Recurrences After Conventional Anterior and Laparoscopic Inguinal Hernia Repair
A Randomized Comparison

Mike S. L. Liem, MD,[*] Eino B. van Duyn, MD,[*] Yolanda van der Graaf, MD,[†] Theo J. M. V. van Vroonhoven, MD,[*] and on behalf of the Coala Trial Group

From the *Department of Surgery, University Hospital Utrecht,
and †Julius Center for General Practice and Patient-Oriented Research, University of Utrecht, Utrecht, The Netherlands

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Abstract

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Objective

To study the long-term recurrence rate and other complications after conventional and laparoscopic inguinal hernia repair.

Summary Background Data

Reliable long-term follow-up of patients with inguinal hernias treated by laparoscopic repair techniques is lacking.

Methods

The authors performed a randomized, multicenter trial in which 487 patients with inguinal hernia were treated by totally extraperitoneal laparoscopic repair and 507 patients were treated by conventional anterior hernia repair. Patients were followed and examined for recurrence and chronic inguinal pain 2, 3, and 5 years after surgery. Risk factors for recurrence and chronic inguinal pain were assessed.

Results

Patients who underwent conventional repair had a high risk for recurrence compared to patients who underwent laparoscopic repair. Risk factors for recurrence were operative time and type of conventional repair. Predictive independent risk factors for chronic inguinal pain were conventional repair (Bassini repairs and non-bassini repairs), inguinal pain before surgery, and perioperative lesion of the ilioinguinal nerve.

Conclusions

Patients with inguinal hernia who undergo laparoscopic repair have fewer recurrences and less chronic inguinal pain than those who undergo conventional open repair. The Bassini repair produces unacceptably high recurrence rates.

Inguinal hernia repair is one of the most common operations performed, and both open and laparoscopic

techniques are used. Several randomized trials have compared both techniques but have not elucidated the place of laparoscopic inguinal hernia repair.[1] Patients with inguinal hernia treated with laparoscopic repair have less postoperative pain and fewer wound infections and return to normal activity and work sooner. However, open repair is less expensive and easier to learn.[2–5] The most important outcome after inguinal hernia repair, however, is recurrence rate. Most randomized trials have been too small to detect differences in recurrence rate, and follow-up is still short. Recurrences can be detected reliably by physical examination, but many patients are generally lost to follow-up. Reliable, complete long-term follow-up has not been reported yet.

Our large, multicenter randomized trial[3] found fewer early complications and chronic inguinal pain and fewer short-term recurrences among patients who underwent laparoscopic repair. We now report the long-term complications and recurrence rate to assess the role of laparoscopic inguinal hernia repair in our patients.

METHODS

Patients were enrolled in teaching and nonteaching hospitals in rural and urban regions between February 1994 and June 1995. Eligible patients had to have a unilateral, primary or first recurrent inguinal hernia. They had to be mentally competent, able to speak Dutch, fit for general anesthesia, and scheduled to undergo elective repair. Patients who were pregnant (>12 week gestation), who underwent another simultaneous surgical intervention, or who had a history of extensive lower abdominal surgery, severe local inflammation, or radiotherapy were excluded.

Randomization was performed before surgery by a central office, and patients were stratified according to hospital and the type of hernia (primary or first recurrent). The study was approved by the medical ethics committees of all hospitals and by the Dutch Health Insurance Council.

Surgical Technique

The open repair consisted of isolation and reduction of the hernia, ligation of the hernial sac and/or reconstruction of the inguinal floor, if necessary. A mesh prosthesis was used for the reconstruction if repair was otherwise insufficient. The laparoscopic technique was a totally extraperitoneal technique in which an unsplit 10 × 15-cm polypropylene mesh was placed without fixing it. During surgery the type of hernia was classified as type 1, 2, 3, or 4 according to the classification of Nyhus.[6]

Data Collection, Follow-Up, and Endpoints

Patients were asked to return to the outpatient clinic 2, 3, and 5 years after surgery. Collection of data was standardized and included a history and a physical examination. A swelling in the groin, pain or discomfort, and a disturbance of sense of touch of the groin, thigh, or scrotum were assessed. Disturbance of sense of touch was defined as a hypesthesia or hyperesthesia in the scrotal, inguinal, or thigh region. Chronic pain was defined as pain present in the groin, scrotum, or medial part of the thigh with or without a disturbed sense of touch that was mentioned by the patient and found at physical examination at the yearly follow-up visit, or discomfort with a disturbed sense of touch found at physical examination. Recurrence of the hernia was 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 the physician was unsure of a recurrence, physical examination was repeated or ultrasonography of the groin was performed. The immediate cause and the relation to surgery of all deaths were assessed.

An experienced resident or surgeon performed follow-up of all patients. To facilitate follow-up of patients, we asked them to visit during "inguinal hernia" office hours. Home visits were conducted for patients unwilling or unable to visit during these office hours. Follow-up was considered complete if it included the results of follow-up physical examination by an experienced physician at the planned times.

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. Data were analyzed on an intention-to-treat basis. All analyses were repeated with the inclusion of eight patients who did not undergo the assigned operation because of a misunderstanding resulting in an unplanned open or laparoscopic repair. If this second analysis was different from the first, it is mentioned in the results. Recurrence-free survival was analyzed with Kaplan-Meier survival curves, and differences between the two treatment groups were tested by the log-rank test.

Prognostic variables for recurrence were studied with multivariate Cox proportional-hazards regression. This regression yields a hazard ratio (HR), which may be interpreted as a relative risk within the average follow-up period. We included sex, age, presence of preoperative pain, conversion to another technique, perioperative and postoperative complications, Nyhus type, and type of conventional open repair. Conventional open repair was classified into two categories: open non-Bassini repair or Bassini repair.

To determine prognostic variables for chronic inguinal pain, we included sex, age, operative time, and perioperative and postoperative complications into a backward stepwise logistic regression analysis. For both prognostic models, variables of alleged biologic importance or whose univariate test had a P of less than .25 were included. [7]

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 exact tests were used to compare proportions. All reported P values are two-tailed.

RESULTS

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We enrolled 1,051 eligible patients in our study period. In this period we recorded 114 eligible patients who were not enrolled. [3] Of the 1,051 enrolled patients, 57 were not included in our main analysis for various reasons. [3] Hence, our main analysis involves 994 patients: 487 patients who underwent laparoscopic repairs and 507 who underwent open repairs (Table 1). In the open repair group, 147 patients underwent Bassini repairs. The remaining 360 patients underwent herniotomy with a high ligation of the hernial sac in 21 patients (6%), a combination of this procedure with a narrowing of the internal ring in 44 patients (12%), a Shouldice technique in 112 patients (31%), a Bassini-McVay technique in 97 patients (27%), a McVay technique in 46 patients (13%), a tension-free repair with mesh in 15 patients (4%), and various other techniques in the remaining 25 patients.

Table 1.PATIENT CHARACTERISTICS

Recurrences

The median follow-up was 44 months (interquartile range 28–50). Recurrences were diagnosed in 21 patients (recurrence rate at 2 years 3.8%; recurrence rate at 4 years 4.9%) in the laparoscopic group and in 43 patients (recurrence rate at 2 years 6.3%; recurrence rate at 4 years 10.0%) in the open surgery group (P = .006) (Fig. 1). A total of 719 patients were seen at 3 or 5 years of follow-up. There were 18 deaths (4%) in the laparoscopic group and 27 (5%) in the open surgery group. All deaths were unrelated to surgery or the placement of mesh. A complete follow-up was obtained in 83% of patients; 94% of patients were seen approximately 2 years after surgery. Further follow-up was not pursued after November 1999. Median follow-up in days and the number of

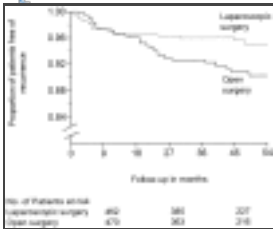deaths were comparable in both groups.

Figure 1. Kaplan-Meier curves for recurrences for patients operated in the open surgery (continuous line) and the laparoscopic surgery group (dotted line) (log rank; P = .006). Median follow-up: 44 months (interquartile range 28 to 50). The numbers **...**

Of the 21 recurrences in the laparoscopic group, 15 (71%) were diagnosed within 1 year after the operation. One surgeon was responsible for 10 of these 21 recurrences. In the open surgery group, 16 recurrences (4%) were diagnosed in the first year after operation. Twenty-three of 64 patients with recurrences underwent a second operation, at which time the recurrence was confirmed.

Risk Factors for Recurrence

Univariate analysis of prognostic variables is shown in Table 2. According to a Cox proportional hazards model, the HR comparing the risk of recurrence for the open non-Bassini group and the Bassini group with the risk of recurrence for the laparoscopic group was 1.64 (95% confidence interval [CI] 0.89–3.04) and 4.26 (95% CI 2.26–8.01), respectively. Operative time showed an adjusted HR ratio of 1.01 per minute (Table 3). No other significant prognostic variables were found.

Table 2. UNIVARIATE ANALYSIS FOR PROGNOSTIC VARIABLES OF RECURRENCE

Table 3. MULTIVARIATE COX REGRESSION ANALYSIS FOR PROGNOSTIC VARIABLES OF RECURRENCE

Chronic Pain

There were 93 cases with chronic inguinal pain, 69 after conventional and 24 after laparoscopic repair. Seventy patients complained of serious pain in the groin, scrotum, or thigh; 41 still had serious chronic pain at the last follow-up visit and 10 indicated it had lessened but was still present. The remaining 23 patients had discomfort with a disturbed sense of touch; 11 patients indicated this had disappeared at their last follow-up visit. Variables predicting chronic inguinal pain were inguinal pain before surgery (adjusted odds ratio 1.67, 95% CI 1.07–2.59), conventional repair (adjusted odds ratio 2.81, 95% CI 1.71–4.64), and lesion of the ilioinguinal nerve during surgery (adjusted odds ratio 1.95, 95% CI 1.01–3.78). None of the patients required surgery for these complaints (Tables 4,5).

Table 4. UNIVARIATE ANALYSIS FOR PROGNOSTIC VARIABLES OF CHRONIC PAIN

Table 5. MULTIVARIATE LOGISTIC REGRESSION ANALYSIS FOR PROGNOSTIC VARIABLES OF CHRONIC INGUINAL PAIN

We found a lower recurrence rate and less chronic inguinal pain in patients with inguinal hernias after laparoscopic repair than after conventional repair. However, between non-Bassini repairs and laparoscopic repairs, the difference in recurrence rate was not statistically significant.

These results confirm our belief that the difference in recurrence rates between the laparoscopic and conventional repair groups is expected to increase over time. The reason for this diverging trend may lie in the use and appropriate placement of mesh in laparoscopic repair. Reinforcement with mesh of the groin from the inside should not cause any recurrence when properly placed. Our comparison between laparoscopic repair with mesh and conventional repair without mesh has been criticized. An appropriate comparison of the laparoscopic repair should have been an open mesh repair.[8] The argument for this criticism is the allegedly common use of these types of repair.[9] These repairs have evolved because the learning curve for conventional mesh repair is shorter than for the laparoscopic repair, costs are lower, and there is accumulating evidence of high recurrence rates after nonmesh open repairs. In many Western countries, however, nationwide figures indicate that many surgeons still perform conventional repairs without mesh. Hence, our conventional group may still be an appropriate control for laparoscopic inguinal hernia repair.

The division of our conventional control group into Bassini repairs and non-Bassini repairs may find support from the recently published reports in which it became clear that Bassini repairs appeared to have unacceptably high recurrence rates.[10–13] We therefore analyzed these repairs separately as a risk factor for recurrence and found that the remaining conventional control group showed a trend toward a higher risk for recurrence, although it did not reach significance. This provides evidence that conventional non-Bassini repairs appear to have a lower recurrence rate than Bassini repairs.

In addition to our analysis, a meta-analysis, with a short follow-up for recurrences, comparing all laparoscopic versus all open repairs, including over 6,000 hernia repairs from 33 trials, including quasi-randomized, small studies, showed a similar point estimate with only slightly more precision than our trial and tended to favor laparoscopic repair.[1]

Other reasons for the nonacceptance of laparoscopic hernia repair may be cost, general anesthesia, and lack of long-term follow-up. Cost has been addressed extensively and will not be discussed here.[14–16] Long-term follow-up remains difficult to obtain as many patients undergoing hernia repair are lost to follow-up.[11,13] Long-term follow-up after inguinal hernia repair has been reported, but has always, deservedly, been viewed with caution.[17,18] Indeed, physical examination has frequently not been included. Only when recurrence has been assessed by physical examination can the recurrence rate of the study be considered reliable.[13] Therefore, we have not conducted telephone or mail surveys to improve our follow-up percentage because it would provide a false certainty on recurrence rates. Our study still has realized an unprecedentedly high follow-up percentage of 83% after 4 years.

Our analysis of recurrences per surgeon, in which one surgeon was responsible for nearly 50% of the laparoscopic recurrences, was not very different from our analysis of recurrences after 2 years.[3] It confirms that the learning curve may have been underestimated during the first year,[19] but that it has been overcome, because this particular surgeon caused only one additional recurrence during our prolonged follow-up. Nevertheless, adequate training by experienced surgeons might have prevented many of these early recurrences and would have demonstrated an even more favorable outcome for laparoscopic hernia repair.

Chronic inguinal pain has been found frequently and poses an interesting and important topic for the surgeon.[20–24] Perioperative lesion of the ilioinguinal nerve increases the risk for chronic pain. Therefore, routinely severing

this nerve may not be justified to obtain a better view of the operative field. Evidently, conventional repair results in an increased risk for chronic inguinal pain relative to laparoscopic repair, and this is another long-term advantage for laparoscopic repair.

Given the superior short-term results, our long-term lower recurrence rate, and fewer cases of chronic inguinal pain, laparoscopic repair is an excellent alternative to conventional nonmesh repairs. Therefore, nationwide transition of open repairs to laparoscopic repair of inguinal hernias should produce better overall results.

Appendix Other members of the Coala trial group are R. U. Boelhouwer and W. F. Weidema (Department of Surgery, Ikazia Hospital, Rotterdam), G-J. Clevers (Department of Surgery, Diakonessenhuis, Utrecht), W. S. Meijer (Department of Surgery, St. Clara Hospital, Rotterdam), A. J. P. Schrijvers (Julius Center for General Practice and Patient-Oriented Research), L. P. S. Stassen (Department of Surgery, Reinier de Graaf Gasthuis, Delft), and J. P. Vente (Department of Surgery, Hofpoort Hospital, Woerden).

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Footnotes

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Correspondence: Mike S. L. Liem, MD, Department of General Surgery, University Hospital Utrecht, G04.228, PO Box 85.500, 3508 GA Utrecht, The Netherlands

E-mail: s.l.liem.@wolmail.nl