representative of those achieved by less experienced urologists. With that stated, these skilled surgeons were in the learning curve and still in a phase of procedure standardization. Nevertheless, this analysis is likely to provide some guidance about what cases to start with for the urologist who is a LESS novice.

3) To our knowledge a comparative analysis with standard laparoscopy and potentially other available scarless options remains to be performed. However, when putting our findings into perspective with reported large series of urological laparoscopy, LESS appears to compare favorably in conversions and complications.[5,6,22–26,29]

CONCLUSIONS

The current large, multi-institutional analysis comprehensively details the conversions and complications of urological LESS. In accordance with previous observations our findings show that urological LESS can be performed with a low complication rate in experienced hands, resembling that in major reported laparoscopic series. The conversion rate suggests that early adopters of the technique have adhered to the principles of careful patient selection and safety in this early phase of LESS development. Besides facilitating future comparisons across institutions, this analysis can be useful to identify modifiable risk factors and ultimately counsel patients on the current risks of urological LESS.

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