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COMPARISON OF CONVENTIONAL ANTERIOR SURGERY AND LAPAROSCOPIC SURGERY FOR INGUINAL-HERNIA REPAIR

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ABSTRACT

Background Inguinal hernias can be repaired by laparoscopic techniques, which have had better results than open surgery in several small studies.

Methods We performed a randomized, multicenter trial in which 487 patients with inguinal hernias were treated by extraperitoneal laparoscopic repair and 507 patients were treated by conventional anterior repair. We recorded information about postoperative recovery and complications and examined the patients for recurrences one and six weeks, six months, and one and two years after surgery.

Results Six patients in the open-surgery group but none in the laparoscopic-surgery group had wound abscesses ($P=0.03$), and the patients in the laparoscopic-surgery group had a more rapid recovery (median time to the resumption of normal daily activity, 6 vs. 10 days; time to the return to work, 14 vs. 21 days; and time to the resumption of athletic activities, 24 vs. 36 days; $P<0.001$ for all comparisons). With a median follow-up of 607 days, 31 patients (6 percent) in the open-surgery group had recurrences, as compared with 17 patients (3 percent) in the laparoscopic-surgery group ($P=0.05$). All but three of the recurrences in the latter group were within one year after surgery and were caused by surgeon-related errors. In the open-surgery group, 15 patients had recurrences during the first year, and 16 during the second year. Follow-up was complete for 97 percent of the patients.

Conclusions Patients with inguinal hernias who undergo laparoscopic repair recover more rapidly and have fewer recurrences than those who undergo open surgical repair. (N Engl J Med 1997;336:1541-7.)

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INGUINAL hernias are common, and although the results of surgical repair are often satisfactory, postoperative recovery may be slow, and the hernia may recur. The period of recovery after repair of inguinal hernia in patients with paid recovery time is four to six weeks in most Western countries.¹⁻⁴ Elimination of anxiety about resuming work could shorten the recovery, but this possibility has not been studied.⁵

Recurrence rates have ranged from less than 1 percent to more than 10 percent, with a follow-up of more than five years.^{4,6} These data should be viewed with some caution, however, because follow-up data are often incomplete and unreliable.^{4,7} Indeed, the overall recurrence rate in the Netherlands, the United Kingdom, and the United States and the results of large, prospective, controlled studies suggest higher rates (up to 15 percent after five years).^{3,7-9}

Laparoscopic techniques for the repair of inguinal hernias have recently been introduced,^{10,11} and in several small trials, these techniques proved superior to open repair in terms of postoperative pain and recovery.^{12,13} These studies were too small, however, to detect differences in recurrence rates.^{8,14-16}

We conducted a multicenter, randomized study to compare conventional anterior repair with extraperitoneal laparoscopic repair in terms of postoper-

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ative recovery, complications, and recurrence rates in patients with primary or first recurrent unilateral hernias.

METHODS

We selected teaching and nonteaching hospitals in rural and urban regions for this study. The sex and age distributions of the people living in these regions were similar to those in the Netherlands as a whole.¹⁷ The surgeons in participating hospitals enrolled patients in the study. The study was approved by the ethics committees at all the hospitals and by the Dutch Health Insurance Council, and all patients gave informed consent.

Characteristics of the Patients

Patients over 20 years old who presented with clinically diagnosed, unilateral inguinal hernias (primary hernias or first recurrences) who were scheduled to undergo surgical repair with general anesthesia were eligible for the study. Exclusion criteria were an additional surgical intervention planned during the hernia repair; a history of extensive lower abdominal surgery, severe local inflammation, or radiotherapy; advanced pregnancy (>12 weeks' gestation); and previous participation in the study (contralateral hernia). Patients who were mentally incompetent or not able to speak Dutch were also excluded.

Base-Line Studies

A standardized history was obtained, and a physical examination performed. Before randomization, the patients were told both orally and in writing that they should resume normal activity after surgery, including work and sports, when they felt able to do so. It was emphasized that this recommendation applied to both surgical techniques.

Random Assignment to Treatment Groups

The patients were randomly assigned to either conventional anterior repair or extraperitoneal laparoscopic repair, with the assignments made at a central office. Randomization was carried out by telephone, according to a computer-generated list, in groups of 25 or 50 patients; within each of these groups, the maximal allowable difference in the number of patients assigned to the two treatments was 4. To ensure an equal distribution of patients in the two treatment groups, they were stratified according to the hospital and the type of hernia (primary or first recurrent).

Surgical Techniques

All 87 surgeons and residents who performed hernia repairs using the conventional anterior approach were experienced in this technique or were supervised by an experienced surgeon. The repair consisted of a reduction of the hernia, ligation of the hernial sac, if necessary, and reconstruction of the inguinal floor with nonabsorbable sutures, if necessary. A mesh prosthesis was not used unless adequate repair was otherwise not possible.

Of the 87 surgeons and residents, 23 also performed laparoscopic repairs. They had ample experience with other laparoscopic procedures and acquired experience with this particular procedure under the supervision of experienced surgeons before they were allowed to participate in the trial.

The laparoscopic technique has been described elsewhere.¹⁸ It was usually performed with the patient under general anesthesia. Balloon dissection was used to develop the preperitoneal space without entering the abdominal cavity. Extensive lateral dissection was performed, with isolation and manipulation of the structures of the spermatic cord. A polypropylene mesh (10 cm by 15 cm) was placed over the myopectineal orifice. The mesh was not split and was not fixed in place. Patients were catheterized only if a full bladder was suspected. Prophylactic antibiotic therapy was not commonly given in either group.

Data Collection and Follow-up

Standardized data collection was performed by the attending resident or surgeon, and each patient was evaluated at the hospital monthly by a physician or data manager from the central study office. The hernia was classified as type I, II, III (subtype A, B, or C), or IV (subtype A, B, or C), according to the classification of Nyhus.¹⁹ The operation time was defined as the time from the first incision to the placement of the last suture.

We collected information about multiple operative and postoperative complications. The operative complications were bleeding from epigastric or testicular vessels, injury to the vas deferens, nerve injuries, peritoneal defects or defects in the hernial sac, pneumoscrotum, and technical defects of laparoscopic instruments or equipment. Cardiovascular complications during surgery were defined as a fall in the diastolic pressure to a level below 50 mm Hg or cardiac arrhythmia. Discontinuation of the original laparoscopic procedure in favor of either a transperitoneal laparoscopic procedure or a conventional procedure was also recorded as a complication.⁶

Postoperatively, all potential complications, such as hematoma, seroma, chronic pain, and wound infection, were assessed and documented. A serious wound infection was defined as the presence of pus or sanguinopurulent discharge at the operative site. A urinary tract infection or epididymitis was recorded only if antibiotic treatment was prescribed. Urinary retention was defined as an inability to urinate, requiring catheterization. Postoperative bleeding was recorded if compression was required to control it. The length of hospitalization, defined as the number of days in the hospital after the day of surgery, was also recorded. Patients were discharged from the hospital if there was no serious infection or bleeding, the patient was able to walk, and only oral analgesic therapy was required to manage pain.

The patients were requested to return to the outpatient clinic at one and six weeks; at six months; and at one and two years for a standardized history taking and physical examination by a resident and, in most cases, by the surgeon who had performed the surgery. The patients were asked to assess the severity of pain at the operative site every day for the first week and at two and six weeks, with the use of a 100-mm visual-analogue scale (scores ranged from 0, for no pain, to 100, for unbearable pain), and to record the use of analgesic drugs. Oral analgesia, initially acetaminophen (500 mg) or a nonsteroidal antiinflammatory drug, was given on request. Chronic pain was defined as pain in the groin, scrotum, or medial part of the thigh that was serious enough for the patient to mention at six months.

The activities of daily living were assessed with a questionnaire from a Dutch health survey,²⁰ modified to include questions applicable to patients who had undergone inguinal-hernia repairs. The scale ranged from 0 (worst score) to 100 (best score).²¹ The modified questionnaire was validated in 110 of the patients. The test-retest reliability was 0.89.^{21,22} The questionnaire was administered one day and one, two, and six weeks after surgery. The patients were also asked to record in a diary the dates on which they resumed normal daily activity at home, returned to work, and resumed their usual athletic activities.

Since differences in advice about returning to work after inguinal hernia repair may affect the validity of this end point,^{1,21,23} all study surgeons and other personnel were instructed to give the same advice about the resumption of work and other activities. In addition, the patients' physicians received a letter explaining the trial and stating that the patients should not limit their activities but do whatever they felt able to do.^{5,21} All patients were either visited or contacted by telephone by a member of the central study office, who was unaware of the treatment assignments, soon after discharge to explain the importance of keeping the diary and answer any questions about the follow-up and resumption of usual activities.

Home visits by experienced physicians were also conducted one and two years postoperatively if patients were unable or did not want to go to the hospital. Follow-up data were considered com-

plete only if they included the results of follow-up physical examinations by an experienced physician at the planned times.

End Points

The primary end point of the study was a recurrence of the hernia, defined as a clinically detectable swelling in the groin or a clearly palpable defect of the abdominal wall in the groin, diagnosed by two physicians. If a physician was unsure whether there was a recurrence, the physical examination was repeated or ultrasonography of the groin was performed.

The main secondary end point was time off from work, defined as the number of days between the day of surgery and the first day a patient returned to work, for all patients who were employed. All deaths were assessed in terms of immediate cause and the relation of the death to the hernia operation. The resumption of usual activities, the score on the activities-of-daily-living questionnaire, postoperative pain, and complications were additional secondary end points.

Statistical Analysis

In the main analyses, we compared conventional open surgery and laparoscopic surgery with respect to the interval between surgery and the diagnosis of a recurrence or the return to work. Data for all patients who were randomly assigned to a treatment group and underwent surgery were analyzed on an intention-to-treat basis. In this analysis, we did not include patients without hernias, those who withdrew their consent before undergoing surgery, those who at the time of surgery were found to be poor candidates for general anesthesia, and those who did not undergo the assigned operation because of a misunderstanding resulting in an unplanned open or laparoscopic repair. No interim analyses were performed.

Continuous, normally distributed data are expressed as means ±SD; other continuous data are expressed as medians with interquartile ranges. For the analysis of differences between groups, we used two-tailed t-tests or, if the results were not normally distributed, nonparametric tests. Chi-square or Fisher's exact tests were used to compare proportions. An analysis of variance for repeated measurements was performed to compare the pain scores for the two groups. Recurrence-free survival and the time to the resumption of normal activity (i.e., daily home activity, paid work, and sports) were analyzed with Kaplan-Meier survival curves, and differences between the two treatment groups were compared by the log-rank test. All reported P values are two-tailed.

RESULTS

We enrolled 1051 patients in the study between February 1994 and June 1995. During this time, 114 eligible patients were not enrolled: 74 refused to participate, 27 could not understand the protocol, and 13 were not enrolled for a variety of reasons. Of the 1051 enrolled patients, 31 (13 assigned to the open-surgery group and 18 assigned to the laparoscopic-surgery group) decided not to undergo surgery, in most cases because of the absence of serious symptoms. Only three of these patients have subsequently undergone surgery.

Eighteen patients (8 in the open-surgery group and 10 in the laparoscopic-surgery group) were excluded. Three of these patients had bilateral repairs, four were considered to be poor candidates for general anesthesia, and three were found not to have inguinal hernias at surgery. An additional eight withdrew informed consent: two wanted open repairs, three wanted laparoscopic repairs, two refused annu-

al follow-up, and one underwent surgery at another hospital. In addition, eight patients did not undergo the assigned procedure because of a misunderstanding between the central office and the surgeon, with six of the patients undergoing unplanned open repairs and two undergoing unplanned laparoscopic repairs.

Hence, our main analysis is based on data from 487 patients who underwent laparoscopic repairs and 507 who underwent open repairs. Randomization was successful, and the two groups were similar at base line (Table 1). A second analysis of recurrence rates included the 8 patients who did not un-

TABLE 1. BASE-LINE CHARACTERISTICS OF 994 PATIENTS WITH INGUINAL HERNIAS REPAIRED WITH OPEN OR LAPAROSCOPIC SURGERY.*

CHARACTERISTIC	OPEN SURGERY (N=507)	LAPAROSCOPIC SURGERY (N=487)
Age — yr	55±15	55±16
Sex — no. (%)		
Male	485 (96)	461 (95)
Female	22 (4)	26 (5)
Height — m	1.78±0.08	1.78±0.08
Weight — kg	78.0±10.3	77.9±11.8
ADL score†		
Median	94	94
Interquartile range	83–100	83–100
Paid work — no. (%)	278 (55)	266 (55)
Participation in sports — no. (%)	177 (35)	198 (41)
Primary hernia — no. (%)	447 (88)	432 (89)
First recurrent hernia — no. (%)	60 (12)	55 (11)
History of contralateral hernia — no. (%)	14 (3)	28 (6)
Clinical presentation — no. (%)		
Swelling in the groin	477 (94)	454 (93)
Discomfort or pain	423 (83)	416 (85)
Coincidental discovery	29 (6)	13 (3)
Potential risk factors for recurrence — no. (%)		
Chronic obstructive pulmonary disease	50 (10)	48 (10)
Benign hyperplasia of the prostate	25 (5)	37 (8)
Constipation	25 (5)	26 (5)
Strenuous activity	122 (24)	103 (21)
Characteristics of hernia — no. (%)		
Left-sided	245 (48)	243 (50)
Right-sided	262 (52)	244 (50)
Medial	267 (53)	259 (53)
Lateral	230 (45)	214 (44)
Unknown	10 (2)	13 (3)
Medial and lateral (pantaloon)	12 (2)	8 (2)
Scrotal	17 (3)	24 (5)

*Plus-minus values are means ±SD.

†ADL denotes activities of daily living.

TABLE 2. CHARACTERISTICS OF SURGERY AND OPERATIVE AND EARLY POSTOPERATIVE COMPLICATIONS.

CHARACTERISTIC	OPEN SURGERY (N=507)	LAPAROSCOPIC SURGERY (N=487)	P VALUE
Operation time — min			<0.001
Median	40	45	
Interquartile range	30–45	35–60	
	no. of patients (%)		
Anesthesia			
General	201 (40)	481 (99)	—
Spinal	306 (60)	6 (1)	—
Prophylactic antibiotics	16 (3)	7 (1)	—
Nyhus classification*			
Type I	45 (9)	25 (5)	—
Type II	129 (25)	199 (41)	
Type III			
A	121 (24)	95 (20)	
B	151 (30)	113 (23)	
C	1 (<1)	0	
Type IV			
A	36 (7)	24 (5)	
B	23 (5)	30 (6)	
C	1 (<1)	0	
Operative complications			
Switch to another surgical technique	—	24 (5)	—
Cardiovascular complications	1 (<1)	2 (<1)	0.62
Vas deferens injury	1 (<1)	1 (<1)	1.00
Arterial bleeding (clips or ligatures required)	2 (<1)	7 (1)	0.10
Balloon rupture during dissection	—	6 (1)	—
Use of extra trocar	—	2 (<1)	—
Broken instruments	0	2 (<1)	0.24
Postoperative complications			
Related death	0	0	—
Serious wound infection (abscess)	6 (1)	0	0.03
Wound infection requiring rehospitalization	2 (<1)	0	0.50
Urinary tract infection	2 (<1)	1 (<1)	1.0
Epididymitis	2 (<1)	3 (1)	0.68
Urinary retention	2 (<1)	5 (1)	0.28
Bleeding	1 (<1)	1 (<1)	1.00
Chronic pain	70 (14)	10 (2)	<0.001
Hematoma at 6 weeks	14 (3)	24 (5)	0.07
Seroma at 6 weeks	0	7 (1)	0.007
Pneumoscrotum at discharge from hospital	—	3 (1)	—

*Type I is an indirect hernia with a normal internal abdominal ring. Type II is an indirect hernia with an enlarged and distorted internal abdominal ring and an intact posterior wall. Type III is a hernia with a posterior-wall defect (A, direct; B, indirect [also pantaloon or scrotal]; or C, femoral). Type IV is a recurrent hernia (A, direct; B, indirect [also pantaloon]; or C, femoral).

dergo the assigned operation (for a total of 493 patients in the laparoscopic-surgery group and 509 in the open-surgery group).

Perioperative and Early Postoperative Results

The mean time from randomization to surgery was 33±36 days in the open-surgery group and 35±33 days in the laparoscopic-surgery group. In

the open-surgery group, a herniotomy with a high ligation of the hernial sac was performed in 21 patients (4 percent). This procedure was combined with a narrowing of the internal ring with sutures in 44 (9 percent), and a mesh prosthesis was inserted and a so-called tension-free repair performed in 15 (3 percent). The remaining 427 patients underwent hernioplasty, with a Bassini technique used in 147 patients (29 percent), a Shouldice technique in 112 (22 percent), a Bassini–McVay technique in 97 (19 percent), a McVay technique in 46 (9 percent), and various other, less well known techniques in the other patients. The number of operations per surgeon ranged from 1 to 33. In the laparoscopic-surgery group, the range was 1 to 74.

The Nyhus classification of the hernias and the operative and early postoperative complications in the two groups are shown in Table 2. The median duration of surgery was five minutes shorter for the conventional repair than for the laparoscopic repair. In the laparoscopic-surgery group, an open procedure was used in 20 patients and a transabdominal preperitoneal laparoscopic procedure was used in 4 (Table 3). During laparoscopic surgery, 115 patients (24 percent) had peritoneal tears, but in only 8 of these patients (7 percent) did the tear result in loss of pneumoperitoneum, requiring a switch to another technique. In 15 patients (3 percent), the epigastric vessels were ligated because they blocked the view of the surgeon; in 2 patients, these vessels were ligated after being injured during the insertion of a trocar. After surgery, 64 patients had a pneumoscrotum (13 percent), which disappeared within one day in all but 3 patients (Table 2). The most severe postoperative complications were serious wound infections in six patients in the open-surgery group (Table 2); two of these patients had to be rehospitalized.

Postoperative Recovery

The visual-analogue pain scores after surgery were lower in the laparoscopic-surgery group than in the open-surgery group (P<0.001), although the difference diminished with time (Fig. 1). Seventeen patients in the laparoscopic-surgery group and 27 in the open-surgery group did not record pain scores; complete data were available for 90 percent of the patients. On the day of surgery, 288 patients (59 percent) in the laparoscopic-surgery group did not require any analgesic drugs for postoperative pain, as compared with 165 patients (33 percent) in the open-surgery group. The proportions of patients not requiring analgesia were 88 and 82 percent, respectively, at one week and 92 and 91 percent, respectively, at six weeks.

The patients in the laparoscopic-surgery group were able to resume normal activity sooner than the patients in the open-surgery group (Table 4). Scores

on the activities-of-daily-living questionnaire, which were available for 98 percent of the patients, were higher in the laparoscopic-surgery group at all times.

Complications and Recurrences

The median follow-up was 607 days (interquartile range, 369 to 731). Recurrences were diagnosed in 31 patients (6 percent) in the open-surgery group and 17 (3 percent) in the laparoscopic-surgery group (P=0.05) (Fig. 2). There were 11 deaths in the open-surgery group and 6 in the laparoscopic-surgery group, all of which were unrelated to the hernia operation. All but 32 patients (3 percent) were examined in 1996.

Among the 17 patients in the laparoscopic-surgery group who had recurrences, 10 (59 percent) were operated on by surgeons who had just begun to perform the operation independently. Six of these 10 patients were operated on by one surgeon, and 3 of his subsequent patients had recurrences. Fourteen of the 17 recurrences (82 percent) in this group occurred within the first year after surgery, whereas in the open-surgery group 15 recurrences were diagnosed during the first year after surgery, and 16 during the second year. All but 12 of the 48 patients with recurrences subsequently underwent additional surgery, at which time the recurrence was confirmed.

The difference in the rates of recurrence between the two groups was similar (P=0.05) when the eight patients who did not undergo the assigned operation were included in the analysis.

DISCUSSION

The results of this study indicate that patients with inguinal hernias recover more rapidly and have fewer recurrences after laparoscopic repair than after open repair. The duration of surgery was only slightly longer (five minutes) with laparoscopic repair, providing little support for the widespread belief that this procedure is more time-consuming than open surgery. Nearly all the laparoscopic operations were performed with general anesthesia, whereas 60 percent of the open operations were performed with spinal anesthesia. The use of general anesthesia might be considered a disadvantage of laparoscopic repair. Nevertheless, the patients in the laparoscopic-surgery group were discharged from the hospital sooner and had less early and late postoperative pain than the patients in the open-surgery group.

The difference in the rates of recurrence in the two groups would appear to be clinically important. With prolonged follow-up, more recurrences may be expected in the open-surgery group,⁹ and these late recurrences may be prevented only by reinforcing the groin region with additional support.²⁴ A late recurrence after laparoscopic surgery may be uncommon because mesh is used routinely to reinforce the

TABLE 3. REASONS FOR A SWITCH TO ANOTHER SURGICAL TECHNIQUE DURING LAPAROSCOPIC REPAIR IN 24 PATIENTS.

REASON	TECHNIQUE USED	
	CONVENTIONAL	TAPP*
	no. of patients	
Loss of pneumoperitoneum	6	2
Adhesions	3	2
Intubation impossible	2	
Inadequate light	2	
Arterial bleeding	2	
Scrotal hernia	2	
Hernial defect too large	1	
Too much adipose tissue	1	
Pain during spinal anesthesia	1	

*TAPP denotes transabdominal preperitoneal laparoscopy.

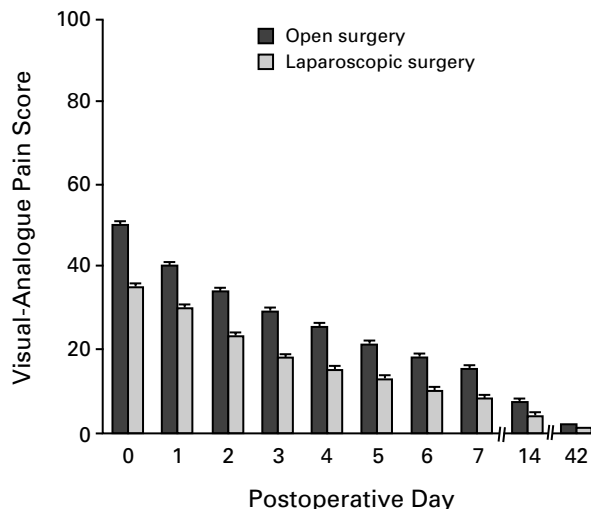


Figure 1. Mean (±SE) Visual-Analogue Scores for Postoperative Pain on the Day of Surgery, during the First 7 Days after Surgery, and at 14 and 42 Days in Patients with Inguinal Hernias Repaired with Open or Laparoscopic Surgery.

A score of 0 denotes no pain, and a score of 100 unbearable pain. Postoperative pain was less severe in the laparoscopic-surgery group (P<0.001).

groin region from inside. The rationale for covering the defect in the abdominal wall with mesh from inside is that the repair can better withstand the pressure to which it is subjected, which originates inside the abdomen.²⁵ The difference in recurrence rates in the two groups can therefore be expected to increase over time.

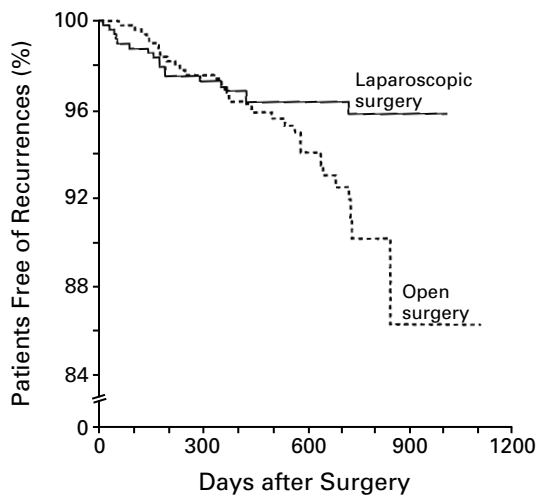
Early recurrences in general may be caused by

TABLE 4. POSTOPERATIVE RECOVERY IN THE TWO TREATMENT GROUPS.*

VARIABLE	OPEN SURGERY	LAPAROSCOPIC SURGERY
	median (interquartile range)	
Postoperative hospital stay (days)	2 (1–2)	1 (1–2)
Time to resumption of normal activity (days)	10 (6–16)	6 (4–10)
Time to return to work (days)	21 (12–33)	14 (7–21)
Time to resumption of athletic activities (days)	36 (24–44)	24 (14–38)
ADL score†		
At 1 day	39 (22–56)	50 (33–67)
At 1 week	72 (56–83)	83 (72–94)
At 2 weeks	83 (72–94)	94 (83–100)
At 6 weeks	83 (72–94)	94 (83–100)

*P<0.001 for all comparisons.

†ADL denotes activities of daily living.



NO. OF PATIENTS AT RISK		
Laparoscopic surgery	455	252
Open surgery	463	248
		9
		14

Figure 2. Kaplan-Meier Curves for Recurrence-free Survival in the Open-Surgery and Laparoscopic-Surgery Groups.

The median follow-up was 607 days (interquartile range, 369 to 731). The P value for the difference in the rates of recurrence between the two groups was 0.05 by the log-rank test.

technical errors.²⁶ All but three recurrences in the laparoscopic-surgery group occurred within one year after surgery, and in most cases, the patients had lateral hernias that had been overlooked. Insufficient lateral preperitoneal dissection, resulting in furled mesh, was another common mistake.¹⁸ Ten of the recurrences were in patients operated on by surgeons

who had limited experience with the laparoscopic procedure, and a single surgeon was responsible for 9 of the 17 recurrences. These findings clearly illustrate the danger of underestimating the skill and experience required to master this technique.

Physical examination during follow-up is indispensable for obtaining reliable data on rates of recurrence, because follow-up by telephone or mail is unreliable.^{4,7,8} Virtually all our patients (97 percent) had follow-up physical examinations performed by two experienced physicians, who made home visits to patients unable or unwilling to come to the hospital for follow-up. Although others^{4,7,27} have recognized the importance of physical examination after hernia repair, the percentages of patients examined during follow-up have usually been lower than in our study.

The patients returned to work sooner after laparoscopic repair than after open repair, as reported in several smaller trials.^{8,15} In our study, the difference was appreciable (a median of seven days). This difference may be explained by the absence of an inguinal incision, the absence of dissection of muscle in the groin during laparoscopic repair, and the tension-free repair, as well as by the lower complication rate.

It may be argued that a small group of surgeons who are interested in a particular procedure will always perform better than those who do not have this special interest and that different levels of experience should be taken into account when comparing our two groups of surgeons. Our surgeons were selected broadly, and the initial errors made by several of them indicate that they were not highly experienced. Within the group performing laparoscopic repairs and within the group performing conventional repairs, there were different levels of experience and skill.

Finally, the hospitals in our study were selected to obtain a representative cross-section of patients and surgeons in the Netherlands. This pragmatic approach may provide an answer to the question of whether the Dutch surgical community is capable of achieving better results overall with a laparoscopic approach than with the open approach currently used. The results of our trial will be used by the government to decide whether laparoscopic repair of inguinal hernias should be included as a reimbursable procedure in our health care system. Given the superior results of laparoscopic repair in terms of recovery and recurrence rates over time, and with the lessons of the learning curve kept in mind, a gradual introduction of laparoscopic hernia repair on a large scale seems warranted, but only if the procedure is supervised by experienced surgeons.

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