Symposium

Is LESS really more?

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ABSTRACT

In the last decade, laparoendoscopic single-site surgery (LESS) has been touted to be the part of the 'evolution' of minimally invasive surgery. The hope is that reduced access points will ultimately decrease pain, morbidity, convalescence, and improve cosmesis. However, what is unique about LESS is that while laparoscopic literature sought to demonstrate superiority of the technique over that of open surgery, the publications on LESS generally seem to seek to demonstrate *equivalence* with laparoscopy, with the major focus being on cosmesis. Unfortunately, even in that regard the objective cosmesis data is lacking. Furthermore, patients rate cosmesis the least important of all factors. LESS has also been associated with increased risk of complication, increased surgical cost, and longer operative times. In the current review, an objective assessment of the literature will be used for comparison between current standard laparoscopic techniques and LESS with the hopes of answering the question: is LESS really more?

Key words: Comparative series of LESS vs. laparoscopy, comparison between LESS and standard laparoscopy, laparoendoscopic single-site surgery, LESS, LESS and cosmesis, LESS and cost, LESS and surgical risk, multiport laparoscopy

INTRODUCTION

After Clayman, Kavoussi and colleagues performed the first laparoscopic radical nephrectomy in 1990, there was tremendous enthusiasm engendered, and numerous reports demonstrated the safety, efficacy and minimally invasive advantages of laparoscopic renal surgery.[1] Soon thereafter, case reports became series, and series became comparative to the open approach. In the vast majority of these studies there was proven benefit in performing the procedures laparoscopically. Using objective metrics, convalescence, pain, bleeding, length of hospital stay and cosmesis were all demonstrated to be decreased or improved when a surgery was performed laparoscopically compared to an open approach. Most importantly, oncological efficacy was demonstrated to be equivalent to open surgery for both radical and partial nephrectomy.

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In the last decade, Natural Orifice Transluminal Surgery (NOTES) and Laparoendoscopic Single-Site Surgery (LESS) have been touted to be the part of the 'evolution' of minimally invasive surgery. Interestingly, the term evolution has been used almost routinely (in both manuscripts and lectures) when describing these novel access strategies. It is certainly a sign of the intrinsic bias demonstrated to date that most LESS and NOTES' investigators use the term evolution without care. Indeed, evolution implies objective testing of a novelty. This testing may be a survival advantage in the classic meaning of the term, or continued practice and development of an access approach when it comes to novel surgical techniques. With regards to surgery, in consideration of the current existing body of literature, the successful evolution to LESS and NOTES is far from ordained.

Both LESS and NOTES have a shared commonality in that the underlying concept is a reduction in the number of access points. The hope is that reduced access points will ultimately decrease pain, morbidity, convalescence, and improve cosmesis.[2,3] While the interest in NOTES has waned in recent years, LESS has been propelled to the forefront of minimally invasive literature. However, what is unique about LESS is that while laparoscopic literature sought to demonstrate superiority of the technique over that of open surgery, the publications on LESS generally seem to seek to demonstrate equivalence with laparoscopy, with the major focus being on cosmesis. In the current review, an objective assessment of the literature will be used for comparison between current standard laparoscopic

techniques and LESS with the hopes of answering the question: is LESS really more?

The surgical mission

The first and foremost factor when performing surgery is curing the pathology.[4] When approach and technique are considered, the most important question that mandates answer is will the pathology be appropriately treated with the absolute best safety profile possible. Secondary to surgical efficacy is pain, convalescence, length of hospital stay and reduced complication rates. Third, and the least important is surgical cosmesis. Indeed, the term 'minimally invasive surgery' has often been bastardized to imply a specific access strategy such as laparoscopy, robotic surgery or endoscopy. The true definition of minimally invasive surgery may have been created by Sir William Osler over a century ago when he said that, "Diseases that harm call for treatments that harm less". We need to continually fight to redefine the term with solid data.

The urological laparoscopic revolution that began 20 years ago followed these mandates, which cemented its role in urology. For many procedures, efficacy was demonstrated to be equivalent to open surgery, and the secondary benefits of an adequate reduction in pain, convalescence and hospital stay was clearly demonstrated to be an adjunct to efficacy. In order for LESS to be considered seriously as a part of our technical armamentarium, there should be a clear demonstration that LESS is equally safe and efficacious to comparative techniques with the additional benefits of decreased pain, convalescence time, and length of hospital stay. Demonstrating that the benefit of LESS is solely improved cosmesis while jeopardizing any other factor is wholly inadequate.

Key Message: Demonstrating that the benefit of LESS is solely improved cosmesis while jeopardizing outcome is wholly inadequate.

Review of benefits

As mentioned previously, laparoscopic surgery became a standard surgical procedure based upon its clear benefit over that of open surgery. By comparison, LESS has not been successfully demonstrated to be an improvement upon current techniques. To that point, Wolf presented the following evidence at the 2011 American Urological Association (AUA) Annual Meeting, upon which we have expanded.[5] There have been 14 published comparative series comparing standard laparoscopy (SL) and LESS [Table 1] and 17 abstracts presented at either the 2010 or 2011 World Congress of Endourology or the 2011 AUA Meeting [Table 2] that evaluate visual analog pain scale (VAPS) results, objective morphine equivalent usage (MSO4) and length of hospital stay (LOS).[6-37] When reviewing Tables 1 and 2, "Yes" means that the report demonstrated that LESS displayed benefit over SL and "No" means that it did not. It is clear that there are far more "No" than "Yes" in both tables. In fact, in the published comparative trials, of 33 measured parameters only 8 (24.2%) demonstrated that LESS was superior to standard laparoscopic techniques. In the recently presented abstracts, only 12/33 parameters (36%) showed that LESS was beneficial. Overall, only 42% (13/31) of all recent comparative abstracts and published

Table 1: Comparative laparoendoscopic single-site surgery vs. SL Series

Comparative LESS vs. SL Series[14]			
Author, Year	VAPS	MSO4	LOS
Raman, 2009[7]		No	No
Tracy, 2009[8]		No	No
White, 2009[9]	Yes		No
White, 2009[10]	No		No
Jeong, 2009[11]		Yes	No
Andonian, 2010[12]	No	No	No
Raybourn, 2010[13]		No	No
Tugcu, 2010[14]	Yes	Yes	No
Canes, 2010[15]	No	No	No
Park, 2010[16]	Yes		Yes
Stein, 2011[17]	No	No	No
Kurien, 2018[18]	Yes	No	Yes
Seo, 2011[19]			No
Lunsford, 2011[20]	No	No	No

Yes – LESS has significant benefit; No – No benefit over SL; VAPS = Visual analog pain scale; MSO4 = Morphine equivalents; LOS = Length of stay

Table 2: Comparative abstracts from WCE 2010 and 2011 and AUA Annual Meeting 2011

	VAPS	MSO4	LOS
Klingler, WCE 2010[21]	No	No	
Seo, WCE 2010[22]			No
Lee, WCE 2010[23]	No	No	No
Huh, WCE 2010[24]			Yes
Rais-Bahrami, WCE 2010[25]		No	No
Ju, WCE 2010[26]	No		No
Ju WCE 2010[27]	No		
Hsueh, WCE 2010[28]		No	Yes
Bazzi, WCE 2010[29]		Yes	Yes
Bazzi, WCE 2010[30]			No
Zhang, WCE 2010[31]		Yes	No
White, AUA 2011[32]	No	Yes	Yes
Ramasamy, AUA 2011[33]		No	Yes
Woldrich WCE 2011[34]	Yes	Yes	
Choi, WCE 2011[35]			No
Park, WCE 2011[36]	No	No	No
Kang, WCE 2011[37]	Yes	Yes	No

Yes – LESS has significant benefit over SL; No– No benefit over SL; VAPS = Visual analog pain scale; MSO4 = Morphine equivalents; LOS = Length of stay

series demonstrated any benefit of LESS over that of standard laparoscopic procedures.

Key Message: As regards VAPS, analgesic use, and LOS, LESS has demonstrated no benefit over current techniques

As a basis of comparison and in order to interpret the significance of these data, it is important to look at the early comparative series between SL and open surgeries [Table 3]. In 13 early comparative series published prior to 2000 that paired SL versus open surgery 100% demonstrated that SL was superior. Moreover, of the 31 individually measured parameters comprising MSO4, LOS and convalescence, all 31 (100%) demonstrated that SL was superior to open surgery. From this it is clear why SL became popular so quickly and by comparison, why LESS has been steeped in controversy.

Cosmesis

As previously demonstrated, as regards postoperative pain, analgesic use, and hospital stay LESS has demonstrated no benefit over SL. However, it has been made abundantly clear by all LESS proponents that the major benefit of LESS is not lower blood loss, surgical outcomes, convalescence, or any other major metric, but actually cosmesis. As such, it would be of value to explore the data that support the possible superior cosmesis associated with LESS surgery.

Of the 13 publications that compare LESS with SL and report on cosmesis, all but 1 suggest that cosmesis is superior in LESS.[7-20] However, when the comparative series are reviewed, only two actually provide data on cosmesis, both in the form of self-reported questionnaires [Table 4]. Of those two, one publication demonstrated improved cosmesis, while the other refutes the finding.[15,18] Put in a different way, 92.3% (12/13) of all published literature that compares LESS vs. SL concluded that the cosmetic outcome after LESS is superior to SL, yet only 7.7% (1/13) provided data to support this conclusion. Furthermore, of the two publications that included self-reported questionnaires, one demonstrated that LESS had cosmetic benefit, and the other that LESS did not. In the current climate of evidence-based medicine, where treatment paradigms are rarely affected without meta-analyses and prospective-randomized trials, it is disheartening to find such a bold conclusion supported by such a paucity of data. At best, based on the evidence, it can be concluded that the cosmetic benefit of LESS is questionable.

Key Message: Only 1 of 13 (7.7%) comparative series between LESS and SL provide data to support the conclusion that LESS offers improved cosmesis over that of SL

a. Author mentioned anecdotal suggestion of satisfactory cosmesis
b. Self-reported patient questionnaire

As cosmesis is the backbone of the LESS argument, it is important to fully dissect the data that is available in the only two comparative series that actually present it. In the study by Canes and colleagues, 17 LESS donor nephrectomies (LESS-DN) were compared to 17 matched SL-DN.[15] There was no difference in the operative time, blood loss, length of hospital stay, complications, or morphine equivalents for LESS vs. SL. For the LESS group there was an increase in warm ischemia time but a decrease in days on oral pills, time to return to work and days to 100% recovery. On a self-reported questionnaire, there was no difference between the LESS and SL groups when evaluating overall experience

Table 3: Early (prior to 2000) Comparative Series for Standard Laparoscopy vs. Open Surgery

Early Comparative Series for Standard Laparoscopy vs. Open Surgery

	MSO4	LOS	Convalescence
Kerbl, 1994[38]	Yes	Yes	Yes
Eden, 1994[39]	Yes	Yes	
Parra, 1995[40]	Yes	Yes	Yes
Doublet, 1996[41]		Yes	
McDougall, 1996[42]	Yes	Yes	Yes
Fornara, 1997[43]	Yes	Yes	Yes
Ratner, 1997[44]	Yes	Yes	Yes
Flowers, 1997[45]	Yes	Yes	Yes
Rassweiler, 1998[46]	Yes	Yes	
Doehn, 1998[47]	Yes	Yes	Yes
Keeley, 1998[48]		Yes	
Ono, 1999[49]	Yes		Yes
Abbou, 1999[50]	Yes	Yes	

Yes – SL has significant benefit over open surgery; No – No benefit over open surgery; MSO4 = Morphine equivalents; LOS = Length of stay

Table 4: Comparative LESS vs. SL Series: Cosmesis

Comparative LESS vs. SL Series: Cosmesis

Author, Year	Cosmesis	Supporting Data
Raman, 2009[7]	Yes	No
Tracy, 2009[8]	Yes	No
White, 2009[9]	Yes	No
White, 2009[10]	Yes	No
Jeong, 2009[11]	Yes	No
Andonian, 2010[12]	Yes	No
Raybourn, 2010[13]	Yes	No
Tugcu, 2010[14]	Yes	No
Canes, 2010[15]	Yes	Yes
Park, 2010[16]	Yes	No
Stein, 2011[17]	Yes	No
Kurien, 2018[18]	No	Yes
Seo, 2011[19]	Yes	No
Lunsford, 2011[20]	-	-

Yes claims cosmetic benefit of LESS over SL (left column) or presents cosmesis data (right column); No – claims no cosmetic benefit of LESS over SL (left column) or presents no cosmesis data (right column)

(9.5 vs. 8.5, *P*=0.053), however, on patient-reported scar satisfaction, LESS rated higher than SL (9.7 vs. 7.7, *P*= 0.003).

In the second study that included cosmetic outcome data, Kurien and colleagues prospectively randomized 50 donor nephrectomy patients to either SL or LESS.[18] Operative times, total ischemia time, complication rates, analgesic use and estimated glomerular filtration rates at one year were comparable for both groups. In the LESS group, the surgeon rated 4 of 10 major steps significantly more difficult and the warm ischemia time was also significantly longer (7.15 vs. 5.11 min, *P*<0.0001). Postoperative VAPS were comparable in the first 48 h after surgery (3.84 vs. 3.68, *P*=0.33), however after 48 h, there was less pain in the LESS group (2.08 vs. 1.24, *P*=0.0004). The donors' postoperative physical quality of life scores, mental quality of life scores, body image scores, and cosmetic scores were all comparable for both groups.

In the two studies that provide cosmesis data, both demonstrated a high overall experience satisfaction rate among donors, while only one demonstrated that LESS rated better than SL in scar satisfaction. However, to compare data quality, the Canes study is Level II data (case-control) while the Kurien study is larger and is a randomized prospective trial (Level I data). It can therefore be concluded that the sole factor (cosmetic outcome) that LESS boasts as being superior to SL is based on Level II data (case control series) from a single study in which patients in both groups were comparably satisfied with their overall outcome and the difference in cosmetic scar satisfaction was marginal. Furthermore, Level 1 data from a larger randomized prospective trial refutes the findings by demonstrating no difference in quality of life, body image, or cosmetic questionnaires.

Despite the lack of objective support, LESS proponents continue to push the improved cosmetic outcomes of LESS. Therefore, the next logical question that should be asked is what is the importance of cosmesis in patients faced with the prospect of surgery? In a recent study by Lucas and associates, 79 patients undergoing surgery for either malignancy (n=53), donor nephrectomy (n=15), or for benign reasons (n=9) were asked to rate the importance of pain, recovery time, treatment success, scars and risk of complications on a 5-point Likert scale.[51] The patients were mostly surgically naïve (n=46), however 10 had undergone a prior SL procedure and 20 an open procedure. Patients rated success (4.71/5) as the most important factor followed by risk of complications (4.22/5), convalescence (3.65/5), postoperative pain (3.43/5), cost (2.68/5) and finally cosmesis (2.22/5). Overall, cosmesis was rated significantly less important (*P*<0.005) than all other factors except cost. Although patients <50 years of age found cosmesis more important than patients ≥50 years of age, the score was still very low and the difference very marginal (2.59 vs. 2.02, respectively, *P*=0.027).

In a related study, 152 patients were polled on their acceptance of LESS and NOTES procedures.[52] Overall, improved cosmesis was not considered a priority and patients were willing to undergo LESS or NOTES only if it incurred no more risk, recovery time, pain, operative time or cost. Taking all these data together, it can be stated that the cosmetic benefits of LESS are poorly supported and are at best, questionable. Furthermore, assuming that in fact there is a cosmetic benefit, patients deem cosmesis the least important of all surgical factors.

Key Message: Level I data demonstrates that surgical cosmesis is comparable between LESS and SL. Furthermore, patients rate cosmesis the least important of all surgical factors.

Surgical outcomes

In the current argument, we have established that the only *potential* benefit of LESS is cosmesis, a claim based almost exclusively on author estimation with little-to-no supporting data. Furthermore, we have also established that in the court of public opinion, surgical cure with a reduced risk of complication is far more important than cosmesis. However, it can be argued that if all other factors between LESS and SL are equal, the potential for improved cosmesis is promising. Therefore, the logical next question is, are all other factors actually equal? Referring back to the Lucas study, surgical success was rated the most important factor among patients undergoing surgery. Due to the lack of long-term data on LESS, commentary on this metric is not currently possible. However, several studies do address the second most important factor, risk of complications.

Tracy and associates recently evaluated the utility of LESS for pyeloplasty, a procedure that does not require incision extension for specimen removal.[8] The standard lap group was matched to the LESS group primarily by age and laterality, and when possible, sex. Suturing in the LESS group was facilitated by an additional 5-mm trocar placed at the future drain site. There were no differences between the groups (LESS vs. SL) with regards to hospital stay (77 vs. 74 h, *P*=0.69), morphine equivalents (34 vs. 38, *P*=0.93), or minor complications (14.3% vs. 14.3%, *P*=1). There was, however, a decreased operative time (202 min vs. 257 min, *P*<0.001) and estimated blood loss EBL (35 mL vs. 85 mL, *P*=0.002) for the LESS group. The authors stipulate, however, that the difference in EBL is likely related to differences in reporting and is unlikely accurate and that the difference in operative times was less likely associated with the surgical technique, and more likely due to the method of stent placement. In the LESS group and in 25% of the laparoscopic group, the stent was placed antegrade through a trocar, while in the remaining 75% of the laparoscopic group, the stent was cystoscopically placed in a retrograde fashion, which requires patient repositioning. In that study, it is the difference in major complications between the LESS and SL groups that is most alarming. There was a trend

towards an over twofold higher major complication rate in the LESS group (21.4% vs. 10%, *P*=0.31). This finding takes on further importance when the way that the patients were chosen is considered. This study was performed in a retrospective manner, suggesting that only the ideal patients were likely chosen for LESS. The authors subsequently matched the SL group to the LESS group, meaning that the entire cohort comprised ideal pyeloplasty patients; case in point—the cohort's body mass index (BMI) was 24. Therefore, the twofold increase in the complication rate among LESS patients occurred in the ideal pyeloplasty patient. Extrapolating, the complication rate would likely climb exponentially as patients stray further from the ideal.

In a second study, the NOTES Working Group retrospectively reviewed a multicentre experience with LESS.[53] Included in the study were 125 patients representing 13.3% of the total number of laparoscopic procedures performed by the group. Overall, complications occurred in 15.2% of patients undergoing LESS. Procedures were divided into non-reconstructive (n=77) and reconstructive (n=48). There were 6 complications (7.8%) in the non-reconstructive group and 13 complications (27.1%) in the reconstructive group, including a complication rate of 37.5% (3/8) for partial nephrectomy, 33.3% (1/3) for ileal ureteral interposition, and 25.7% (9/35) for pyeloplasty. Taken alone, the complication rates are significantly higher than what would be expected. However, it is again important to realize that the cohort represents a carefully selected, ideal group of patients, as evidenced by the fact that the entire cohort represents only 13.3% of the laparoscopic experience of the same multicenter group. With this in mind, the exceedingly high complication rate in this ideal cohort is alarming. More to the point, almost half of the complications (6/13) were major complications (Clavien III). The one thing that can be gleamed from the cosmesis data as it relates to complications is that cosmesis is far less important than the risk of complications and that patients in general do not want to sacrifice outcomes for improved cosmesis. However, based on these studies, LESS clearly increases the major complication rate, which is the second most important factor patients consider when undergoing surgery.

The next two Lucas study factors, convalescence and postoperative pain, are equivocal between the LESS and SL groups, but what about the fourth factor, cost?

In a recent study by Lunsford and colleagues 30 patients undergoing either LESS (n=10) or SL (n=20) were evaluated for peri-operative outcomes along with a cost analysis.[20] BMI was significantly lower in the LESS group (24 vs. 27.1, *P*=0.005), but all other demographics including age, sex, previous abdominal surgeries, and number of renal arteries and veins were comparable. Peri-operative metrics including EBL, LOS, OR Time, VAPS, and MSO4 were also equivalent between the groups. However, the authors found that the LESS group incurred a 10% greater variable direct cost. The authors concluded that with no proven benefit to the patient, including cosmesis, an increase in cost for laparoscopic donor nephrectomies could only be justified if it translated into more willing donors, which would be difficult to demonstrate. These data were supported by earlier findings by Tugcu and colleagues, who found that LESS was more expensive, ranging from $1,600 to $2,000 compared to SL which ranged from $450 to $600.[14]

What about operative time? White and colleagues compared LESS retroperitoneal cryoablation (n=5) and SL retroperitoneal cryoablation (n=5).[10] In a similar methodology to that of Tracy, the SL group was subsequently matched to the LESS group. The groups were matched with respect to age, BMI, and tumor size. There were no differences between LESS and SL groups as regards blood loss (75 vs. 100 mL, *P*=0.552), or hospital stay (1.4 vs. 1.8 days, *P*=0.242), however, operative time was longer for the LESS group (174 vs. 120 min, *P*<0.001). The time difference between the LESS and SL group represents a 45% increase in operative time, and this in the ideally selected patient. Again, extrapolating, it can be concluded that operative time will likely increase as patients deviate from the ideal.

Key Message: LESS is associated with increased risk, cost and operative time compared to SL.

CONCLUSION

Currently, there is no clearly demonstrated benefit of LESS. Furthermore, the claim that LESS provides improved cosmesis is poorly supported and had mixed results in the available data. In patient polls, surgical success, risk, pain, convalescence and cost all ranked higher than cosmesis. While surgical success cannot be evaluated due to lack of data, risk of complications and cost is higher for LESS than SL, with no added benefit in pain or convalescence. Furthermore, the increased risk and cost is in exchange for questionably improved cosmesis, which ranked last in importance among surgical patients. With these data in mind, the only plausible conclusion is that LESS is definitely not more.

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