# Comparison of Laparoscopic and Open Repair With Mesh for the Treatment of Ventral Incisional Hernia

## *A Randomized Trial*

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**Background:** Laparoscopic repair of ventral incisional hernias has not been proved to be safer than open mesh repair.

**Design:** Prospective randomized trial conducted between February 1, 2004, to January 31, 2007.

**Setting:** Four Veterans Affairs medical centers.

**Participants:** One hundred sixty-two patients with ventral incisional hernias.

**Interventions:** Standardized laparoscopic or open repair.

**Main Outcome Measures:** Overall complication rates at 8 weeks and the odds of complications, adjusted for study site, body mass index, and hernia type.

**Results:** Of the 162 randomized patients, 146 underwent surgery (73 open and 73 laparoscopic repairs). Complications were less common in the laparoscopic group (23 patients [31.5%]) compared with the open repair group (35 patients [47.9%]; adjusted odds ratio [AOR], 0.45; 95% confidence interval [CI], 0.22-0.91; $P=.03$). Surgical site infection through 8 weeks was less common in the laparoscopic group (5.6% vs 23.3%; AOR, 0.2; 95% CI, 0.1-0.6). The mean worst pain score in the laparoscopic group was 15.2 mm lower on a visual analog scale at 52 weeks (95% CI, 1.0-29.3; $P=.04$). Time to resume work activities was shorter for the laparoscopic group than for the open repair group (median, 23.0 days vs 28.5 days), with an adjusted hazard ratio of 0.54 (95% CI, 0.28-1.04; $P=.06$). Overall recurrence at 2 years was 12.5% in the laparoscopic group and 8.2% in the open repair group (AOR, 1.6; 95% CI, 0.5-4.7; adjusted $P=.44$).

**Conclusions:** Laparoscopic repair was associated with fewer, albeit more severe, complications and improved some patient-centered outcomes.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00240188

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THE APPEARANCE OF VENTRAL incisional hernias (VIHs) after laparotomy is an important postoperative problem. Advances in anesthesia techniques, adequate prevention and treatment of infection during surgery, and the use of new suture materials have reduced the incidence of incisional hernias. Nevertheless, incisional hernias still occur in up to 23% of patients 13 years after surgery.[1]

Many different techniques are in use for repairing VIH, and with the advent of laparoscopy, yet another technique is being advocated.[2] Laparoscopic repair has been reported in some studies[3-5] to be superior to open repair owing to fewer complications, less pain, and earlier return to work. In addition, the lower complication rate with laparoscopy is a major contributing factor to a lower incidence of recurrence.[6] However, laparoscopic repair requires significant experience and expensive equipment and supplies. Furthermore, to our knowledge, no conclusive randomized trial of sufficient size and power has been conducted to establish the superiority of laparoscopic VIH repair.[6-8] Therefore, general acceptance of the laparoscopic procedure remains mixed, with most surgeons calling for its proper evaluation. We conducted a multicenter randomized trial to compare complication rates and other outcomes after either laparoscopic or open repair of VIH with mesh.

*See Invited Critique at end of article*

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**Group Information:** A list of the Veterans Affairs Ventral Incisional Hernia Investigators appears on page 327.

## METHODS

### STUDY POPULATION, RECRUITMENT, STUDY INTERVENTION, AND FOLLOW-UP

Patients who were 18 years or older, had a diagnosis of VIH measuring 25 to 225 $cm^2$, gave written informed consent for randomization, and had a negative pregnancy test result (in women of childbearing age) were eligible for random assignment to laparoscopic or open repair with mesh at general surgery clinics in 4 Veterans Affairs (VA) medical centers. The exclusion criteria included American Society of Anesthesiologists class IV (ie, systemic disease that is a constant threat to life) or class V (ie, unlikely to survive for 24 hours, with or without an operation) hernias that could not be detected on physical examination, primary or umbilical hernia, severe comorbid conditions likely to limit survival to less than 2 years, cirrhosis with or without ascites, bowel obstruction (partial or intermittent), strangulation, peritonitis, perforation, local or systemic infection, and emergency operation.

Randomization was performed using a computer-generated, permuted-block sequence and was stratified according to the type of hernia (first time or recurrent), body mass index (calculated as weight in kilograms divided by height in meters squared) ($<35$ or $\geq 35$), and study site (VA medical center). The protocol was approved by the institutional review board at each site. Details of the study design are in a previous article.[9]

All of the patients underwent standardized hernia repairs by attending general surgeons who had performed at least 10 laparoscopic or 10 open repairs to qualify for participation in this study. The participating surgeons' self-reported experience from their affiliated university hospital practice and the VA was recorded at the beginning of each operation. The surgeons agreed to follow a precise protocol, including pretrial submission of a videotaped laparoscopic procedure that was reviewed by a surgeon member of the study's executive committee (K.M.F.I. or L.N.). The presence of the attending surgeon scrubbed throughout the procedure was required.

For the laparoscopic repair, the method of Gagner,[10] as shown in a videotape from the American College of Surgeons Library, was selected using a polytef (polytetrafluoroethylene [PTFE]) dual mesh, transabdominal fixation sutures every 6 cm, tacks between sutures, and mesh to fascia overlap of at least 3 cm. For the open procedure, the Chevrel technique, consisting of a components separation with on-lay polypropylene mesh, was adopted.[11-13] Details of the procedures were agreed on by all of the participating surgeons in a pretrial meeting. Standardized anticoagulation and antiplatelet protocols were established. A first-generation intravenous cephalosporin (clindamycin for patients allergic to cephalosporin) was given to all of the patients within 30 minutes of incision. Intraoperatively, body temperature was controlled, the scrub technique was standardized, and all of the patients underwent placement of an iodophor-impregnated adhesive drape (Ioban; 3M, St Paul, Minnesota) over the abdomen. Postoperative pain was treated using a standardized pain management protocol. Patients were given standardized postoperative instructions and were encouraged to wear an abdominal binder for as long as could be tolerated.

### DETERMINATION OF THE PRIMARY OUTCOME

The primary outcome measure was the percentage of patients who had at least 1 complication in the 8 weeks after the repair. In the primary analysis, all classes of complications were weighted equally. In addition, each complication was graded using the classification of Dindo et al,[14] ranging from class I, denoting minimal deviation from the normal postoperative course, to class V, indicating postoperative death.

### DETERMINATION OF SECONDARY OUTCOMES

Intraoperative, immediate postoperative (within 14 days), and delayed postoperative complications were recorded in the hospital and at 2-, 4-, and 8-week postoperative visits. At each postoperative visit, each patient was examined by an independent surgeon to determine the presence or absence of recurrence. Recurrences were confirmed by examination by a second surgeon, by computed tomography of the abdomen, or during a second operation. Patient-centered outcomes (pain, functional status, and activity levels) were assessed at baseline, 2 and 8 weeks postoperatively, and at 1 year. Pain was assessed using a visual analog scale. Functional status was assessed using the Medical Outcomes Study 36-Item Short Form Health Survey (MOS SF-36), version 2.

### ORGANIZATION AND MONITORING

Quality control was ensured through initial individual site visits by the chair (K.M.F.I.) of the study during laparoscopic and open procedures and by random videotaping and review of laparoscopic procedures. All of the operative reports were checked for protocol deviations by an independent surgeon (L.N.), and feedback was given to each site. A data and safety monitoring board consisting of 2 expert surgeons (not otherwise involved in the trial), a biostatistician, and an anesthesiologist regularly reviewed the progress of the study.

### STATISTICAL ANALYSIS

This study was designed to detect a difference of 15% (32% vs 17%) in complication rates between the groups with a sample size of 310 patients, assuming a 10% dropout rate, power of 80%, and a 2-sided type I error of 5%. At the end of the planned recruitment period, a sample size of 162 patients was achieved. The data and safety monitoring board voted not to extend the recruitment period because there was a statistically significant difference in the primary outcome measure whose magnitude showed consistency by calendar time in the study and across the 4 study sites.

Differences in baseline characteristics between the laparoscopic and open repair groups were compared using the Pearson $\chi^2$ test or the Fisher exact test for discrete variables and the unpaired *t* test for continuous measurements. The primary analysis was based on a modified intention-to-treat population. In this analysis, patients who underwent surgery and had at least 1 follow-up visit were included. Two sensitivity analyses based on all the randomized patients were performed to determine how different outcomes might impact the final results. We first classified those who did not undergo surgery as having had a complication and then as not having a complication.

Overall complication rates at 8 weeks (primary outcome) were analyzed by means of logistic regression, and the laparoscopic and open repair groups were compared adjusting for the stratification factors in the randomization scheme (VA study site, first time or recurrent hernia, and body mass index $<35$ vs $\geq 35$). Pain and functional health status were compared between the 2 groups using mixed-effects analysis of variance to account for patient to patient variability in individual scores. Times to return to normal activity were compared between the 2 groups using Cox regression. All comparisons between the 2 groups were adjusted for the stratification factors. All of the tests were 2-sided, and $P \leq .05$ was considered statistically significant. Alpha levels were not adjusted for comparing multiple secondary end points. All of the analyses were performed using a statistical software package (SAS version 9.1; SAS Institute Inc, Cary, North Carolina).

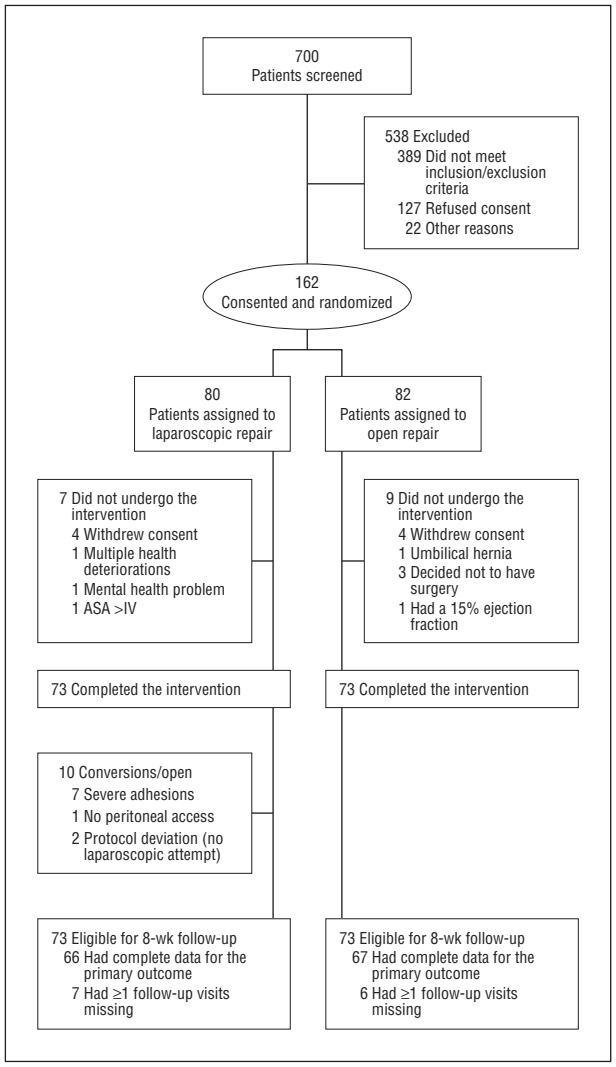


**Figure 1.** Flowchart of patients screened for participation in the study. Of the 389 patients who did not meet the inclusion and exclusion criteria, 39 had hernias not detected on physical examination, 86 had hernias smaller than 9 $cm^2$ or larger than 225 $cm^2$, 196 had primary ventral or umbilical hernias, 50 had American Society of Anesthesiologists (ASA) class IV or V, 9 had severe comorbidities and were unlikely to survive the follow-up period, and 9 had cirrhosis.

**Table 1. Baseline Characteristics of the 146 Study Patients by Treatment Group**

| Variable | Laparoscopic Repair Group (n=73) | Open Repair Group (n=73) | *P* Value |
|---|---|---|---|
| Age, mean (SD), y | 61.2 (9.9) | 59.6 (9.0) | .32 |
| Male sex[a] | 67 (91.8) | 67 (91.8) | ≥.99 |
| Hispanic[a] | 4 (5.5) | 11 (15.1) | .10 |
| Race[a,b] | | | |
| White | 67 (91.8) | 64 (87.7) | .59 |
| Black | 6 (8.2) | 9 (12.3) | |
| BMI, mean (SD) | 30.6 (4.4) | 31.2 (5.9) | .45 |
| Abdominal wall, mean (SD) | | | |
| Previous abdominal incisions, No. | 1.9 (1.3) | 1.9 (1.4) | .95 |
| Size of defect, $cm^2$[c] | 45.7 (50.5) | 45.9 (52.5) | .98 |
| Findings[a] | | | |
| Palpable on impulse | 7 (9.6) | 8 (11.0) | ≥.99 |
| Visible when standing | 66 (90.4) | 65 (89.0) | |
| Duration of hernia[a] | | | |
| <6 wk | 3 (4.1) | 0 | .44 |
| 6 wk-1 y | 26 (35.6) | 29 (39.7) | |
| >1 y | 42 (57.5) | 43 (58.9) | |
| Unknown | 2 (2.7) | 1 (1.4) | |
| Reducibility[a] | | | |
| Spontaneously | 15 (20.5) | 10 (13.7) | .76 |
| Easily | 52 (71.2) | 57 (78.1) | |
| With difficulty | 4 (5.5) | 4 (5.5) | |
| Not reducible | 2 (2.7) | 2 (2.7) | |
| Comorbidities[a,d] | | | |
| Chronic constipation | 7 (9.6) | 8 (11.0) | ≥.99 |
| >10% loss of body weight | 3 (4.1) | 3 (4.1) | ≥.99 |
| Long-term corticosteroid use | 3 (4.1) | 4 (5.5) | ≥.99 |
| AIDS | 1 (1.4) | 0 | ≥.99 |
| Severe COPD | 5 (6.8) | 7 (9.6) | .76 |
| Chronic cough | 4 (5.5) | 6 (8.2) | .74 |
| Anticoagulants | 38 (52.1) | 41 (56.2) | .74 |
| Diabetes with medications[a] | | | |
| No diabetes | 57 (78.1) | 62 (84.9) | .63 |
| Oral hypoglycemics | 12 (16.4) | 8 (11.0) | |
| Insulin | 4 (5.5) | 3 (4.1) | |
| Smoker[a] | 21 (28.8) | 29 (39.7) | .22 |
| Alcohol, >2 drinks/d[a] | 7 (9.6) | 5 (6.8) | .76 |
| ASA classification[a] | | | |
| I (health) | 9 (12.3) | 11 (15.1) | .85 |
| II (mild systemic) | 57 (78.1) | 54 (74.0) | |
| III (severe systemic) | 7 (9.6) | 8 (11.0) | |

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COPD, chronic obstructive pulmonary disease.

[a] Data are reported as number (percentage) unless otherwise indicated.

[b] Race was self-reported and was selected from a provided list of options.

[c] Defect size measured on physical examination is smaller than that measured intraoperatively and as reported in the text.

[d] Coexisting conditions were determined to be present or absent by the examining physician according to criteria on the basis of current medications and problem lists in the medical records (diabetes mellitus, AIDS, corticosteroid use, anticoagulants, and weight loss) or on the basis of the patient's own report (chronic cough, smoking, and alcohol consumption).

## RESULTS

### BASELINE CHARACTERISTICS OF THE PATIENTS

Between February 1, 2004, and November 30, 2006, 700 patients were screened, and 411 were ineligible (**Figure 1**). Of the 289 eligible patients, 162 (56.1%) with VIH met the enrollment criteria, consented to participate, and were randomized to receive either laparoscopic (n=80) or open (n=82) hernia repair. One hundred forty-six patients underwent surgery (73 laparoscopic and 73 open), and 16 (7 assigned to laparoscopic and 9 assigned to open repair) received no surgery (Figure 1). The 8-week follow-up period was completed in 133 patients. **Table 1** provides the baseline characteristics of the 146 patients included in the analysis according to treatment group. Demographic characteristics, features of the hernia, coexisting conditions, and American Society of Anesthesiologists classifications were similar in the 2 groups.

Ten patients (13.7%) assigned to the laparoscopic repair group received an open repair intraoperatively; in 7 patients, adhesions were extensive, and conversion from laparoscopic to open repair was performed; bowel injury occurred in 3 of these patients during the laparo-

**Table 2. Postoperative Complications (Primary and Secondary Outcomes)**

| | Patients, No. (%) | | | | |
|---|---|---|---|---|---|
| | Laparoscopic Repair (n=73) | Open Repair (n=73) | *P* Value[a] | Odds Ratio (95% Confidence Interval) | Attributable Risk per 100 Persons[b] |
| Primary outcome | | | | | |
| Overall complications through 8 wk | 23 (31.5) | 35 (47.9) | .03 | 0.5 (0.2-0.9) | –16.4 |
| Intraoperative complications | | | | | |
| Injury to bowel | 3 (4.1) | 0 | | | |
| Problems related to anesthesia | 1 (1.4) | 0 | | | |
| Other | 3 (4.1) | 1 (1.4) | | | |
| Overall | 7 (9.6) | 1 (1.4) | .046 | 8.9 (1.0-76.9) | 8.2 |
| Short-term postoperative complications | (n=72) | (n=73) | | | |
| Hernia site infection | 2 (2.8) | 16 (21.9) | | | |
| Wound hematoma | 2 (2.8) | 2 (2.7) | | | |
| Bleeding | 1 (1.4) | 1 (1.4) | | | |
| Intra-abdominal abscess | 2 (2.8) | 2 (2.7) | | | |
| Ileus/bowel obstruction | 3 (4.2) | 2 (2.7) | | | |
| Seroma | 6 (8.3) | 18 (24.7) | | | |
| Skin necrosis | 2 (2.8) | 3 (4.1) | | | |
| Other | 10 (13.9) | 5 (6.8) | | | |
| Overall | 15 (20.8) | 33 (45.2) | .001 | 0.3 (0.1-0.6) | –24.4 |
| Serious complications within 30 d | (n=68) | (n=72) | | | |
| Sepsis | 2 (2.9) | 0 | | | |
| Urinary tract infection | 1 (1.5) | 0 | | | |
| Other | 1 (1.5) | 1 (1.4) | | | |
| Overall | 3 (4.4) | 1 (1.4) | .25 | 4.1 (0.4-45.5) | 3.0 |
| Long-term (8 wk) postoperative complications | (n=69) | (n=70) | | | |
| Hernia site infection | 1 (1.5) | 1 (1.4) | | | |
| Wound hematoma | 0 | 0 | | | |
| Intra-abdominal abscess | 1 (1.5) | 0 | | | |
| Ileus/bowel obstruction | 1 (1.5) | 0 | | | |
| Seroma | 0 | 0 | | | |
| Skin necrosis | 0 | 0 | | | |
| Other | 1 (1.5) | 1 (1.4) | | | |
| Overall | 3 (4.4) | 2 (2.9) | .69 | 1.5 (0.2-9.4) | 1.5 |

[a] Adjusted for stratification factors (site, hernia type, and body mass index); adjusted *P* values for subgroup analysis are not reported owing to the small number of events.

[b] Attributable risk in the laparoscopic procedure (eg, –5.2 indicates that the incidence of complication will decrease by 5.2 per 100 individuals in the laparoscopic procedure).

scopic attempt. Of the other 3 patients, laparoscopic access could not be obtained in 1 and was not attempted in 2, and the surgeons proceeded with an open repair.

Median operating time was 155 minutes for laparoscopic repair and 127 minutes for open repair (*P*=.02). The size estimate of the defect measured preoperatively was similar in both groups (Table 1); when measured intraoperatively (during insufflation in the laparoscopic group), the mean (SD) defect size was 123.7 (134.0) $cm^2$ in the laparoscopic group compared with 68.1 (71.0) $cm^2$ in the open repair group (defect size: 95% confidence interval [CI], –91 to –21; *P*=.002). The mean (SD) mesh size in the laparoscopic group was 266.4 (154.3) $cm^2$ compared with 189.2 (169.3) $cm^2$ in the open repair group (mesh size: 95% CI, 24 to 130; *P*=.005). Thirty-nine patients in the open repair group had a drain placed for 1.7 days compared with 8 in the laparoscopic group for 1.8 days (these were patients converted from laparoscopic to open repair). Thirty-four patients were hospitalized in each group. Mean (SD) hospital length of stay was 4.0 (3.5) days in the laparoscopic group and 3.9 (3.1) days in the open repair group (hospital length of stay: 95% CI, –1.7 to 1.5; *P*=.91).

## COMPLICATIONS

At 8 weeks, complications were significantly less common in the laparoscopic group (23 of 73 patients [31.5%]) compared with the open repair group (35 of 73 patients [47.9%]; adjusted odds ratio [AOR], 0.45; 95% CI, 0.22-0.91) (**Table 2**). When all of the patients who did not undergo surgery were treated as having a complication, the AOR was 0.48 (95% CI, 0.25-0.91); when all the patients who did not undergo surgery were treated as having no complications, the AOR was 0.50 (0.25-1.0).

Intraoperatively, bowel injury (3 of 73 patients [4.1%]) occurred only in the laparoscopic group. These injuries were recognized and addressed intraoperatively by converting the laparoscopic procedure to an open repair and placing a polypropylene mesh, as described in the study protocol.

Up to 4 weeks postoperatively, surgical site infection was less common in the laparoscopic group than in the open repair group (2.8% vs 21.9%; OR, 10.5; 95% CI, 2.3-48.2; *P*=.003). During the same time frame postoperatively, seroma was less likely to occur in the laparoscopic group compared with the open repair group (8.3% vs 24.7%; OR, 4.5; 95% CI, 1.5-13.4; *P*=.006). In patients who had a compli-

cation, more severe complications occurred more frequently in the laparoscopic vs the open repair group (30% vs 9%; OR, 4.7; 95% CI, 1.1 to 20.5; *P*=.04) (**Figure 2**).

Comparison of complication rates adjusting for baseline pain scores and MOS SF-36 scores revealed a significantly lower complication rate for the laparoscopic group compared with the open repair group. The OR was 0.45 when adjusted separately for baseline pain at rest and during normal activity, for worst pain, for physical component scores, and for mental component scores. The OR was 0.37 when adjusted for baseline pain during work or exercise.

## RECURRENCE

The overall recurrence rate up to 2 years for the laparoscopic repair group (9 of 72 patients [12.5%]) was no different from that for the open repair group (6 of 73 patients [8.2%]; AOR, 1.6; 95% CI, 0.5 to 4.7; adjusted *P*=.44). However, this study was not powered for a comparison of recurrence rates. Of the patients who developed a recurrent hernia after laparoscopic repair, 1 had a surgical site infection with abscess, 2 were converted to open repair, 1 had a postoperative trocar hernia, and 5 had no postoperative complications. Among the patients who developed a recurrent hernia after open repair, 2 had multiple complications, including surgical site infection with intra-abdominal abscess after the index repair, and 1 had a seroma. The other 3 patients who developed a recurrence after an open repair had no postoperative complications.

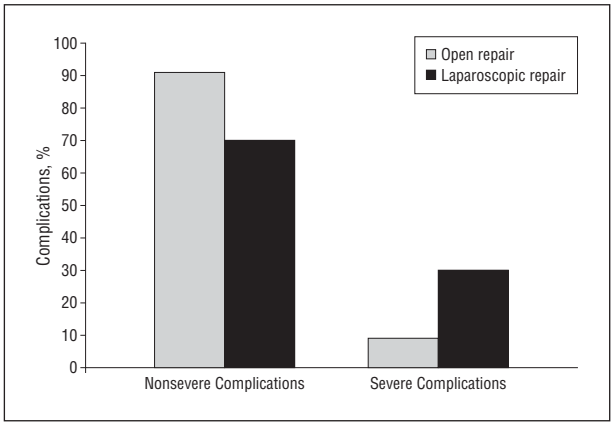


**Figure 2.** Classification by severity of complications for open and laparoscopic ventral incisional hernia repair.

## PATIENT-CENTERED OUTCOMES

Baseline pain scores and MOS SF-36 scores were not statistically significantly different at baseline between the laparoscopic and open repair groups. Pain at rest, during normal activities, and during work or exercise and perception of worst pain significantly improved by 8 weeks for the laparoscopic and open repair groups compared with baseline pain scores, but the improvements were not statistically significant between the 2 groups (**Table 3**). At 52 weeks, patients in the laparoscopic group experienced lower levels of pain (at rest, during normal activities, and during work or exercise) than did those in the open repair group, but the differences were not statistically significant. The mean worst pain score in the laparoscopic group was 15.2 mm lower than that in the open repair group at 52 weeks (95% CI, 1.0-29.3; *P*=.04).

No differences in the times to resume normal activities (daily, work, recreational, social, and sexual activities) were observed between the 2 groups. The median time to resume daily activities was 8 days for both groups. The time to resume work activities for the laparoscopic group was shorter (median, 23.0 days; interquartile range, 30 days) compared with that for the open repair group (28.5 days; 44 days), with an adjusted hazard ratio of 0.54 (95% CI, 0.28-1.04; *P*=.06) from Cox regression. Both groups had improved physical (9% from baseline of 38 laparoscopic patients and 13% from baseline of 40 patients who underwent open repairs) and mental (4% from baseline of 45 laparoscopic patients and 6% from baseline of 48 patients who underwent open repairs) component scores on the MOS SF-36 across time (physical component scores for both groups were worsened at 2 weeks), but no significant differences in the improvements between the groups were observed.

## COMMENT

This multicenter randomized trial compared laparoscopic repair to open Chevrel repair of VIH. Overall, the likelihood of developing complications up to 8 weeks postoperatively was approximately 50% lower in patients whose hernias were repaired by means of the laparoscopic technique, but serious complications, such as bowel injury, were more common in the laparoscopic group. Of all of the complications, surgical site infections and seromas in the early postoperative period were significantly more common in the open repair group. The infection rate for open repair

**Table 3. Comparison of Pain Scores[a]**

| | Within Groups (Baseline vs 8 wk) | | | | | | | | Between Groups at 8 wk (Laparoscopic vs Open) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Laparoscopic Repair | | | | Open Repair | | | | | |
| | Baseline | 8 wk | Difference | *P* Value | Baseline | 8 wk | Difference | *P* Value | Difference | *P* Value |
| Pain at rest | 25.1 | 15.0 | 10.1 | .01 | 31.0 | 15.4 | 15.6 | <.001 | 5.5 | .17 |
| Pain during normal activities | 38.9 | 24.0 | 14.9 | .003 | 42.2 | 20.9 | 21.3 | <.001 | 6.4 | .18 |
| Pain during work or exercise | 52.7 | 22.4 | 30.3 | <.001 | 66.1 | 20.8 | 45.3 | <.001 | 15.0 | .06 |
| Perception of worst pain | 38.6 | 19.2 | 19.4 | <.001 | 49.1 | 18.0 | 31.1 | <.001 | 11.7 | .07 |

[a] Pain scores were estimated from mixed-effects analysis of variance adjusted for stratification factors.

is similar to that previously reported.[9,15] Seromas occurred more frequently in open repair despite more frequent placement of drains and the consistent use of abdominal binders in both. Although seromas are more commonly described in patients undergoing laparoscopic repair,[9] their occurrence was more frequent in open repair in a recently published small randomized trial.[15]

Bowel perforation occurred uniquely in the laparoscopic group as the open Chevrel repair technique does not require entry into the peritoneal cavity. The rate of laparoscopic bowel injury is similar to that previously reported.[8,9,16] All bowel perforations were recognized intraoperatively, and the hernia repair was converted to an open procedure; none of these patients developed a surgical site infection. Other researchers[17] have reported successful management by performing the bowel repair laparoscopically, monitoring the patient in the hospital with a planned return to the operating room, and laparoscopic placement of mesh. Bowel perforation might also be missed intraoperatively or manifest after surgery. Sepsis sets in within 96 hours of surgery, so early diagnosis and intervention are critical.[18,19] Intraoperative conversion occurred in 8 patients (10.9%). Although this rate is similar to rates in some reported series,[20-22] it is higher than those in centers that perform high volumes of laparoscopic repairs by dedicated experts.[23-25]

The recurrence rate was not statistically significantly different between laparoscopic and open repairs up to 2 years, but this study was not powered to detect differences in recurrence rates. The reported recurrence rate is an average of 4.9% (12.5% in this series) for laparoscopic repair[2] and 5.5%[26] (8.2% in this series) for open Chevrel repair. The higher rates of recurrence seen in the present patients could reflect the tight surveillance established in a prospective trial.

Of all of the patient-centered outcomes, pain at 52 weeks was significantly improved in the laparoscopic group. None of the patients in the laparoscopic group required suture removal or repeated injection with a local anesthetic to treat anchoring suture–related pain, as reported by some researchers.[27,28]

Shorter hospital stay and decreased postoperative morbidity have been demonstrated recently after laparoscopic ventral hernia repair in a 10-year institutional cohort study.[29] However, operating room costs can be significantly greater with laparoscopic repair than with open repair. The operative time in the present study, as in most other series, was significantly longer for laparoscopic repair, which also adds to the cost of this operation. However, the length of hospital stay for laparoscopic repair was not different from that for open repair.

This study has several limitations. The patient population comprises mostly men who are older than what is reported elsewhere. Information on surgeons' experience was self-reported and may not have been precise. Although preoperative measurement of the abdominal wall defect was similar between the 2 groups, these preoperative measurements were smaller than the intraoperative measurements; in addition, the defect measured in the laparoscopic group intraoperatively was larger than that in the open repair group, most likely due to insufflation of the peritoneal cavity at the time of measurement. The study did not achieve the recruitment target but achieved a statistically significant difference in the primary outcome, which was confirmed by sensitivity analyses. We conclude that for VIH, the laparoscopic technique results in fewer, albeit more serious, complications.

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**INVITED CRITIQUE**

# Interpreting Comparative Effectiveness Studies

## *Does Surgeon Expertise Matter?*

Surgeon factors, including technical proficiency, may be crucial in assessing the comparative effectiveness of competing interventions. In this multicenter clinical trial from Itani et al, laparoscopic repair of abdominal wall hernias was associated with lower overall complication rates (due primarily to fewer surgical site infections) and modestly shorter recovery times than was open repair. However, these benefits of laparoscopic repair were offset by more serious complications, particularly bowel injuries. Conversions to open surgery (10%) were also common and much more frequent in this trial than was reported in previous studies.[1-3]

Although such findings could be explained by patient case mix or more complete ascertainment of adverse outcomes by the investigators, they may also reflect a relative lack of experience or expertise with laparoscopic repair of abdominal wall hernias in surgeons from the 4 participating VA hospitals. This problem has plagued previous VA trials involving hernia surgery. In a much larger trial[4] comparing laparoscopic and open repair of inguinal hernias, laparoscopic repair was associated with markedly higher rates of serious complications, conversions, and hernia recurrence than had been reported in previous clinical trials. In that study, adverse outcomes occurred primarily at the hands of low-volume laparoscopic surgeons. Laparoscopic inguinal hernia repair by high-volume surgeons had more favorable outcomes than did open repair.

Whether the comparative effectiveness of laparoscopic and open repair of abdominal wall hernias is similarly influenced by surgeon experience and expertise cannot be inferred from the data provided by Itani et al. However, open repair surgery may remain the safer option for surgeons who perform this procedure infrequently.

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