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The necessity for prospective evidence for single-site umbilical laparoscopic surgery

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During the past 10 years, the minimally invasive technique has become the standard approach for many thoracic, abdominal, and pelvic procedures in adults and children. We now know there are well-defined benefits to this approach. However, when it was introduced, the laparoscopic technique was quickly adopted without appropriate clinical evidence to justify its advantages over open surgery. With continued efforts to increase the benefits of minimally invasive surgery for their patients, surgeons have developed new techniques to further decrease the trauma of the operation and improve the postoperative cosmetic appearance for the patient. These innovations range from decreasing the size of the ports and instruments to the current group of techniques termed "scarless" surgery. In today's era of evidence-based medicine, it is important to scientifically evaluate the benefits of a new approach or technique. This article seeks to review the history of laparoscopic surgery, apply lessons learned during the past 10 years to the evolution of single incision laparoscopic surgery, and urge for sound prospective evaluation for the use of laparoscopic surgery using a single umbilical incision.

Videoscopic approaches to operations have allowed surgeons in every discipline to perform procedures without the large incisions traditionally necessary for exposure with the open approach. The transition toward minimally invasive approaches to surgery began more than 2 decades ago and has been irreversibly cemented in practice. This evolution is based on clear advantages to the patient, including less postoperative pain, more rapid recovery, and superior cosmesis. After initial good outcomes were reported with the laparoscopic approach in the early 1990s, it quickly was adopted as the preferred approach for many operations, almost always without prospective comparative data. However, evidence-based medicine is now becoming a basic guiding principle of medical training and practice.

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Surgeons have traditionally trailed the medical disciplines in both the acquisition of quality evidence and the application of this evidence into practice. As opposed to the introduction of new medications, which requires a prolonged and rigorous course of prospective studies with careful data collection and monitoring, new surgical equipment and technical innovations often are used by innovative surgeons without comparative data. These innovations are then quickly adopted by others without documentation of the advantages or disadvantages. This was the case for many laparoscopic procedures in the early 1990s. In the current medical environment, such innovation without data is becoming less acceptable. It is the surgeon's responsibility to prove that the benefits outweigh the risks before allowing wide adaptations of new techniques. As we continue to try to improve the benefits of minimally invasive surgery with the advent of single-site procedures, we must avoid some of the same mistakes made during the early part of the laparoscopic revolution. Prospective randomized trials are necessary to define which outcome variables are improved by

single-site approaches and to quantify the degree of differences in these outcome variables. Such data acquisition will enable surgeons to better discuss the advantages and disadvantages of one approach vs another with their patients.

Transition from open operations to laparoscopy

The early laparoscopic and thoracoscopic experience was met with apprehension and resistance. However, these reports provided the groundwork for preparing the surgical community for a shift in mindset toward minimally invasive surgery.[1] In 1987, when Phillippe Mouret was credited with performing the first laparoscopic cholecystectomy, it ignited the release of a wave that has continued to grow and evolve during the past 20+ years. Laparoscopic surgery became widely accepted because there were obvious and clear benefits to this approach for the patient. Postoperative hospitalization and convalescence after major abdominal operations were dramatically reduced. Consequently, there was a tremendous demand, largely driven by patients and market forces, with laparoscopy being advertised to the public as "surgery without knives."

Hospital systems capitalized on this shift, seeing an opportunity to increase their revenues by reducing the cost of postoperative hospitalization in addition to providing a valuable asset in competitive advertising. Influenced by these forces, the surgical community rapidly accepted laparoscopy and bypassed the standard stages of scientific evolution supported by evidence. However, the rapid and widespread use of laparoscopic cholecystectomy by surgeons not trained in the laparoscopic era resulted in a significant increase in the incidence of bile duct injury.[2]

Because of this unacceptable trend, a consensus conference was held by the National Institutes of Health in 1992.[3] The panel aptly referred to the task of evaluating the available data on laparoscopic cholecystectomy as an attempt to focus on a swiftly moving target. They determined that there were a myriad of limitations with the available data. These limitations included the fact that all the data were retrospective in nature, that there was a bias toward reporting favorable results, that follow-up was limited, that the learning curve was not addressed, and that there were obvious variations in techniques and skills. These concerns exist at the initiation of any new approach, including our present situation with single-site umbilical laparoscopic surgery (SSULS). Despite these limitations, the National Institutes of Health panel concluded that laparoscopic cholecystectomy was safe and effective in the appropriate setting and that it offered the benefits of decreased pain and convalescence. Although the data showed that the rate of common bile duct injuries was increased, the rate was still low enough that the benefits outweighed the risks.

Because a guiding principle of evidence-based medicine in the evaluation of comparative therapies is an assessment of risk, these bile duct injuries need to be appreciated. The consequences of some bile duct injuries are so catastrophic that a patient may progress down a path toward transplant or death. Because of these possible adverse outcomes, it seems difficult to weigh the catastrophic outcomes of a few patients against clear benefits experienced in the remaining population. The tale of the development of laparoscopic cholecystectomy is an important one to remember during the development of SSULS procedures because these new approaches have the potential to pose a similar quandary for surgeons and patients.

With the introduction of laparoscopy, there was an obvious and unmistakable difference in the patient's outcome because of the morbidity of an open operation. This difference was exaggerated with the operations that required a large incision, such as cholecystectomy, fundoplication, splenectomy, nephrectomy, adrenalectomy, and others. These operations all quickly transitioned to the laparoscopic approach as the preferred technique, without prospective comparative data, and in some cases without even good retrospective comparative data. This evolution occurred because the advantages to the patient were clear enough from the outset that performing a prospective randomized trial would have been ethically challenging because of a lack of reasonable equipoise. This same scenario does not exist when considering the transition from laparoscopy to single site procedures because the incremental advantages of SSULS over conventional laparoscopy are probably small, if even real.

To compare a similar scenario, we should examine a condition in which the open operative approach is associated with low morbidity, thus offering fewer benefits when the operation is performed laparoscopically. This seems to be the case with appendectomy, which, when performed open, is usually a short procedure through a 2- to 3-cm incision. The decrease in morbidity offered by a laparoscopic appendectomy is not as clear as the aforementioned examples, and the use of a minimally invasive approach has been slower to be applied, and still has not been universally embraced.[4] Additional factors that have delayed the routine use of laparoscopic appendectomy have included the performance of the laparoscopic appendectomy during the night and the uncertainty of creating the pneumoperitoneum in a patient with peritonitis.

The first evidence for the advantages of the laparoscopic approach for appendectomy began to surface in the early 1990s and showed that laparoscopic appendectomy was safe and feasible. Because of the arguable advantages of laparoscopy, as well as the equipoise that existed from the fact that some surgeons believed that laparoscopy was better and others did not, numerous randomized trials were undertaken to compare open vs laparoscopic appendectomy in adults.[5-7] These trials had mixed results, which sparked further controversy whether laparoscopic appendectomy was superior to open appendectomy. Advocates for laparoscopy pointed out a shorter-length of hospitalization, less pain, less recov-