Complications and conversions of upper tract urological laparoendoscopic single-site surgery (LESS): multicentre experience: results from the NOTES Working Group

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OBJECTIVE

To present complications and rates of conversion from LESS to conventional laparoscopy (CL) at the time of upper tract LESS urologic procedures.

PATIENTS AND METHODS

Patients undergoing LESS upper tract procedures between September, 2007 and November, 2008 (n = 125) were identified at six high-volume academic centers pioneering urologic LESS procedures. All LESS procedures were performed transperitoneally via a single umbilical incision using either adjacent conventional trocars or a dedicated single-site access device. Reconstructive procedures incorporating a single planned 2 mm accessory needle port were included as LESS procedures and were not considered conversions.

Patients undergoing LESS procedures requiring conversion to CL with the placement of additional ports were identified. Conversion was defined as the placement of additional 5 or 10/12 mm ports beyond the primary incision. In each case the operative reports were reviewed, the reason for conversion was determined, and the number and types of additional ports and complications were noted.

RESULTS

Upper tract LESS procedures were performed in 125 patients comprising 13.3% of the total 937 laparoscopic procedures performed at the participating institutions during this time period. Conversion to CL was necessary in 7 patients (5.6%) undergoing LESS requiring the addition of 2–5 ports.

Reasons for conversion included:

- facilitate dissection in 3 (43%),
- facilitate reconstruction in 3 (43%),
- control of bleeding in 1 (14%).

All attempted LESS cases were completed laparoscopically without need for open conversion.

Complications occurred in 15.2% of patients undergoing LESS surgery. Three of the 7 patients that required conversion to CL developed postoperative complications (Clavien grade II in two and IIIa in one).

Limitations of this study included the inability to standardize LESS patient selection criteria, instrumentation and surgical technique as well as the lack of available complete data from a CL control group for comparison.

CONCLUSION

LESS surgery is technically feasible for a variety of upper urinary tract reconstructive and ablative procedures, although it appears to be associated with higher rates of complications than in mature CL series. Conversion to CL occurs infrequently and may be a reflection of stringent patient selection.

KEYWORDS

LESS, single site, single port, laparoscopy, complications

What's known on the subject? and What does the study add?

Several studies have shown the feasibility of performing both complex and reconstructive laparoendoscopic single site (LESS) surgical procedures in urology. To date, no studies have evaluated the rates of conversion to conventional laparoscopy and complications at the time of LESS procedures in urology.

This study, a compilation of results from members of the NOTES working group, is the first study to address the rates of complications and conversions to conventional laparoscopy at the time of LESS surgery in urology.
INTRODUCTION

Since 1990, laparoscopy has developed from a novel surgical approach into the standard of care for the performance of a large variety of surgical procedures spanning across multiple specialties. Laparoendoscopic single-site surgery (LESS) has developed as an evolution of this technology in an attempt to minimize the trauma and improve cosmesis associated with accessing the abdominal cavity. LESS is typically performed by introducing multiple instruments through a single skin site either using conventional ports placed side-by-side or via a purpose-designed multi-lumen port [1]. The closely packed and somewhat parallel instruments present new technical challenges to the surgeon trying to perform the procedure.

Any new technology must undergo rigorous evaluation of risks and benefits before its widespread application. To more closely critique the results of LESS surgical endeavours, the Urology NOTES (Natural Orifice Translumenal Endoscopic Surgery) and LESS Study Group was created to pool results to allow for a more fair and substantive analysis of outcomes [2]. This study represents the first of what will probably be many investigations looking critically at the group’s results.

Within a short time multiple reports of LESS procedures have appeared in the literature, primarily focused on technical feasibility. The advantages of LESS surgery over standard laparoscopy, beyond the cosmetic benefit, remain largely unproven, so it is critical to show the safety of this approach. To primarily evaluate the safety profile, a multi-institutional retrospective review of LESS procedures performed at six high-volume centres was conducted to determine the rate and nature of complications as well as the risk of conversion at the time of LESS procedures.

RESULTS

A combined total of 937 laparoscopic upper tract procedures including nephrectomy (n = 672), pyeloplasty (n = 106) and adrenalectomy (n = 43) were performed at the participating institutions (see Fig. 1). Of these, a total of 125 were attempted with LESS techniques through an umbilical incision representing 13.3% of the overall laparoscopic experience. Of those undergoing attempted LESS procedures, seven (5.6%) required conversion to CL techniques to safely complete the procedure. Reasons for conversion included:

1. The closely packed and somewhat parallel instruments present new technical challenges to the surgeon.
2. The use of straight, fixed bent, or articulating instruments/cameras were not dictated by the study design, but rather were left to the discretion of the surgeon.
3. Cases were included as LESS cases if they met the criteria for inclusion in LESS studies set forth by the Urologic NOTES Working Group [3].

Cases requiring the placement of additional ports beyond the standard single site were defined as requiring conversion. By consensus of the Laparoendoscopic Single-Site Surgery Consortium for Assessment and Research, a single 2-mm needlescopic port was allowed within the definition of LESS procedures in an attempt to provide enhanced patient safety, increased intraoperative dexterity, and an expanded clinical repertoire of LESS surgery [4].

Complications were noted and compared across all LESS procedures. Additional comparison was made with regard to the types and rates of complications by the nature of the procedure (extirpative/ablative versus reconstructive). Patients requiring conversion to CL at the time of LESS were included in the LESS treatment arm as part of an intention-to-treat analysis during complication calculations, but conversion was not considered a complication per se.

###FIG. 1. Schematic showing the number of cases performed at six high-volume institutions performing laparoscopic urological procedures. Numbers in parentheses represent the number of patients in each group and the percentage of the total laparoscopic group represented within that category. Complication rates are reported within each category as determined by intention-to-treat analysis. CL, conventional laparoscopy; LESS, laparoendoscopic single-site surgery.

- **Laparoscopic upper tract urological procedures** (n = 937; 100%)
  - **CL procedures** (n = 812; 86.7%) Excluded from analysis
  - **LESS procedures** (n = 125; 13.3%)
    - Complication rate = 15.2%

- **Completed LESS** (n = 74; 7.9%)
  - Complication rate = 6.7%
  - **Converted to CL** (n = 3; 0.3%)
    - Complication rate = 33%

- **Extirpative/Ablative LESS Procedures** (n = 77; 8.2%)
  - Complication rate = 7.8%

- **Reconstructive LESS Procedures** (n = 48; 5.1%)
  - Complication rate = 27.1%

- **Completed LESS** (n = 44; 4.7%)
  - Complication rate = 25%
  - **Converted to CL** (n = 4; 0.4%)
    - Complication rate = 50%
facilitation of dissection in three, facilitation of reconstruction in three, and control of bleeding in one (Table 1). A range of 2–5 (mode 2) additional ports were added during conversions. No patient required open conversion to complete the procedure.

Complications occurred in 19 of 125 LESS cases with an overall complication rate of 15.2% (see Table 1). Three of the seven patients requiring conversion to CL developed postoperative complications (one urine leak, one postoperative haemorrhage requiring transfusion, and one deep venous thrombosis requiring anticoagulation). The technique of LESS varied between institutions and has been described in detail elsewhere [1,5–10].

A subset analysis of those LESS procedures requiring reconstructive techniques (i.e. pyeloplasty, partial nephrectomy, ileal ureteral interposition, ureteroneocystostomy) revealed a much higher rate of complications (13/48; 27.1%) than those procedures that were purely extirpative or ablative in nature (i.e. simple/donor/radical nephrectomy, adrenalectomy or cryoablation) (6/77; 7.8%) (Table 2).

**DISCUSSION**

The above data suggest that LESS procedures can be performed safely in most cases with careful patient selection. Although a large number of laparoscopic cases are performed at the contributing institutions, only a small proportion of the overall laparoscopic experience (13.3%) is with LESS techniques, reflecting the stringent patient selection even by surgeons experienced with CL and LESS surgery. The stringent patient selection is further reinforced by the fact that despite this preliminary experience with LESS only 5.6% of cases were converted to CL and no patient required open conversion. Furthermore, all conversions were elective and only one case was converted for haemorrhage. When looking historically at the early series of laparoscopy in the general surgical literature when laparoscopic cholecystectomy was in its infancy, rates of conversion from laparoscopy to open ranged from 4 to 5% [11–13]. In the urological literature, early rates of conversion from CL to open techniques during planned laparoscopic nephrectomy ranged from 8 to 10% [14–16]. The current rate of conversion reported in this series of LESS in its infancy compares very well with the historical rates described during the infancy of what is now accepted as a standard of care.

As can be seen in Table 1, no one procedure appeared to be more prone to requiring conversion to CL than the others. Although the number of patients remains small, patient age and body mass index also did not appear to be predictive of conversion to CL. Further studies powered for and aimed at identifying risk factors for complications and conversion may allow for the establishment of better patient selection criteria for appropriate LESS surgical candidates.

The overall complication rate of LESS procedures was 15.2% in this series. Unfortunately, perioperative and complication data were not available from the

| Procedure                                | Age (years) | BMI (kg/m²) | EBL (ml) | Operative time (min) | Number of added ports | Types of added ports | Reason for conversion | Complications* |
|------------------------------------------|-------------|-------------|----------|----------------------|-----------------------|----------------------|----------------------|-----------------|
| Case 1 Simple nephrectomy                | 61          | 30.3        | 250      | 300                  | 3                     | One 5-mm, two 12-mm  | Aid in dissection   | DVT requiring anticoagulation for 3 months |
| Case 2 Nephroureterectomy (with open bladder cuff excision) | 75          | 31.6        | 400      | 225                  | 3                     | One 5-mm, two 12-mm  | Control bleeding   | None            |
| Case 3 Renal cyst excision               | 47          | 45.7        | 20       | 165                  | 2                     | Two stab incisions    | Aid in dissection   | None            |
| Case 4 Pyeloplasty                        | 53          | 23.6        | 50       | 240                  | 5                     | Five 5-mm            | Aid in reconstruction | None            |
| Case 5 Pyeloplasty                        | 29          | 35.8        | 50       | 248                  | 2                     | One 5-mm, one 12-mm  | Aid in dissection   | None            |
| Case 6 Partial nephrectomy                | 66          | 29.3        | 500      | 330                  | 2                     | One 5-mm, one 12-mm  | Aid in reconstruction | Blood loss anaemia requiring transfusion of 2 units packed red blood cells |
| Case 7 Ileal ureteral interposition (with extracorporeal ileal harvest via umbilical incision) | 23          | 23.9        | 250      | 420                  | 3                     | Two 2-mm, one 5-mm  | Aid in reconstruction | Urine leak resolved with nephrostomy tube placement/ percutaneous urinoma drainage |

* Superscripts indicate complication grade according to Clavien classification system.
participating institutions for all CL cases so a meaningful comparison with regard to complication rates between LESS and CL procedures was not possible. It should be pointed out, however, that the rate of complications was much higher (27.1%) in the cases requiring reconstructive techniques than those simply requiring extirpative or ablative techniques (7.8%) (Table 2). This is testament to that fact that precise suturing and retraction are significantly more difficult using LESS techniques than with CL, in large part because of the limited instrument triangulation typically required for these complex manoeuvres. Although attempts to overcome this limitation with fixed bent and articulating instruments have provided some improvement [1,7,10,17–20], all but one case of conversion from LESS to CL was converted because help was needed in dissection or reconstruction (Table 1). With the development of improved instrumentation and access devices, and possibly the advent of purpose-designed robotic platforms, as well as the development of new surgical skill sets and training, these limitations may be overcome in the future. At present these limitations remain obstacles toward the safe general dissemination of these techniques.

The nature of the complications seen in the reconstructive and non-reconstructive LESS cases were also significantly different. Although those seen in the non-reconstructive group (deep venous thrombosis, postoperative fever, port-site haematoma, duodenal injury, corneal abrasion and anti-emetic-induced dyskinesia) are disconcerting outcomes, they would be less likely to be directly ascribed to the procedure or the approach in most cases. Conversely, the complications seen in the reconstructive group were more than likely directly attributed to the need for reconstructive techniques during performance of the operation. It should be emphasized that reconstructive LESS procedures represent the most difficult category of cases and should be reserved for only very highly selected patients in the hands of experienced laparoscopic and LESS surgeons.

Urine leak is a known complication after reconstructive urological procedures with reported rates of < 1% after pyeloplasty in contemporary series [21–23]. The rates of two of 35 (5.7%) and one of three seen during pyeloplasty and ileal interposition, respectively, in this series suggest that even in skilled and experienced laparoscopists’ hands, suturing using the LESS platform can be difficult. The urine leak noted after ileal ureteral interposition occurred in a patient who required conversion from LESS to CL to aid in the reconstruction. The number of patients undergoing LESS that had complications is so small that the impact of different techniques on complications is difficult to assess. It should be noted that all three urine leaks in this series resolved with percutaneous intervention and/or stenting and further conservative treatment without the need for re-operation. We recommend that if the angles for precise suturing and reconstruction appear suboptimal, there should be a very low threshold of adding additional ports to facilitate the procedure.

| Table 2 LESS complications – sub-analysis by reconstructive nature of procedure |
|---------------------------------|----------------|-------------------|
| Non-reconstructive procedures   | 77             | 6 (7.8)           |
| Simple nephrectomy              | 37             | 4 (10.8)          |
| Donor nephrectomy               | 18             | 2 (11.1)          |
| Cryoablation of renal tumour    | 12             | 0 (0)             |
| Radical nephrectomy             | 5              | 0 (0)             |
| Renal cyst excision             | 2              | 0 (0)             |
| Nephroureterectomy              | 2              | 0 (0)             |
| Adrenalectomy                   | 1              | 0 (0)             |
| Pyeloplasty                      | 35             | 9 (25.7)          |
| Partial nephrectomy             | 8              | 3 (37.5)          |
| Ileal ureteral interposition    | 3              | 1 (33.3)          |
| Ureteroneocystostomy            | 2              | 0 (0)             |
|                           |              |                   |
| Types of complications*         |                |                   |
| Non-reconstructive procedures   |                |                   |
| Postoperative fever (n = 1)     |                |                   |
| Port-site haematoma (n = 1)     |                |                   |
| Deep venous thrombosis (n = 1)  |                |                   |
| Duodenal injury (n = 1)         |                |                   |
| Corneal abrasion (n = 1)        |                |                   |
| Anti-emetic-induced dyskinesia  |                |                   |
| Urinary tract infection (n = 2) |                |                   |
| Haematuria (n = 1)              |                |                   |
| Upper extremity neuropraxia     |                |                   |
| Postoperative haemorrhage (n = 3)|                |                   |
| two required angiobebolization  |                |                   |
| one developed infected haematoma with MRSA bacteraeemia |          |                   |
| Urine leak (n = 1)              |                |                   |
| Urine leak (n = 2)              |                |                   |
| Postoperative obstruction (n = 3)|                |                   |
| one required stenting with subsequent resolution |          |                   |
| two clinically insignificant radiographic findings in asymptomatic patients |          |                   |
| one required conversion from LESS to CL to aid in the reconstruction |          |                   |
| Urine leak (n = 1)              |                |                   |
| Urine leak (n = 1)              |                |                   |
|* Superscripts indicate complication grade according to Clavien classification system.
CONFLICT OF INTEREST

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Brian H. Irwin: none
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Abbreviations: CL, conventional laparoscopy; LESS, laparoendoscopic single-site surgery; NOTES, Natural Orifice Translumenal Endoscopic Surgery.