

Laparoscopic vs Open Incisional Hernia Repair

A Randomized Clinical Trial

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Importance: Incisional hernia is the most frequent surgical complication after laparotomy. Up to 30% of all patients undergoing laparotomy develop an incisional hernia.

Objective: To compare laparoscopic vs open ventral incisional hernia repair with regard to postoperative pain and nausea, operative results, perioperative and postoperative complications, hospital admission, and recurrence rate.

Design: Multicenter randomized controlled trial between May 1999 and December 2006 with a mean follow-up period of 35 months.

Setting: All patients were operated on in a clinical setting at 1 of the 2 participating university medical centers or at the other 8 teaching hospitals.

Participants: Two hundred six patients from 10 hospitals were randomized equally to laparoscopic or open mesh repair. Patients with an incisional hernia larger than 3 cm and smaller than 15 cm, either primary or recurrent, were included. Patients were excluded if they had an open abdomen treatment in their medical histories.

Intervention: Laparoscopic or open ventral incisional hernia repair.

Main Outcome Measures: The primary outcome of the trial was postoperative pain. Secondary outcomes were use of analgesics, perioperative and postoperative com-

plications, operative time, postoperative nausea, length of hospital stay, recurrence, morbidity, and mortality.

Results: Median blood loss during the operation was significantly less (10 mL vs 50 mL; $P = .05$) as well as the number of patients receiving a wound drain (3% vs 45%; $P < .001$) in the laparoscopic group. Operative time for the laparoscopic group was longer (100 minutes vs 76 minutes; $P = .001$). Perioperative complications were significantly higher after laparoscopy (9% vs 2%). Visual analog scale scores for pain and nausea, completed before surgery and 3 days and 1 and 4 weeks postoperatively, showed no significant differences between the 2 groups. At a mean follow-up period of 35 months, a recurrence rate of 14% was reported in the open group and 18%, in the laparoscopic group ($P = .30$). The size of the defect was found to be an independent predictor for recurrence ($P < .001$).

Conclusions and Relevance: During the operation, there was less blood loss and less need for a wound drain in the laparoscopic group. However, operative time was longer during laparoscopy. Perioperative complications were significantly higher in the laparoscopic group. Visual analog scores for pain and nausea did not differ between groups. The incidence of a recurrence was similar in both groups. The size of the defect was found to be an independent factor for recurrence of an incisional hernia.

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INCISIONAL HERNIA IS THE MOST FREQUENT surgical complication after laparotomy. Up to 30% of all patients undergoing laparotomy develop an incisional hernia. This is associated with discomfort, pain, respiratory restriction, and dissatisfactory cosmetic results.¹⁻⁶ The associated morbidity often results in subsequent hernia repair.^{7,8} Although significant improvements have been achieved in the field of incisional hernia concerning operative technique and the use of prosthetic materials, recurrence rates remain high at 32% to 63%.⁹ Risk factors associated with recurrence, such as hernia size, unfortunately cannot be influenced.¹⁰ The

quest for more effective and less invasive techniques continues.

The introduction of minimally invasive surgery in the early 1990s enabled the possibility of laparoscopic incisional hernia repair.¹¹ Laparoscopy has proved to be a safe, effective, efficient, and less painful technique for many types of surgery and has become the current “gold standard” for cholecystectomy, for example.¹² Laparoscopic incisional hernia repair is a widely used and accepted operative technique, assuming general advances of laparoscopy are also valid for this group. Recent studies have shown that in the short term laparoscopic repair is superior to open repair in terms

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of less blood loss, fewer perioperative complications, and shorter hospital stay.^{13,14} Long-term outcomes such as recurrence rates are yet unknown. So far, level 1 randomized clinical trials for benefits or disadvantages of laparoscopic incisional hernia repair are scarce.¹⁵

The ongoing debate about the expected merits of laparoscopic vs open incisional hernia repair prompted the need for a level 1 randomized controlled trial. The aim of this study was to compare laparoscopic vs open ventral incisional hernia repair with regard to postoperative pain and nausea, operative time, blood loss, perioperative and postoperative complications, length of hospital stay, and recurrence rates.

METHODS

Approval was obtained from the Erasmus Medical Center ethical committee and the local ethical committees of all 9 participating centers prior to enrollment of patients in this study. Informed consent was obtained for all patients. The consent form and consent process were carefully evaluated by the Erasmus Medical Center ethical committee and data monitoring committee on a continual basis. All participating centers provided experienced and dedicated hernia surgeons.

Inclusion criteria were hernia diameter between 3 and 15 cm, location at the ventral abdominal wall at least 5 cm from the costae and inguinal area, indication for elective repair, age 18 years or older, and written informed consent. Exclusion criteria included a contraindication for pneumoperitoneum, an absolute contraindication for general anesthesia, and a history of an open abdomen treatment. Patients participating in other trials were also excluded.

After obtaining informed consent, patients were randomized by computer-generated lists stratified by center and primary or recurrent incisional hernia. Patients and medical staff were not blinded to the allocated procedure.

LAPAROSCOPIC INCISIONAL HERNIA REPAIR

Laparoscopic incisional hernia repair was performed through 3 to 5 abdominal trocars (one 10 mm and 2 to four 5 mm). Pneumoperitoneum was achieved by Veress needle or open introduction of a blunt-tip trocar for inflation with carbon dioxide to achieve intra-abdominal pressure up to 15 mm Hg. A 0° or 30° laparoscope was used to provide a view of the inner surface of the abdominal wall. The additional 5-mm trocars were positioned at the opposite site of the hernia. The hernia port size was measured. Extensive adhesiolysis was performed if necessary using diathermy. The omentum and bowel were detached from the abdominal wall to expose the hernial defect. The hernia sac was not dissected. The mesh was introduced into the abdominal cavity through the 10-mm trocar. The mesh was then placed over the defect with at least 5-cm overlap at all sides. Fixation of the mesh was achieved by 5-mm nonabsorbable tackers (Protack AutoSuture; Tyco Healthcare). A concentric ring of tackers was placed in the peripheral margin of the mesh. Transfascial sutures were often used for mesh positioning and supplementary fixation. Hemostasis was achieved before removal of the trocars. All 10-mm trocar fascial defects were closed. Skin defects were closed with absorbable monofilament sutures.

OPEN INCISIONAL HERNIA REPAIR

Incisions were made in the old scar depending on the localization and size of the hernia. The subcutaneous layer and scar tissue were dissected from the abdominal wall to identify and expose the hernia sac. The hernia port size was measured. Dissection of the hernia sac from beneath the rectus muscles was performed if possible.

Opening and resection of the hernia sac was avoided. Whenever possible, the posterior rectus sheath or peritoneum was dissected from the rectus muscles. After closing of the peritoneum or posterior rectus sheath, a mesh was positioned preperitoneally or in the sublay position, respectively, with at least 5-cm overlap at all sides. The mesh was fixated to the rectus muscle at each corner and side with nonabsorbable (polypropylene) sutures. The anterior rectus sheath was closed only if tension-free repair was possible. The use of wound drainage was not protocolized for the study. Subcutaneous drains with low-vacuum closed systems were placed in case of large dissection areas. The skin was closed with monofilament absorbable sutures or staples.

POSTOPERATIVE CARE

After the operation, patients were transported to the surgical ward. Patients in whom extubation was not possible were admitted to the intensive care unit for observation and ventilatory support. Postoperative analgesia consisted of paracetamol and nonsteroidal anti-inflammatory drugs or intravenous analgesics if necessary. Patients were discharged from the hospital when they mobilized autonomously.

PRIMARY AND SECONDARY OUTCOMES

The primary outcome of the trial was postoperative pain. Secondary outcomes were use of analgesics, perioperative and postoperative complications, operative time, postoperative nausea, length of hospital stay, recurrence, morbidity, and mortality.

FOLLOW-UP EVALUATION

Preoperatively, patients were asked to complete visual analog scales for pain and nausea. Follow-up visual analog scales were completed at 3 days, 1 week, and 4 weeks postoperatively. After discharge from the hospital, patients were invited for follow-up visits at outpatient clinics at 1 week, 6 weeks, 1 year, and 5 years.

STATISTICAL ANALYSES

All patient data were analyzed on an intention-to-treat basis. Patients who did not undergo incisional hernia repair or withdrew consent were excluded from analysis.

Since there were no data available in this field at the time, prior power calculation could not be performed. It was thought that relevant differences could be detected with 200 patients.

Time until recurrence was evaluated using Kaplan-Meier curves and the log-rank test. Pain and nausea visual analog scale scores were compared with repeated-measures analysis of variance. Other continuous variables were compared using an independent-samples *t* test or Mann-Whitney test in cases of nonnormal distribution.

Statistical analysis was performed using SPSS (IBM SPSS). $P \leq .05$ (2-tailed) was considered significant.

RESULTS

Between May 1999 and December 2006, 206 patients were randomly assigned to undergo either laparoscopic ($n=99$) or open ($n=107$) incisional hernia repair. The 2 groups were similar in age, sex ratio, mean body mass index, American Society of Anesthesiologists score, hernia size, and preoperative comorbidity (**Table 1**). Twelve patients withdrew consent or underwent no incisional hernia repair after randomization. In total, 194 patients were included for analysis (**Figure 1**).

Table 1. Patient Characteristics

Characteristic	No. (%)		P Value
	Open (n = 100)	Laparoscopic (n = 94)	
Male	59 (59)	56 (60)	.94
Age, y, mean (SD)	56.7 (12.8)	59.1 (12.8)	.80
Preoperative BMI, mean (SD)	29.3 (4.6)	28.3 (4.7)	.81
Primary incisional hernia	82 (82)	71 (76)	.27
Recurrent incisional hernia	18 (18)	23 (24)	
Hernia diameter, cm, median (IQR)	5 (4-10)	5 (4-8)	.44
ASA class			.43
I	25 (25)	21 (22)	
II	52 (52)	56 (60)	
III	19 (19)	12 (13)	
IV	1 (1)	0	
Missing data	3 (3)	5 (5)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IQR, interquartile range.

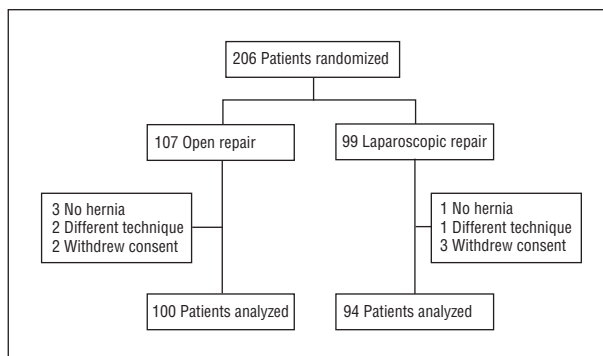
OPERATIVE RESULTS

Operative data for both groups are shown in **Table 2**. The mean operative time in the laparoscopic group was significantly longer than in the open group (76 minutes vs 100 minutes; $P = .001$). In the laparoscopic group, 8 of the 94 patients (8.5%) required conversion to open repair because of technical reasons. The estimated blood loss was significantly higher in the open group compared with the laparoscopic group (median, 50 mL vs 10 mL; $P = .05$). None of the patients required blood transfusion. Closed suction drains were placed subcutaneously in 45 patients in the open group and in the abdominal cavity in 3 patients in the laparoscopic group ($P < .001$).

The overall perioperative complication rate for laparoscopic repair (10%) was significantly higher than open repair (2%) ($P = .049$). The operative complications included enterotomy, serosal bowel injury, and bladder perforation. Postoperative complications occurred more often in the laparoscopic group; however, the difference in postoperative complications was not significant (35% vs 26%; $P = .13$). Important postoperative complications in both groups were hematomas, wound infections, airway infections, and urinary tract infections (**Table 3**). The median duration of hospital stay was similar in the laparoscopic and open groups (3 days [interquartile range (IQR), 2-4 days] and 3 days [IQR, 2-5 days] days, respectively; $P = .50$). Preoperative measured hernia size was equal in both groups (median, 5 cm [IQR, 4-10 cm] in the open group vs 5 cm [IQR, 4-8 cm] in the laparoscopic group; $P = .44$).

POSTOPERATIVE PAIN AND NAUSEA

There were no significant differences in preoperative and postoperative pain scores (**Figure 2**). During 4 weeks of follow-up, pain scores were similar. At the 4-week follow-up, 23 patients (25%) in the laparoscopic group and 24 patients (24%) in the open group reported persisting pain, requiring prolonged analgesia use ($P = .54$). Visual analog scale scores for nausea were also comparable for both groups.

**Figure 1.** Flowchart of patients in the study.**Table 2. Perioperative Outcomes**

Results	Open (n = 100)	Laparoscopic (n = 94)	P Value
Operative time, min, mean (SD)	76 (33)	100 (49)	.001
Estimated blood loss, mL, median (IQR)	50 (10-100)	10 (1-40)	.05
Conversion, No. (%)	...	8 (8.5)	...
Wound drain, No. (%)	45 (45)	3 (3)	<.001
Length of hospital stay, d, median (IQR)	3 (2-5)	3 (2-4)	.50

Abbreviations: ellipses, not applicable; IQR, interquartile range.

Table 3. Intraoperative and Postoperative Complications

	No. of Patients (No. of Complications)		P Value
	Open (n = 100)	Laparoscopic (n = 94)	
Intraoperative complications	2 (2)	9 (9)	.049
Serosal bowel injury	0	1 (1)	
Enterotomy	1 (1)	5 (5)	
Urinary bladder perforation	0	1 (1)	
Other	1 (1)	2 (2)	
Postoperative complications	26 (35)	35 (51)	.13
Wound infection	5 (5)	4 (4)	
Wound dehiscence	3 (3)	0	
Fascia dehiscence	1 (1)	0	
Hematoma	11 (11)	10 (11)	
Seroma	4 (4)	7 (7)	
Severe pain	0	12 (13)	
Airway infection	3 (3)	3 (3)	
Urinary tract infection	1 (1)	4 (4)	
Phlebitis	2 (2)	0	
Ileus	0	2 (2)	
Postoperative bleeding	1 (1)	2 (2)	
Relaparotomy	1 (1)	2 (2)	
Other	3 (3)	5 (5)	

FOLLOW-UP/RECURRENCE

At a mean (SD) follow-up of 35 (33.3) months after index surgery, 146 of 194 patients (75%) completed follow-up (**Figure 3**). Patients were examined at the outpatient clinic for the presence of incisional hernia in standing and decubitus positions. In case of doubt, ultrasonography or computed tomography scan was performed. Cumulative recurrence rates were 18% ($n = 17$).

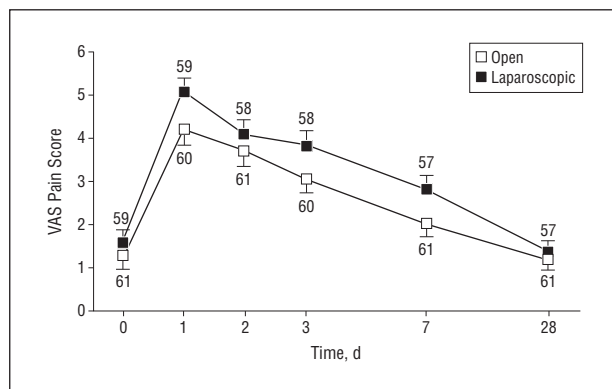


Figure 2. Visual analog scale (VAS) scores for postoperative pain. The numbers that are reported in the Figure indicate the number of patients evaluated at the different times. The error bars represent standard errors.

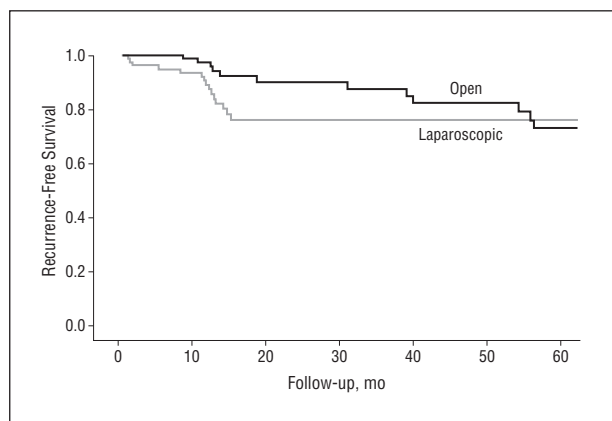


Figure 3. Follow-up for recurrence.

	Open (n = 100)	Laparoscopic (n = 94)	P Value
Follow-up, mo, mean (SD)	36.5 (33.1)	34.2 (33.5)	.40
Recurrence rate, No. (%)	14 (14)	17 (18)	.30 ^a

^aCalculated using the log-rank test.

in the laparoscopic group vs 14% (n = 14) in the open group (P = .30) (**Table 4**). Recurrence rates in the different hospitals ranged from 0% to 33%. There were no significant differences between centers regarding recurrence rates.

COMMENT

The underlying study is not the first evaluation of the value of laparoscopic incisional hernia repair. Earlier trials were either not randomized, enrolled small numbers of patients, or included varied study populations. To our knowledge, this multicenter study is the largest randomized controlled trial comparing laparoscopic and open incisional hernia repair.

In our study, laparoscopic incisional hernia repair was not associated with less postoperative pain and nausea compared with open incisional hernia repair. The operative time was significantly longer for laparoscopic re-

pair. Also, perioperative complications were significantly higher in the laparoscopic group. During a median follow-up period of 14 months, recurrence rates were comparable. Hernia size was, as previously reported, positively correlated with recurrence rates (P = .01).¹⁰

The basic techniques of laparoscopic incisional hernia repair have not been subject to major changes since their introduction in the early 1990s.¹¹ Prospective studies on operative and long-term results have led to improvement of techniques and implant materials. For example, after Halm et al¹⁶ reported high rates of adhesions and bowel resection associated with intraperitoneal use of polypropylene mesh, use of this technique became obsolete. Meanwhile, significant improvements have been achieved in research and development of less adhesive prosthetic materials.

For open incisional hernia repair, sufficient evidence exists to support the superiority of mesh repair over suture repair in terms of recurrences.^{9,17} Polypropylene is the most widely used material for open mesh repair and is most often placed in the sublay (retromuscular) position.¹⁸ A recent Cochrane review, however, yielded insufficient evidence as to which type of mesh or which mesh position (only or sublay) should be used.¹⁹ In the underlying trial, the use of mesh was mandatory for all incisional hernia repairs, frequently using polypropylene material in the sublay or intraperitoneal position.

Shorter operative time for laparoscopic incisional hernia repair was reported by a number of recently published studies,^{13,14,20,21} while other studies show no differences or longer operative times in the laparoscopic group.^{22,23} In small incisional hernia, introduction of trocars and positioning of instruments can be time-consuming. In the open technique, the hernia is often already reduced within this time. In the laparoscopic technique, the positioning and fixation of the mesh to the ventral abdominal wall can be time-consuming. A major factor that might have affected the operative time in the laparoscopic group was the extensive adhesiolysis in the midline of the abdominal wall. Adhesiolysis was necessary for positioning the mesh but also for observing any other small hernia or "Swiss-cheese" defects. A combination of these factors could possibly explain the significantly longer operative time in the laparoscopic group. One hundred minutes to perform a laparoscopic ventral incisional hernia repair, however, is reasonable and conforms to data from previous studies.^{13,14}

Several small randomized studies reported no differences in postoperative pain after laparoscopic and open incisional hernia repair.^{13,14,20} One trial reported reduced use of analgesics after laparoscopic repair.²¹ Postoperative pain after incisional hernia repair often originates not from the hernia itself, but from the surrounding tissues. Mesh fixation materials, eg, tackers or transfascial sutures, are believed to be responsible for postoperative pain.²⁴ The advantages of laparoscopy regarding surgical wounds and wound pain could possibly be offset by mesh fixation materials such as tackers and transfascial sutures.

Several studies have shown a shorter length of hospital stay after laparoscopic incisional hernia repair (1.5 vs 3 days).^{13,14,20-22} After laparoscopic surgery, patients are expected to mobilize and recover faster. This, however, could not be confirmed by our data since length of hospital stay was comparable for both groups.

Previous studies have not shown significant differences in recurrence rates for laparoscopic and open incisional hernia repair.^{13,14,20-22} Contrary to previous studies that reported recurrence rates up to 20% with mesh repair, there are some studies showing exceptionally low recurrence rates varying between 0% and 5%.^{9,13,14} In this study, recurrence rates were found to be similar for both groups at an overall rate of 17% (14% vs 18%; $P = .30$). These relatively high recurrence rates, compared with recent studies, could possibly be explained by obligatory clinical examination of all patients included in our study. Likewise, patients who did not report any complaints or symptoms of possible recurrence by questionnaire were also invited to the outpatient clinics. Another explanation could possibly be the smaller numbers of included patients in previously conducted studies, resulting in exceptionally low recurrence rates due to chance.

Based on this large randomized clinical trial, laparoscopic incisional hernia repair is an effective technique with recurrence rates comparable with open repair. Perioperative complications, however, were significantly higher after laparoscopic repair. Common advantages of laparoscopic surgery, such as reduced amount of blood loss and less wound drainage, also applied for this study. Despite the statistical difference in blood loss between the 2 techniques, the clinical significance is negligible. Short-term benefits of laparoscopic incisional repair described in previous studies, eg, perioperative complications, operative time, and length of hospital stay, could not be confirmed. Long-term results and data on cost-effectiveness are necessary to make a more complete comparison between the 2 operative techniques.

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