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The Effect of Product Safety Courses on the Adoption and Outcomes of LESS Surgery

Paul G. Toomey, MD, Sharona B. Ross, MD, Edward Choung, MD, Natalie Donn, MS, Michelle Vice, BS, Kenneth Luberice, MS, Michael Albrink, MD, Alexander S. Rosemurgy, MD

ABSTRACT

Background and Objectives: As technology in surgery evolves, the medical instrument industry is inevitability involved in promoting the use and appropriate (ie, effective and safe) application of its products. This study was undertaken to evaluate industry-supported product safety courses in laparoendoscopic single-site (LESS) surgery, by using the metrics of surgeons' adoption of the technique, safety of the procedure, and surgeons' perception of the surgery.

Methods: LESS surgery courses that involved didactic lectures, operative videos, operation observation, collaborative learning, and simulation, were attended by 226 surgeons. With Florida Hospital Tampa Institutional Review Board approval, the surgeons were queried before and immediately after the course, to assess their attitudes toward LESS surgery. Then, well after the course, the surgeons were contacted, repeatedly if necessary, to complete questionnaires.

Results: Before the course, 82% of the surgeons undertook more than 10 laparoscopic operations per month. Immediately after the course, 86% were confident that they were prepared to perform LESS surgery. Months after the course, 77% of the respondents had adopted LESS surgery, primarily cholecystectomy; 59% had added 1 or more trocars in 0–20% of their procedures; and 73% held the opinion that operating room observation was the most helpful learning experience. Complications with LESS surgery were noted 12% of the time. Advantages of the technique were better cosmesis (58%) and patient satisfaction (38%). Disadvantages included risk of complications (37%) and higher technical demand (25%). Seventy-eight percent viewed LESS surgery as an advancement in surgical technique.

Conclusion: In multifaceted product safety courses, operating room observation is thought to provide the most helpful instruction for those wanting to undertake LESS surgery. The procedure has been safely adopted by surgeons who frequently perform laparoscopies. The tradeoff is in performing a more difficult technique to obtain better cosmesis for the patient. We must continue to conduct critical evaluations of product safety courses for the introduction of new technology in surgery.

Key Words: Laparoendoscopic single-site surgery, Product safety courses, Single-incision laparoscopic surgery

INTRODUCTION

The combination of refinements in laparoscopic instruments and ever-growing surgical experience with laparoscopy have led surgeons to conceptualize and pursue laparoscopic surgery through a single incision at the umbilicus. This approach has many names and many acronyms. Our choice of name, laparoendoscopic single-site (LESS) surgery, has been introduced into the common domain, and its use cannot be restricted by patent or trademark. Among the other names that have been given to this approach are the trademarked names, Single Incision Laparoscopic Surgery (SILS) (Covidien, Mansfield, Massachusetts) and Single Port Access (SPA) surgery (Drexel University College of Medicine, Philadelphia, Pennsylvania). LESS surgery has myriad applications. It is a natural progression of minimally invasive surgery, and more specifically, of laparoscopic surgery. As minimally invasive surgical techniques evolve, particularly for single-port surgery, the medical equipment industry inevitably will promote the use and appropriate (ie, effective and safe) application of their products, particularly the new ones.

LESS surgery requires advanced skills and techniques on the part of the surgeon, some of which are generally not needed when they perform operations by conventional laparoscopy. The technique involves a learning curve and

Florida Hospital Tampa, Tampa, Florida (all authors).

Disclosures: Drs. Ross and Rosemurgy have received honoraria from Covidien and Olympus for speaking engagements.

Address correspondence to: Alexander S. Rosemurgy, MD, Florida Hospital Tampa, 3000 E. Fletcher Avenue, Suite 310, Tampa, FL 33613. Telephone: 813- 615-7030, Fax: 813-615-8350, E-mail: arosemurgy@hotmail.com

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the application of additional instrumentation to facilitate adaptation and proficiency.[1] Given these needs, the surgical instrument industry has provided product safety courses to promote the appropriate use of their products. Furthermore, the collaboration between surgeons and the industry is, at some level, essential for medical innovation and progress.[2–6] This collaboration is of immense benefit to the patient; however, it is important that surgeons carefully examine the dynamic relationship between the health care provider and the industry. Are the goals of the industry congruent with those of health care providers? Does the industry promote patient welfare and safety? Surgeons must critically evaluate the introduction and adoption of new technology in surgery through industry-sponsored product safety courses. This study was undertaken to evaluate these industry-sponsored product safety courses in LESS surgery by using metrics of surgeons' perceptions of the technique, their adoption of the procedure, and product and procedure safety. Our hypothesis in undertaking this study was that the product safety courses would promote the adoption and safe application of LESS surgery and ensure surgeons' proficiency.

METHODS

Courses

Beginning in November 2008 and continuing through November 2011, the Florida Hospital Tampa hosted training courses, sponsored by Olympus (Olympus Surgical and Industrial American, Inc., Center Valley, Pennsylvania), Stryker (Stryker, Kalamazoo, Michigan), and Covidien (Covidien, Inc., Mansfield, Massachusetts), that offered surgeons product safety instruction for LESS surgery. These courses provided didactic lectures, video presentations of LESS operations, instrumentation and "toolbox" familiarization, operating room observations, simulation experiences, close interaction with faculty, and collaborative learning among participating surgeons.

The participants in this study included 226 surgeons who attended the LESS surgery courses. Each course was attended by approximately 6–12 surgeons and lasted 1 evening and the next day until 5 PM. The didactic lectures covered all aspects of LESS surgery from instrumentation and access through wound-closure techniques. The video presentations were edited videos of LESS procedures focusing on foregut operations, including cholecystectomy, fundoplication, Heller myotomy, adrenalectomy, gastric resection, distal pancreatectomy, splenectomy, and bowel surgery, including colon resection. Observation of the procedures required learners to be present in the operating room during the operations. Instrument familiarization was hands-on, with instruction by teaching surgeons along with observation and input from industry representatives. Simulation was conducted in animate liver and gallbladder specimens with teaching surgeon supervision. Cholecystectomy, including suturing and knot tying, were reviewed until proficiency was achieved as subjectively judged by a teaching surgeon. Each surgeon had access to multiple specimens, to ensure a satisfactory simulation experience. Company representatives were present during all phases of the educational experiences and courses. Teaching–learning surgeon interaction was encouraged and sought. Specific questions to assess surgeons' perception of LESS surgery were developed especially for use in this study.

Measures

With local institutional review board approval, the surgeons were queried before and immediately after the courses, to assess their attitudes toward the LESS technique, and months later were contacted by mail, phone, and the Internet to determine their adaptation and safety experiences with LESS surgery. Before the start of the product safety courses, the surgeons were queried about their overall experiences with laparoscopic surgery, such as the approximate number of laparoscopic operations that they were undertaking per month (Appendix 1). The participants were also asked questions regarding their activity and experience with laparoscopy, perception of LESS surgery, operative variety, number of LESS operations attempted and completed, complications associated with the procedure, and rankings of attributes and undesirable components of the surgery. Utilizing a Likert scale, 1 (Most Helpful) to 10 (Least Helpful), participants were ask to list and score the most helpful part of their learning experience. Participants were also asked to rank the desirable and undesirable attributes of LESS surgery in order of importance, 1 (Most Important) to 10 (Least Important). Six to eighteen months after attending the course, the surgeons were contacted, often repeatedly, to again complete the questionnaires.

Research Design and Statistical Analyses

A database was compiled and stored on Excel spreadsheets (Microsoft Corp., Redmond, Washington). Statistical analyses were performed with the Mann-Whitney U test and Wilcoxon matched-pairs test, using Instat, version 3.06, and Prism 5 (GraphPad Software Inc., San Diego, California). Data were also subsequently entered into the statistical program SPSS 17.0 (IBM Corporation, Armonk,

New York). Frequency data were evaluated, and Pearson correlations were computed to determine whether there are significant relationships among indicators of LESS surgery perception (eg, risk, difficulty, and cosmesis). Statistical significance was accepted with 95% confidence. Unless otherwise stated, data are presented as the median (mean ± SD).

RESULTS

The product safety courses on LESS surgery were attended by 226 surgeons over the span of 3 years, from November 2008 through November 2011. Months later, surgeon attendees were contacted to determine attitudes about the adoption and the safety of LESS surgery, with an average follow-up time after the course of 18 months: 113 (50%) surgeons responded to the survey; 88 (39%) did not respond, despite repeated contacts; and 25 (11%) could not be located and were lost to follow-up, despite repeated efforts.

Before the courses, 82% of the surgeons performed more than 10 laparoscopic operations per month: median, 20 (mean, 24 ± 13.6). When asked about their LESS experiences, the total number of LESS operations attempted before the surgeon attended the course were 13 (46 ± 3.3), and LESS operations completed were 15 (36 ± 5.9). Reasons for attending the product safety course were, in order of frequency, to learn an advanced technique in laparoscopic surgery, to avoid being "left behind" by those who adopted the procedure early, and to learn more about LESS surgery to decide whether it would be suitable for them. A few attended in response to encouragement from industry representatives.

In completing the Post-Event Evaluation questionnaire (Appendix 2) after the product safety course, 91% of participants thought that the course was sufficient to warrant the use of LESS surgery, and 86% believed that they were prepared to use the technique. Regarding the use of LESS surgery after the course, the later (18-month) follow-up found that 63% of the respondents had performed a cholecystectomy, 11% had undertaken an appendectomy, 9% had placed a gastric band, 8% had performed a colectomy, and 3% had repaired an inguinal hernia. The reported number of LESS operations performed were cholecystectomy, 15 (33 ± 48.5); appendectomy, 5 (11 ± 15.7); gastric band, 7 (46 ± 103.2); colectomy, 7 (14 ± 17.9), and hernia repair, 3 (11 ± 15.2).

Participants were queried about the most helpful part of the learning experience on the 1–10 Likert scale, with 1 being most helpful and 10 being least helpful: 73% thought that the operating room observation was the most helpful. In order of most to least helpful, operating room observation were scored as 2, operative videos and question-and-answer sessions as 5, didactic teaching as 6, and collaborative learning as 7. They thought that the simulation experience was the least helpful, giving it a score of 8. Similarly, the participants were queried about their impressions of LESS surgery. They believed that its most important attribute was better cosmesis (Likert score, 2). They reported patient satisfaction to be the second most important attribute (score, 4), followed by surgeon satisfaction (score, 6). They ranked "less pain" and "quicker return to activities" as the least important aspects of the LESS technique (score, 8).

The survey also asked participants to rank undesirable components of LESS surgery, with a Likert score of 1 being extremely undesirable and 10 being least undesirable. The three most undesirable components were that the operations were more technically difficult, operating room time was increased, and risk of complication was higher (score, 4 for all). The respondents noted that the most frequent complications were umbilical or incisional hernia, followed by umbilical wound infections and common bile duct injury, although the reports of these events were all anecdotal. With regard to adding trocars at incisions distant from the umbilicus, 29% of the surgeons responded that they had never used additional trocars, 59% reported that they had in 1–20% of the LESS operations, and 3% responded that they had in 100% of the operations. Last, when participating surgeons were asked whether patients had sought their services because they provide LESS surgery, 38% responded that patients had and 62% that they had not.

DISCUSSION

Minimally invasive surgery is increasingly the focus of general surgery for patients and surgeons. In its evolving form, minimally invasive surgery is here to stay, and patients are evermore seeking it. Advances in techniques in minimally invasive laparoscopic surgery have been relentless, such as LESS surgery, which was first performed in about 2007. The recent interest and widespread implementation of LESS surgery stem from many factors, including advancements in commercially available access port technology, education, simulation, patient interest, application in a variety of operations, and development of standard approaches.[7–16] LESS surgery is undertaken through a single incision or single port entry, almost always at the umbilicus, and has many applications in

surgery. It offers improved cosmesis, and arguably, decreased postoperative pain. However, it poses technical challenges not encountered in conventional laparoscopy, and there is a learning curve associated with it.[1] Many medical instrument manufacturers have supported and promoted product safety courses to train surgeons and stimulate the use of LESS surgery, albeit with motives that extend beyond altruism. They promote interest in LESS surgery to patients and surgeons, application of their products, and use of their instruments. Thus, the industry is a major stakeholder, and our goal was to evaluate the effect of product safety courses on adoption and outcomes of LESS surgery, as well as to make a critical evaluation of the collaboration between surgeons and the medical device industry.[2] Herein, we report that such product safety courses leave a favorable opinion of LESS surgery, are associated with a high adoption rate, and are apparently safe.

The product safety courses on LESS surgery sponsored by Olympus, Covidien, and Stryker on LESS surgery were offered to practicing surgeons. The participants were general surgeons who performed laparoscopic procedures in a variety of surgical subspecialties (eg, bariatric surgery). Before the course, most surgeons had been performing, on average, more than 20 laparoscopic operations per month and had had previous exposure to LESS operations. It seems, in retrospect, that some of the surgeons were not particularly adept at or interested in laparoscopic surgery; they should not have been among those invited to attend the courses. In the future we will limit the invitations to surgeons with significant laparoscopic skills (eg, cholecystectomy and, preferably, advanced laparoscopic operations) who are interested in professional growth, if we are able to discern these traits. After the completion of the product safety course, the most of the participants who responded thought that the course was sufficient to promote the use of LESS surgery and were confident that they were prepared to use the technique. Months later, approximately three quarters of the questionnaire respondents had adopted LESS surgery—primarily, LESS cholecystectomy, with LESS appendectomy a distant second. Most surgeons had used an additional trocar distant from the umbilicus in less than 20% of their surgeries. Typical complications associated with LESS surgery were infrequent but varied widely, as expected, with umbilical hernia being the most common. Notably, half the surgeons responded to the questionnaire sent to them months after the course.

Most surgeons regarded operating room observation as the most helpful learning experience, followed by operative videos and question-and-answer sessions. That the simulation experience and collaborative learning were viewed as least helpful was an unexpected outcome. We were of the opinion that we had allocated sufficient time to complete useful tasks. The scores assigned to the simulation experience raise many questions, in that we thought that it would be the most valued offering. To the contrary, it was the least valued. Hands-on instrumentation was plentiful during the simulation experience; the model is well established in student, resident, and surgeon training; and instruction was readily available, with instructors literally hovering over the trainees.

The participants reported that the most important attributes of LESS surgery were better cosmesis, along with patient and surgeon satisfaction, but decreased postoperative pain was not included. They ranked as the most undesirable aspects of LESS surgery the risk of complications, such as injury to a bile duct and bleeding and the more technically demanding aspects of the procedure. Obviously, LESS cholecystectomy and LESS procedures in general have learning curves associated with them. We believe that performance of LESS surgery quickly becomes easier, with a learning curve that is definable, safe, and short. Finally, when the participating surgeons were asked about patients' demand for their service because of the availability of the LESS procedure, only about one-third responded that patients sought their services because they offered the technique. The medical instrument manufacturers, more than patients, may be "driving the bus." Patient interests, concerns, goals, and wishes continue to be defined and, undoubtedly, to evolve.[14,15]

After completion of the product safety course, most surgeons thought that the LESS technique was an advancement in minimally invasive surgery. They viewed the sessions as beneficial to surgeons, in that the courses encouraged adoption of the technique, promoted positive perceptions, and inspired confidence. According to the survey, most of the surgeons who undertook the course now engage in a wide spectrum of LESS operations with infrequent complications. The surgeons generally were very positive about using the technique after the course and implemented it in their practice.

A great deal of progress has been made in LESS surgery. A learning curve for LESS cholecystectomy has been defined.[1] Postgraduate education has been thoughtfully evaluated,[3,12] simulation has been studied,[7,11] and concepts of LESS surgery have been considered and recon-

sidered.[8,9,13,16] A consortium has laid the framework for standardizing results for LESS cholecystectomy to shorten the learning curve.[10,16]

However, the industry's return on investment is unclear. As mentioned earlier, their role is not simply altruistic. The companies' motivation is to sell more instruments, devices, and products, and they are therefore stakeholders in advancing the safe use of the technique. Without their interest, however, progress in surgical technology would be impeded. Arguably, the proliferation of laparoscopy would have been much slower without the industry's involvement in education, research, development, and patient and public education. Productive relationships between the industry and physicians promote communication and innovations that result in the development of devices of immense benefit to the patient. The need for product refinement and support, education, and testing make it necessary for close collaboration between surgeons and the industry. This overlapping educational process and collaborative relationship can lead to conflicts of interest for physicians and incongruent goals among patients, health care providers, and the industry.[13–15] Roles must continue to be defined.[9,12,14] We must continue to critically evaluate the introduction and adoption of new technologies in surgery through product safety courses.

References:

1. Hernandez J, Ross S, Morton C, et al. The learning curve of laparoendoscopic single-site (LESS) cholecystectomy: definable, short, and safe. *J Am Coll Surg*. 2010;211:652–657.

2. Nakayama DK. In defense of industry-physician relationships. *Am Surg*. 2010;76:987–994.

3. Mirheydar H, Jones M, Koeneman KS, Sweet RM. Robotic surgical education: a collaborative approach to training postgraduate urologists and endourology fellows. *JSLS* 2009;13:287–292.

4. Singh N, Bush R, Dalsing M, Shortell CK. New paradigms for physician-industry relations: overview and application for SVS members. *J Vasc Surg*. 2011;54:26S–230S.

5. Van Haute A. Managing perceived conflicts of interest while ensuring the continued innovation of medical technology. *J Vasc Surg*. 2011;54:31S–33S.

6. Zucker D. Ethics and technology transfer: patients, patents, and public trust. *J Investig Med*. 2011;59:762–767.

7. Brown-Clerk B, de Laveaga AE, LaGrange CA, et al. Laparoendoscopic single-site (LESS) surgery versus conventional laparoscopic surgery: comparison of surgical port performance in a surgical simulator with novices. *Surg Endosc*. 2011;25:2210–2218.

8. Islam A, Castellvi AO, Tesfay ST, et al. Early surgeon impressions and technical difficulty associated with laparoendoscopic single-site surgery: a Society of American Gastrointestinal and Endoscopic Surgeons Learning Center study. *Surg Endosc*. 2011; 25:2597–2603.

9. Ross S, Roddenbery A, Luberice K, et al. Laparoendoscopic single site (LESS) vs. conventional laparoscopic fundoplication for GERD: is there a difference? *Surg Endosc*. 2013;27:538–547.

10. Ross S, Rosemurgy A, Albrink M, et al. Consensus statement of the consortium for LESS cholecystectomy white paper. *Surg Endosc*. 2012;26:2711–2716.

11. Santos BF, Enter D, Soper NJ, Hungness ES. Single-incision laparoscopic surgery (SILS) versus standard laparoscopic surgery: a comparison of performance using a surgical simulator. *Surg Endosc*. 2011;25:483–490.

12. Stroup SP, Bazzi W, Derweesh IH. Training for laparoendoscopic single-site surgery and natural orifice transluminal endoscopic surgery. *BJU Int*. 2010;106:934–940.

13. Tsai AY, Selzer DJ. Single-port laparoscopic surgery. *Adv Surg*. 2010;44:1–27.

14. Lucas SM, Baber J, Sundaram CP. Determination of patient concerns in choosing surgery and preference for laparoendoscopic single-site surgery and assessment of satisfaction with postoperative cosmesis. *J Endourol*. 2011;26:585–591.

15. Ross SB, Hernandez JM, Sperry S, et al. Public perception of LESS surgery and NOTES. *J Gastrointest Surg*. 2012;16:344–55.

16. Gill IS, Advincula AP, Aron M, et al. Consensus statement of the Consortium for Laparoendoscopic Single-Site Surgery. *Surg Endosc*. 2010;24:762–768.

Pre-Event Questionnaire

(Please write clearly)

Name: _____

Address: _____

Phone Number: _____

Email: _____

Surgical Specialty: (Please circle) General, Bariatric, Gynecologic, MIS, Other (specify):

Academic or Community Based (Please circle)

Hospital Affiliation: _____

Training Surgeon: _____

Focus Procedure of Training Event: _____

Date of Training Event: _____

1. What are your objectives in attending this event? Please circle all that apply.
   A. To be introduced to LESS surgery
   B. To expand your armamentarium of MIS surgery
   C. To improve your current techniques of LESS surgery
   D. To learn about new advances in instrumentation for LESS surgery

3. What percentage of your practice involves laparoscopy?
   A. 0%
   B. 1%-25%
   C. 26%-50%
   D. 51%-75%
   E. >75%

4. What types of laparoscopic operations does your practice include? Please mark all that apply and indicate the number per month.
   A. Cholecystectomy (IOC/no IOC): _____
   B. Heller myotomy: _____
   C. Nissen fundoplication: _____
   D. Hernia repair: _____
   E. Adrenalectomy: _____
   F. Hysterectomy: _____
   G. Appendectomy: _____
   H. Colectomy: _____
   I: Other (Please describe): _____

5. How many years have you practiced as a laparoscopic surgeon? _____

6. Have you ever attempted LESS surgery?
   Y N

7. Do you believe that LESS surgery is the "end point" for minimally invasive laparoscopic surgery?
   Y N

8. Do you feel that you have the support of your hospital administration and/or surgery department to start implementing LESS surgery at your hospital?
   Y N

9. Do you plan to take any more courses (in addition to this course) before you start to do LESS surgery at your hospital?
   Y N

10. Are there any other avenues you will pursue to perfect your technique, such as other courses?
   Y N
If yes, can you describe what options you will pursue?

11. Do you have the necessary equipment in place at your institution to do LESS surgery?
   Y N
If no, how do you intend to obtain the equipment?

12. Are patients requesting LESS surgery at your institution or in your community?
Y N
If yes, how did they learn about LESS surgery?

13. Do you intend to market LESS surgery as part of your practice?
Y N
If yes, how would you market LESS surgery?

14. Are there requirements at your hospital that you must fulfill before you can implement LESS surgery at your institution?
Y N
If yes, what are they?

15. Are there any issues regarding cost related to the incorporation of LESS surgery in your practice?
Y N
If yes, what are they?

16. Do you have to obtain new privileges at your hospital to do LESS surgery?
Y N

17. May we re-contact you in the future to assess how this training has helped you in your surgical practice?
Y N

Thoughts:

Post-Event Evaluation

(Please write clearly)

Name: _____

1. Were your objectives met in attending this event? If no, please explain.
   Y N

2. Have your impressions of LESS surgery changed?
   Y N

If yes,
   A. Positive
   B. Negative

3. Are you going to incorporate LESS surgery into your practice?
   Y N

   If so, with which operation? Please mark all that apply.

   A. Cholecystectomy (IOC/no IOC): _____
   B. Heller myotomy: _____
   C. Nissen fundoplication: _____
   D. Hernia repair: _____
   E. Adrenalectomy: _____
   F. Hysterectomy: _____
   G. Appendectomy: _____
   H. Colectomy: _____
   I: Other (Please describe): _____

4. After attending the course at Florida Hospital Tampa, do you feel prepared to incorporate LESS surgery into your practice?
   Y N

5. Did the LESS surgery movies enhance the course?
   Y N

6. Was the simulation lab beneficial to you?
   Y N

7. Please rate your overall experience of the event on a scale of 1 to 10.
   _____

8. Please rate the trainers on a scale of 1 to 10.
   _____

9. Which portion of the course was most beneficial? Why?
   A. Operating room
   B. Movies/Discussion
   C. Simulation Lab

10. Which portion of the course would you change?
   A. Operating room
   B. Movies/Discussion
   C. Simulation Lab
   D. None
   How?

11. Did you get enough personal attention?
   Y N

12. If you were designing the course, what percentage of time would you allow for each portion?
   A. Operating room: _____
   B. Movies/Discussion: _____
   C. Simulation Lab: _____

13. Please provide any other suggestions on enhancing this event.