Chapter 19. Learning Curves for New Procedures – the Case of Laparoscopic Cholecystectomy

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Background

Minimal access surgery began in the early 1980s with the introduction of laparoscopic fallopian tube ligation. The first laparoscopic cholecystectomy was performed 7 years later, and was rapidly embraced as the preferred method for cholecystectomy despite a lack of evidence to support the safety of the new technique.[1-6] In response to several deaths and complications associated with laparoscopic cholecystectomy, the New York State Department of Health issued guidelines for the credentialing of surgeons who wished to perform the procedure.[7,8] At the same time, a National Institutes of Health Consensus conference published recommendations regarding indications for laparoscopic cholecystectomy.[1]

Clinical trials comparing the laparoscopic procedure with other approaches eventually revealed that the newer procedure to be less morbid than traditional open cholecystectomy, or even mini-laparotomy.[9-16] Importantly, though, it also became clear that acquiring the skills to perform this new procedure involved a substantial surgical "learning curve."[17-22] This learning curve no longer affects patients undergoing laparoscopic cholecystectomy, as training has become a required part of all surgical residency programs, with graduating surgery residents typically having performed more than 50 laparoscopic cholecystectomies.[23,24] However, the growth of laparoscopic cholecystectomy has been followed by equally rapid development and application of minimal access procedures in virtually every surgical specialty. This chapter considers the patient safety issues that arise with the diffusion of a new procedurally-based technology. It highlights the "learning curve" inherent in any new procedure, as competence invariably grows with practice (see Chapter 18). Because it is so widely performed and has the largest literature describing its record, this chapter focuses on lessons learned from the introduction of laparoscopic cholecystectomy.

Practice Description

Although there are a wide variety of procedure-specific techniques in minimal access surgery, all operations utilize videoscopic or digital imaging in conjunction with remote manipulation. In general, the operator works from two-dimensional, magnified video images of the operative field while manipulating long narrow instruments placed into the operating cavity from outside the body. To become proficient in minimal access techniques, the surgeon must develop skills in interpreting a three-dimensional environment as a two-dimensional image, and learn how to do familiar tasks (eg, suture) with familiar instruments in an unfamiliar manner. Importantly, the surgeon never actually touches the tissue being moved with his or her hands.[21,25] This loss of tactile input is the major factor in making minimal access techniques difficult to learn.

Prevalence and Severity of the Target Safety Problem

Complications from minimal access procedures fall into 2 general categories: those directly resulting from the laparoscopic intervention (ie, trocar injuries, dissection injuries, insufflation-associated events)[26] and those associated with the operation itself (eg, bile duct injury with cholecystectomy, gastric injury with fundoplication).*[17-22] For laparoscopic cholecystectomy, a survey of 1750 surgery department chairpersons reported that bowel and vascular injuries (laparoscopic-specific injury) occurred in 0.14% and 0.25% of cases respectively, while the rate of bile duct injuries (procedure-specific) was 0.6%.[3] The bile duct injury rate was lower at institutions that had performed more than 100 cases. Although this study was large, as a survey it likely underestimates the true rate of complications. Other multi-institutional reports of laparoscopic cholecystectomy in the United States have noted a similar bile duct injury rate and report mortality rates of 0.04% to 0.1%.[5,21,25,29] Although undoubtedly underestimated, even these rates are higher than those associated with open cholecystectomy.

Opportunities for Impact

As set forth above, laparoscopic cholecystectomies is a standard part of surgical residency training.[23,24] Nearly all general surgeons who did not train in the current era have received postgraduate training in basic laparoscopic techniques. This training often takes the form of a 2-3 day course involving hands-on experience with animal models and laboratory-skills sessions, then observation or assisting with cases primarily performed by another surgeon, finally, performing cases supervised by an experienced laparoscopist, and finally performing cases independently.[6,24,30]

Proficiency in traditional techniques does not automatically translate to minimal access methods. We identified one study investigating whether the level of surgical training (attending surgeon versus chief resident) affected the performance of cholecystectomy.[17] This study suggested that, despite operating on more complex patients, the adverse event rate for surgical chief residents learning laparoscopic cholecystectomy was similar to that of attending physicians (who had far more operative experience).

Similarly, skills obtained with one minimal access procedure do not transfer to others. The operation of laparoscopic fundoplication for gastroesophageal reflux disease entered into surgical practice after laparoscopic cholecystectomy. Therefore, most surgeons who performed it had basic laparoscopic skill sets. Studies investigating its implementation suggest a threshold of 25-30 cases before surgeons attain proficiency,[31-34] in contrast to a threshold of about 15-20 cases for laparoscopic cholecystectomy.[25,29,30,35] In recognition of this lack of transferability, performing laparoscopic cholecystectomies does not qualify a surgeon to perform laparoscopic colon resection without first undergoing additional training specifically in laparoscopic colon techniques.[6,36] The need for specific new training has been seen with other procedures as well.[37-41]

* A third problem concerns the potential adverse effects at the population. While the procedure itself may be less morbid, the rate at which this 'safer' procedure is performed may increase substantially to the point that the complications experienced by the patient population as a whole do not decrease.[27] This problem has been documented with laparoscopic cholecystectomy,[12,28] but processes for improved patient selection have not received sufficient testing to permit review of a particular safety practice relating to procedure "appropriateness."

Thus, determination of a minimum number of cases required to become proficient (as an aid to credentialing or proctoring activities), or determining methods to shorten the time needed to attain this level of skill will have a clear impact on patients undergoing minimal access procedures. This impact is likely to become greater as the breadth and complexity of procedures approached through minimal access techniques grows.

Study Designs

Using a structured MEDLINE search, we sought to identify papers that either reported a threshold number of cases required to attain proficiency, or explicitly compared training techniques for laparoscopic cholecystectomy in terms of patient outcomes. Our literature search found a large number of reports describing retrospective analyses or reports from procedure registries. These studies did not report training protocols, specific physician characteristics or surgeon-specific volumes, and were therefore excluded from our review. In addition, we found several review articles.[42-44] The first of these reviews focused primarily on statistical techniques for documenting and analyzing learning curves,[42] and the other two[43,44] did not meet criteria for systematic reviews. Nonetheless, the bibliographies of all 3 articles were scanned for relevant studies.

Study Outcomes

All studies reported clinical outcomes (Level 1), most commonly bile duct injury. Other complications (eg, insufflation or trocar injuries) were very unusual, and mortality was rare.

Evidence for Effectiveness of the Practice

Three studies specifically addressed the relationship between surgical experience in the performance of laparoscopic cholecystectomy and a well-defined adverse outcome, bile duct injury. The first reported 15 bile duct injuries in over 8000 laparoscopic cholecystectomies.[30] Multivariate analysis showed that the only significant factor in predicting this adverse event was the experience of the surgeon ($p=0.001$). Rapidity of learning was not significantly related to a surgeon's age, size of practice, or hospital setting. Ninety percent of injuries were predicted to occur during a surgeon’s first 30 cases. Gigot et al[35] reported the incidence of bile duct injury was 1.3% when the surgeon had performed fewer than 50 cases and 0.35% afterwards ($p<0.001$). However, bile duct injuries still occurred with surgeons who had performed >100 cases.[35] Similar results have been observed in other studies of bile duct injury with laparoscopic cholecystectomy,[45] suggesting that something beyond the learning curve accounts for many laparoscopic errors. Examination from error analysis suggests that these events occur because of visual and perceptual difficulties involved in the operator/equipment interface.[46,47]

We identified one prospective cohort study from Japan that compared the effectiveness of 2 training courses for laparoscopic cholecystectomy.[2] In this study, one group of 8 surgeons was assigned to 10 supervised laparoscopic cholecystectomies as part of their initial training; a second group of 8 surgeons had only 2 observed training sessions. Complications that occurred over 21 months after completion of the 4 months of training were assessed by means of a questionnaire sent to all participants. The surgeons who had trained with 10 supervised procedures had 0.5% major complications (bleeding, bile duct injury or bile leakage) versus 2% for the surgeons trained with only 2 procedures ($p=0.03$). The incidence of major complications occurring during the initial 10 operations was higher among unsupervised surgeons ($p=0.005$).

Outside of laparoscopic cholecystectomy, we identified one study examining complication rates of urologic laparoscopic surgeons after completing a 2-day training seminar.[48]

Because the study relied on surveys of participants at 3 and 12 months after course completion, it is likely biased toward underestimating the incidence of adverse events. Nevertheless the study showed that surgeons who performed procedures without additional training were 3 times more likely to have at least one complication compared with surgeons who sought additional training. Additionally the presence of skilled associates and the development of a surgical team impact favorably on reducing the number of complications.[48,49]

Potential for Harm

It is unlikely that the specific introduction of training and requirements for a baseline of surgical experience in minimal access surgery procedures will lead to adverse events.

Costs and Implementation

In the initial introduction of laparoscopic cholecystectomy most surgeons attended at least one didactic and hands-on course in operative technique and instrument manipulation. Some of these experiences included operative procedures in animals and utilization of static training boxes and devices that may speed the acquisition of perceptual and motor skills. The need for practice in the development of technical skills is vital, and laboratory courses, training devices and simulators (Chapter 45) are being tested for their ability to improve operator skills.[50-55] There is insufficient evidence to make a recommendation of the superiority of one training method over any other and costs are presently undetermined.

After sufficient laboratory experience and practice, it is recommended that the procedure be performed initially in only carefully selected patients under the supervision of an experienced surgeon.[56-58] How practicing groups of providers obtain an experienced consultant is variable.[59,60] Surgical training fellowships in minimal access surgery have been established and graduates of these programs have the requisite expertise to supervise others. Unfortunately, such fellowship graduates are in short supply. Telemedicine may play a role in the mentoring and technical support for surgeons performing new techniques as it provides a means for remote performance of a procedure with real-time expert supervision and guidance.[61,62]

Comment

Minimal access surgery has become extraordinarily popular largely in response to market forces. The single most important predictor of adverse events in minimal access procedures is the experience of the provider with the specific operation. Surgeons must acquire the necessary technical skills and expertise before performing new procedures on patients. Hospitals and payers should help ensure that providers possess the requisite experience before allowing procedures to be performed in their facilities or paying for them, since patients alone will generally be unable to determine surgeon competency.

A number of governing bodies and surgical societies have published guidelines that outline standards for training for postgraduate surgeons for skill acquisition in minimal access surgery,[1,56-58,63-66] but these recommendations are based more on common sense and clinical experience than rigorous evidence. It is not known how influential these guidelines are in the granting of privileges. Continued research is needed to determine the threshold for safe performance of this and other procedures, the most effective training methods to ensure competence, and strategies to minimize patient harm while proceduralists gain the experience they need to be competent and to train others.

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