Review Article

Complications of laparo-endoscopic single-site surgery in urology

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ABSTRACT

The objective was to give a general overview of common complications and rates reported in the current literature during performance of a variety of urologic procedures using laparo-endoscopic single-site surgery or LESS. A search of published reports using Pubmed and MEDLINE was performed with the following search terms: laparo-endoscopic single-site surgery, LESS or laparo-endoscopic single-site surgery complications within the date range of 2005--2011. Studies that were deemed appropriate and relevant to the current symposium were chosen for review. Overall complication rates were reported as ranging between 10% and 25%. In general, reconstructive procedures had consistently higher rates of complications than their extirpative/ablative counterparts (27% vs. 8%). There remain insufficient data to comment on differences in the rates or types of complications related to variations in the approach (transperitoneal vs. retroperitoneal), site of surgery (upper tract vs. lower tract) or specific technique used (instruments, access devices, robotic platforms, etc.). Complication rates associated with LESS in urology appear only slightly higher than with conventional laparoscopy. However, with proper patient selection and careful application of these techniques, proofs of concept and technical feasibility have been shown in several series. There continues to be a need for more standardization of the technique and reporting as well as more collaborative efforts to fully address questions of safety and efficacy of these new procedures.

Key words: Complications, LESS, laparoscopy, laparoendoscopic surgery, minimally invasive, single site, single port

INTRODUCTION

A paradigm shift, as outlined in Thomas Kuhn's book *The Structure of Scientific Revolutions* (1962), is manifested by a change in the basic assumptions of generally accepted scientific structure or theory. The most recent major paradigm shift in urologic surgery occurred with the widespread adoption of laparoscopy following the first laparoscopic nephrectomy by Clayman in the early 1990s. The leap from open surgery to minimally invasive laparoscopic procedures represented a great advance. With the turn of the 21st century, refinements in techniques, instrumentation, optic, and robotic technologies along with consumer/patient driven demands for cosmesis have led to the furtherance of minimally invasive techniques in urology. Since the initial conception of surgery through naturally occurring body orifices and small single incisions, denoted as natural orifice transluminal endoscopic surgery (NOTES) and laparo-endoscopic single-site surgery (LESS), respectively, we have seen an evolution of techniques from bench-top testing to animal feasibility studies to human prospective case series. With any new paradigm shift in thought or technique comes the imperative to track outcomes and complications in order to compare them to the generally accepted concepts, procedures, and standards of care.

Here, we strive to provide an overview of currently reported rates and types of complications seen in the literature describing our experience with LESS procedures. While the initial literature regarding the proof of concept and technical feasibility is becoming more robust, the standardization of procedural techniques and outcomes reporting in the LESS literature continue to lack uniformity.

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HISTORY OF LESS COMPLICATION REPORTING

The vast majority of complication data from the early experience with LESS in urology comes from several small[1-6] and a few larger case series.[7,8] In an attempt to

more formally study the experience with LESS procedures, the Endourology Society's Urologic NOTES Working group was formed and charged with addressing issues of safety, efficacy, and implementation of these techniques. They subsequently cofounded LESSCAR or the laparo-endoscopic single-site surgery consortium for assessment and research in 2008, specifically to monitor these. In their white paper consensus statement in 2010 they define the surgical approach known as LESS as encompassing the following: A single entry point, being applicable to multiple locations including the abdomen and pelvis, to include laparoscopic, robotic or endoscopic surgery via umbilical or extraumbilical approach and the inclusion of intra- and transluminal approaches.[9] The NOTES working group published their first multiinstitutional study in 2011. They took this opportunity to look specifically at rates of complications and conversion to conventional laparoscopy in the early experience with upper tract LESS procedures.[10]

Overall complications of LESS

The earliest large case series in the literature pertaining to LESS in urology were published in the same issue of *Urology* in early 2009 by Desai and White both from the Clelevand Clinic Foundation in Cleveland, Ohio, USA. Both series were primarily descriptive in nature and discussed their complications using different reporting methods.

Desai *et al.* reported on 100 patients who underwent a variety of upper and lower tract urologic LESS procedures. They included 33 via a transvesical approach and 67 transperitoneally via the umbilicus. A combined complication rate of 14% (n=5 intraoperative and n=9 postoperative) was reported with the majority (8 of the 14) being in the transvesical LESS group. A conversion rate of 10% was presented, including 3 to conventional laparoscopy (CL), 4 to open surgery, and 3 requiring an additional 5 mm port.[7] Although the Clavien complication grading system was not used, a grade V incident was noted with a death in a Jehovah's witness patient refusing transfusion.

Concurrent with publication of the above series, White *et al.* reported on their experience with their first 100 LESS cases. No intraoperative complications were noted, but 6 (6%) conversions to CL were described. They had an overall 11% complication rate without the conversion data with the vast majority being grade II or lower. They report nine Clavien grade II incidents; one Clavien grade IIIb due to recto-urethral fistula formation requiring operative intervention and one grade IVa due to a patient requiring ICU admission with transfusion and subsequent angioemoblization.[8]

The most recent large, single institution series, presented by Choi *et al.*, reports an intraoperative complication rate of 4.1% and postoperative rate of 5.3% in their 171 patient case series. Intraoperative complications included an IVC injury requiring open conversion, a renal vein injury, 2 bowel injuries, 2 diaphragmatic injuries, and a ureteral injury. They also described multiple conversions to limited port laparoscopy (n=4) as well as "mini-incision" open conversions (n=5). Postoperative complications were primarily minor, but also included wound dehiscences (n=3), a retroperitoneal abscess, acute renal failure, and stent migration.[11]

The largest aggregate case series to date was reported by Kaouk *et al.* It represented the efforts of a large, world-wide, multi-institutional experience consisting of 1076 patients. The paper pooled data describing LESS surgery patients, their complications, and conversion rates from 18 participating institutions. In many cases patients (and their complications) had been reported by individual surgeons/authors in their own respective smaller case series. The paper presents an aggregate overall complication rate from these institutions of 15%. Eighty-six percent of cases involved work on the upper urinary tract and 84% of the series were purely extirpative or ablative without a reconstructive component. In this series, an additional port was placed in 23% of cases. Of these two-thirds were either a 5 mm or 12 mm port with the remainder being a mixture of needlescopic and other ports. Their overall conversion rate was described as 20.8% with 1% requiring conversion to open surgery. The intraoperative complication rate was 3.3% with a postoperative complication rate of 9.5%.[12] Again, the majority of the complications were of low Clavien grades (I and II).

Table 1 describes the most commonly reported or cited reasons for conversion and complications identified following a Pubmed and MEDLINE search performed with the following search terms: Laparo-endoscopic single-site surgery, LESS or laparo-endoscopic single-site surgery complications within the date range of 2005--2011. While we understand that this likely is a nonexhaustive list due to search limitations, it appears to provide a good representation of the expected scope and types of common and rare complications reported in the literature.

Upper urinary tract and lower urinary tract LESS

The vast majority of the series published to date have described the experience with upper tract disease. In the current literature, two pooled series look specifically at the use of LESS for upper tract disease – one by Greco *et al.* and one by Irwin, *et al.* Because of the paucity of reported lower tract cases, we also present aggregate data from several studies reporting complication rates in lower urinary tract LESS procedures without stratification by approach or platform preference, i.e., commercial or home-made port, laparoscopic or robotic, extirpative/ablative or reconstructive, etc.

Greco *et al.* looked at LESS procedures performed at four institutions in a series comprising 192 cases.[13] They classified

Table 1. Major reasons cited for conversion and a selective list of reported complications[7,8,10-13,15-20]

Reasons for conversion	Postoperative complications§ Clavien grade
Difficult dissection/exposure/retraction	Pain (I)
Difficulty suturing	Pyrexia (I)
Aid in reconstruction	Ileus (II)
Control of bleeding	UTI (II)
Failure to progress	Bleeding requiring transfusion (II)
	Bleeding requiring angioembolization (IIIa)
	Bowel/splenic/diaphragmatic injury (IIIb)
	Urinary/anastomotic leak (IIIb)
	Fistula formation (rectourethral) (IIIb)
	Vascular injury (IVC, renal, gonadal vein) (IV)
	Mortality (V)

§Most complications cited in the literature were of Clavien grade I or II.

Table 2: Selective cumulative data for lower urinary tract LESS

Procedure	Number of cases
Simple prostatectomy	32
Radical prostatectomy	6
Sacral colpopexy	13
Radical cystectomy	3
Partial cystectomy	3
Ureteral reimplantation	3
Other‡	12
All cases	72
	Conversion (%)
	n=4 (5.5%)
	Complication (%)
	n=10 (13.8%)

‡3 ileal ureter, 3 varicocelectomy, 1 transvesical mesh sling removal, 1 hysterectomy, 1 urachal mass excision, 1 orhiectomy, 1 seminal vesiculotomy, 1 retroperitoneal mass excision (cystic lymphangioma).

their complication rates as early (<30 days), intermediate (31--90 days), and late (>90 days). Complications were recorded using the Clavien-Dindo grade[14] system with an overall complication rate of 17% with the highest clustering in the grades I and II. The presence of a complication showed a statistically significant positive association with both high ASA score (P=0.034) and malignant pathology (P=0.039). In their analysis, a conversion to open surgery from LESS was considered a complication (n=4), but not if converted to conventional laparoscopy (6% of cases). They report needing an additional port, often termed "limited port laparoscopy," in 40% of cases. It is unclear from their presentation whether these cases met the generally accepted definition of LESS (if only an additional needlescopic port < 3 mm was used) or whether they should be considered conversions as additional port size was not reported in the study.

Irwin *et al.* reported on a multi-institutional experience with 125 cases. They described an overall complication rate of 15.2% with all cases completed either as LESS or via CL without the need for open conversion. They used a more stringent definition of conversion: Addition of at least one 5 or 10/12 mm trocar (5.6%). They also classified their complications using the Clavien system of reporting with reconstructive cases having a higher complication rate compared to the extirpative/ablative, 27.1% and 7.8%, respectively.[10] Those complications occurring in the reconstructive groups (urine leaks, bleeding, etc.) were felt to be more likely directly related to technical difficulties related to the surgical platform than were those seen in the extirpative/ablative cases (DVT, UTI, neuropraxia, etc.).

Due to the paucity of dedicated lower tract LESS series presented independently in the literature, we have gathered information from several studies[7,8,11,12] that were included for this paper to describe the aggregate experience with lower tract LESS. Table 2 presents the rates of conversion and complications described therein.

Data from Kaouk's study of 1076 patients included a total of 130 lower tract LESS procedures. While there was no specific break-down of complication or conversion rates for lower tract LESS in their presentation, it is unlikely that it differs dramatically from the above experience. Of note, some of the more devastating complications described in the literature (including a recto-urethral fistula following radical prostatectomy and at least one death following a simple prostatectomy) have been seen in the lower tract experience.

Extirpative/ablative and reconstructive LESS

Because of the technical challenges involved with suturing with the current LESS platforms, several authors have hypothesized that complication rates may be expectedly higher in procedures requiring a reconstructive component (pyeloplasty, partial nephrectomy, nephroureterectomy, radical prostatectomy, ureteral reconstruction, etc.) than in those that are purely extirpative or ablative (simple nephrectomy, cyst decortication, renal cryotherapy, etc.). To date, however, no study has been reported having been designed specifically to address this question.

Irwin *et al.*, in their series of upper tract LESS procedures described above, reported a higher complication rate with reconstructive procedures (27.1%) compared to that seen with extirpative/ablative procedures (7.8%), in a retrospective subset analysis.[10] While this study may have been underpowered for this type of description, it was the first attempt to address the question of complications being related to procedure-specific platform-related difficulties in this way. It is interesting to note that Greco, in a similar

subset analysis, showed no difference in extirpative/ablative versus reconstructive LESS complication rates.

Best *et al.* reported on 28 patients that underwent pyeloplasty. Their 25% (n=7) complication rate was remarkably similar to that seen in Irwin's series, and is markedly higher than would be expected in contemporary series of CL pyeloplasty. Again, the types of complications, including obstructions (n=2) and urine leaks (n=3), were felt to be potentially directly related to the reconstructive component of the case. They did not consider conversion a complication and hence excluded patients who underwent conversion from LESS to CL in their analysis. They pointed to a marked learning curve with 71% (n=5) of their complications being seen in the initial 10 cases and only 29% (n=2) in the final 18 cases.[15]

DISCUSSION

As can be seen in the early reporting of LESS case series, there has been no standardization of reporting format for complications. Furthermore, there has been no consensus about whether a conversion to CL should be considered a complication or simply noted in the description of the series. While the Clavien system was not originally conceived to describe complications in a urologic surgical population, it has been embraced as a standard for such reporting and has helped to alleviate shortcomings of standardization in some of the more recent LESS series. The inclusion of conversion data in the complication rates continues to vary from author to author. To avoid confusion we should standardize the definition of what constitutes a complication. We should decide whether the addition of a single 5 mm or 10 mm port during the performance of a pure LESS procedure should be reported in the complication rate, simply be noted in the text or whether a standard line describing conversions should be developed for reporting purposes.

In addition to standardization of reporting, difficulties in making any generalization about complications are introduced by the lack of standardized techniques. To date, no standardized approach has been developed to describe appropriate patient selection criteria, surgeon learning curve, use of homemade or commercially available single port devices and instruments or other critical criteria which may impact complication, and conversion rates. The surgical approach and modality seem to have an interesting interplay with the type of procedure in determining not only the rates, but also the types of complications seen. This is suggested by the fact that with reconstructive LESS both Irwin and Best saw rates of complications higher than those have been seen in contemporary CL series for the same procedures. While this difference was not corroborated by Greco's experience, the types of complications appeared to be directly attributable to technical difficulties related to the reconstructive components of many of these cases.

It remains to be determined if the future of LESS lies in R-LESS or other technologies as a means of overcoming some of these difficulties primarily related to suturing with the current platforms and instrumentation. The experience with R-LESS remains small in the current literature. For example, of the 1076 cases presented by Kaouk only 13% of the total cases were conducted with robotic-assisted techniques. Lee *et al.* reported on 68 R-LESS procedures [16] while Choi recently described an additional 73 R-LESS upper tract surgeries.[11] In both series the vast majority were for partial nephrectomy. These series described similar rates of complications as seen in the conventional LESS groups and continued difficulty with dissection and reconstructions with complications including renal vein injury, ureteral injury, positive margins with partial nephrectomy, postoperative hemorrhage, and others. The lack of standardization in definitions and technique in the above makes it impossible to present a coherent comparison of complication rates between the series. From these, it is not clear that R-LESS in its current form derives any advantage over conventional LESS techniques.

No large-scale, multicentered, prospective, randomized controlled studies have been conducted thus far utilizing LESS. The most mature studies comparing LESS to CL exist in the area of donor nephrectomy (DN). Kurien *et al.* performed a prospective randomized comparison of 50 patients undergoing LESS-DN versus 50 patients undergoing CL-DN.[17] Afaneh *et al.* compared patients undergoing similar procedures in matched cohorts (n=50 in each group) in a retrospective manner.[18] Both trials showed no difference in incidence of intraoperative or postoperative complication rates. A prospective nonrandomized comparison of 64 patients undergoing nephrectomy was recently reported by Mir *et al.* Thirty patients undergoing LESS nephrectomy were compared to 34 performed via CL. The modality of surgery was dictated by the surgeon's clinical judgment of patient candidacy for LESS. Mir reported a complication rate of 13% in LESS cases and 15% for CL cases with a conversion rate of 3% from LESS to CL.[19] Seo, on the other hand, reported a 10% complication rate with LESS radical nephrectomy (n=10) compared to 17% for CL radical nephrectomy (n=12) with all cases being completed successfully without conversion.[20]

Current experience may actually be underestimating the potential for complications with potential biases being present at both the surgeon level and the patient selection level. Currently the highest volume of cases are being performed primarily at centers of excellence, highly skilled and experienced in CL techniques. With wide-spread dissemination of these techniques to less experienced facilities, at least an initial rise in complication rates might be expected. As these techniques have been developed, there has been strong emphasis placed on patient selection (low BMI, few prior abdominal procedures, low ASA scores, etc.) by early adopters of these techniques. Again, as these

procedures are generalized to the greater population of patients, an expected rise in complication rates might be seen.

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