A Prospective, Randomized Controlled Trial of Single-Incision Laparoscopic vs Conventional 3-Port Laparoscopic Appendectomy for Treatment of Acute Appendicitis

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BACKGROUND: Proponents of single-incision laparoscopic surgery (SILS) claim patients have less pain, faster recovery, and better long-term cosmetic results than patients who undergo multiport laparoscopy. However, randomized comparisons are lacking. This study presents the results of a prospective randomized trial of SILS or 3-port laparoscopic appendectomy.

STUDY DESIGN: Adults with uncomplicated acute appendicitis were randomized 1:1 to either SILS or 3-port laparoscopic appendectomy. The primary end point was early postoperative pain (measured by opiate usage and pain score in the first 12 hours). Secondary end points were operative time, complication rate (including conversions), and recovery time (days of oral opiate usage and return to work). After 6 months, body image and cosmetic appearance were assessed using a validated survey.

RESULTS: The trial was planned for 150 patients, but was halted after 75 patients when planned interim analysis showed that SILS patients had more postoperative pain (pain score: 4.4 ± 1.6 vs 3.5 ± 1.5; $p = 0.01$) and higher inpatient opiate usage (hydromorphone use: 3.9 ± 1.9 mg vs 2.8 ± 1.7 mg; $p = 0.01$) than 3-port laparoscopy. Operative time for SILS averaged 40% longer (54 ± 17 minutes vs 38 ± 11 minutes; $p < 0.01$). Only 1 SILS case was converted to 3-port. There were no significant differences in length of stay, complications, oral pain medication usage after discharge, or return to work. After 6 months, body image and cosmetic appearance were excellent for both groups and indistinguishable by most measures. However, 3-port patients reported better physical attractiveness (4.0 ± 0.4 vs 3.8 ± 0.4; $p = 0.04$) and SILS patients reported better scars (score 18.4 ± 2.7 vs 16.4 ± 3.0; $p < 0.01$). Results are reported as mean $\pm$ SD.

CONCLUSIONS: Single-incision laparoscopic surgery appendectomy resulted in more pain and longer operative times without improving short-term recovery or complications. Long-term body image and cosmetic appearance were excellent in both groups. (J Am Coll Surg 2014;218: 950–959. © 2014 by the American College of Surgeons)

Recent advances in laparoscopic instrumentation have made it possible to perform intra-abdominal operations entirely through a small incision that can be hidden within the umbilicus. The goal is to perform surgery with fewer incisions and no visible scars. Potential benefits are faster recovery, less pain, fewer wound complications, better long-term cosmetic results, and no need to violate a natural orifice. The term *SILS*, for single-

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incision laparoscopic surgery, is being used to describe such techniques, and many have touted SILS as a major breakthrough in minimally invasive surgery.

In the past 5 years, SILS techniques have been developed to perform cholecystectomy, appendectomy, hysterectomy, bariatric procedures, hernia repair, fundoplication, colectomy, and nephrectomy.[1-14] Some have suggested that SILS is a better strategy than natural orifice transluminal endoscopic surgery to provide "scarless" surgery because SILS can be performed with conventional laparoscopic instrumentation, there is no need to perforate the vagina or a hollow viscus, and most laparoscopic surgeons already possess the necessary skills. Single-incision laparoscopic surgery has received major industry attention; in January 2009, the first SILS port and trocar system (SILS Port; Covidien) received FDA approval and began marketing in the United States, followed quickly by other similar devices.[15]

On the other hand, results of conventional multiport laparoscopy are already excellent, and direct comparisons of SILS with conventional laparoscopy are lacking. Because SILS requires a larger incision than a standard laparoscopic incision, some have wondered if SILS might actually cause more pain, more wound complications, and longer recovery.[16] Others have questioned whether elimination of 5-mm ports translates into improved cosmetic appearance because 5-mm scars are often barely noticeable after a year.

Only 2 studies have prospectively compared SILS with multiport laparoscopic procedures for appendectomy, neither of which assessed long-term cosmetic appearance.[17,18] The literature consists mostly of retrospective case series that lack a control population. We conducted a prospective, randomized controlled trial of SILS vs conventional 3-port laparoscopic appendectomy for the treatment of acute appendicitis. We hypothesized that SILS patients would experience less pain and have better long-term cosmetic outcomes than 3-port laparoscopic patients.

METHODS

Study design

This was a single-center, prospective, equally randomized (1:1), unblinded, parallel-group study designed to assess the superiority of SILS appendectomy to conventional 3-port laparoscopy with respect to postoperative pain. The trial was approved by an IRB and registered as ClinicalTrials.gov identifier: NCT00997516.

Participants

The study population consisted of all patients from May 2010 to November 2012 who presented to the University of California, San Francisco emergency department and were diagnosed with acute appendicitis on the basis of clinical and radiographic evaluation. Patients who met the inclusion and exclusion criteria (Table 1) were invited to participate in the trial and were enrolled by the principal investigator. After providing informed consent, patients received intravenous fluids and preoperative broad-spectrum antibiotics to cover gram-negative rods and anaerobes.

Patients were then assigned to conventional laparoscopic appendectomy or SILS appendectomy in a 1:1 ratio by a computerized random number generator (http://www.random.org). A random number between 1 and 1000 was picked; even-numbered patients received 3-port laparoscopic appendectomy, odd-numbered patients received SILS appendectomy. There was no blocking or stratification variables used during randomization. Randomization occurred after informed consent was obtained from the patient and before induction of anesthesia. The patient was unaware of the randomization until after the completion of the operation.

Interventions and surgical technique

All operations were performed by a single surgeon (JTC) experienced in both 3-port and SILS appendectomy. The study surgeon had performed >25 SILS and 3-port appendectomies before the start of the trial.

For conventional laparoscopic appendectomy, patients were placed in the supine position and a general anesthetic was given. An orogastric tube, sequential compression devices, and Foley catheter were placed. The left arm was tucked and the abdomen shaved as necessary. The umbilical skin was anesthetized with 5 mL 0.25% Marcaine. A 15-mm vertical incision was made within the umbilical stalk, the fascia was retracted, and a 15-mm vertical fascia incision was made. A 12-mm Hasson port was placed through the fascia and the abdomen insufflated to 15 mmHg with carbon dioxide gas. Diagnostic laparoscopy was then performed. If a diagnosis other than acute appendicitis was made (such as pelvic inflammatory disease, sigmoid diverticulitis, cecal diverticulitis, Crohn's disease, perforated duodenal ulcer), the patient was excluded from the study and treated appropriately. After the abdominal wall was anesthetized with 0.25% Marcaine, additional 5-mm ports were placed in the left lower quadrant and suprapubic midline. The appendix was exposed and retracted anteriorly. The mesoappendix was divided with sequential fires of a cutting-and-sealing device (Ligasure; Covidien). The base of the appendix was ligated with a linear stapler or looped suture. The appendix was removed through the umbilical incision after first placing it into a sterile bag. Minimal irrigation was used; perforated cases were treated with