Hernia (2013) 17:203–209
DOI 10.1007/s10029-012-0955-9

ORIGINAL ARTICLE

Long-term follow-up after incisional hernia repair: are there only benefits for symptomatic patients?

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Received: 7 October 2011 / Accepted: 13 June 2012 / Published online: 11 July 2012

Abstract
Introduction Incisional hernias are among the most frequent complications in visceral surgery and are currently considered to be an indication for surgery in all cases, regardless of the patient's symptoms. However, it still remains unclear to what extent surgery actually results in improvement according to objective (e.g., less pain or dysesthesia) or subjective criteria (e.g., less discomfort or better cosmetic result). The purpose of this prospective study was to identify patients who derive objective and subjective benefit from surgical repair.
Materials and methods This prospective study included patients who underwent open incisional hernia repair with mesh implantation from December 2006 to April 2009. Data were collected before and 18 months after surgery. Pain intensity was rated on the numerical analog scale (NAS) pre- and postoperatively. Patients were divided into oligosymptomatic (NAS 0–3) and symptomatic (NAS 4–10) groups based on their preoperative pain level, and the postoperative outcome of the two groups was compared by standardized questionnaire.
Results Ninety patients were prospectively enrolled, 45 (50 %) of each gender. Prior to surgery, 43 patients (47.8 %) were oligosymptomatic, and 47 (52.2 %) reported clinically relevant pain. Eighteen months after surgery, 7.5 % of the oligosymptomatic patients complained of clinically relevant pain; its rate remained unchanged. The symptomatic group showed a significant reduction in clinically relevant pain from 100 % to 14.0 %, ($p < 0.001$). The percentage of patients with clinically relevant dysesthesia was 12.5 % in the oligosymptomatic and 20.9 % in the symptomatic group 18 months postoperatively. The overall recurrence rate was 13.3 % after 18 months without difference in both groups. A reduction in discomfort in the surgical area was reported by 77.5 % of the oligosymptomatic and 79.1 % of the symptomatic patients.
Conclusions Symptomatic patients definitely profit from surgical repair in the long-term course. However, the notable postoperative rate of clinically relevant pain and dysesthesia in oligosymptomatic patients and their high recurrence rate cast doubt on whether they really benefit from surgical repair. The remarkable degree of subjective satisfaction in oligosymptomatic patients should not be underestimated.

Keywords Oligosymptomatic incisional hernia · Pain · Open mesh repair · Long-term course

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Introduction

Incisional hernia is one of the most frequent complications after abdominal surgery [1–4]. Its annual incidence exceeds 400,000 in the USA [5]. Despite the development of various tension-free techniques, incisional hernia repair is still associated with a high recurrence rate of 10–50 % [6–9]. Treatment of incisional hernias thus poses a significant surgical and socioeconomic challenge.

Up to now, surgical repair has been considered the only reasonable therapy for all incisional hernias, regardless of the symptoms. The most important reason given is the

relatively low risk of surgery compared to the potential risk of incarceration with serious complications. Furthermore, incisional hernias tend to enlarge, which makes their repair increasingly difficult.

In fact, the actual risk of incarceration in the entire vulnerable population is unknown due to the lack of a systematic trial in incisional hernia patients. Some smaller studies have reported acute incarceration as the indication for surgery in 6–14.6 % of incisional hernia repairs [10–12]. In our previous study, only 3.2 % of the patients developed acute incarceration requiring emergency repair [13].

Much more precise data are available for minimally symptomatic inguinal hernias in men. Fitzgibbons et al. found a low incarceration risk of 1.8/1000 patient-years in inguinal hernia patients observed for at least 2 years. Pain during normal activities did not differ between surgical repair and watchful waiting after a 2-year follow-up [14]. According to the European Hernia Society guidelines, surgical repair is no longer the only treatment option for minimally symptomatic inguinal hernias, and watchful waiting should be considered [15].

The low incarceration risk, the high risk of recurrence, and the clinically relevant rate of postoperative pain and discomfort [16, 17] raise the question of whether the general indication for surgical treatment of incisional hernias is justified.

In order to identify the patients who profit from surgical repair, we divided the total prospectively enrolled population into oligosymptomatic and symptomatic groups based on preoperative pain intensity. After a 6-month follow-up, we found that only symptomatic patients benefited from surgical repair in terms of pain reduction, whereas oligosymptomatic patients even experienced an increase in their pain level [13]. However, this increase could be due to normal postoperative pain, which can last longer than 6 months.

To find out whether these effects persist, we now report the long-term results in the same population (oligosymptomatic and symptomatic patients) 18 months after surgery.

Patients and methods

Patients

All patients who underwent elective incisional hernia repair with mesh in our department were prospectively enrolled in this trial. They were recruited from December 2006 to April 2009. Exclusion criteria included the following: trocar hernia, hernia size <3 cm (measured intraoperatively), suture repair of incisional hernia, under age 18, refusal to give informed consent, and a lack of cognitive ability to respond to the questionnaire. In order to determine which patients benefit from surgical treatment, the population was divided into oligosymptomatic and symptomatic groups based on preoperative pain intensity.

All incisional hernias were treated with a lightweight, partly absorbable polypropylene–polyglactin mesh (Vypro II®, Ethicon GmbH, Hamburg, Germany). The mesh overlapped the fascial margin by 5 cm on all sides and was fixed by 2.0 polypropylene sutures (Ethicon® GmbH, Hamburg, Germany). The peritoneum and anterior fascial layer were closed whenever possible without tension. The mesh was placed in the retromuscular space (sublay technique). The interventions were performed by 9 different surgeons (residents under the supervision of a consultant, fellows, consultants, and head of the department). All patients received antibiotic prophylaxis with 1.5 g of cefotiam intravenously 30 min before skin incision.

Methods

Prospective data collection and patient interviews were used to gather patient characteristics such as sex, age, body mass index, ASA score, hernia risk factors, time of manifestation of the hernia, hospitalization time, operating time, surgeon, surgical technique, and intraoperative hernia size. The hernia was diagnosed clinically in the majority of cases; ultrasound was used to clarify uncertain findings.

The patients were interviewed preoperatively at the time of admission. Early postoperative complications were detected by examining the patient during their hospital stay.

Pain intensity was determined by questionnaire before as well as 6 and 18 months after surgery. Pain was defined as “an unpleasant sensory experience, which was associated with actual or potential tissue damage, or described in terms of such damage” [18]. Pain in the surgical area was graded using the numerical analog scale (NAS) ranging from 0 (no pain) to 10 (greatest pain imaginable). The current classification system defined a NAS score of 1–3 as pain causing minor impairment and a score of >3 as pain causing clinically relevant impairment. Based on preoperative pain intensity, patients were classified into a group with little or no pain (NAS 0–3, hereafter referred to as “oligosymptomatic”) and a group with clinically relevant pain (NAS 4–10, hereafter referred to as “symptomatic”). The two groups were comparatively evaluated with regard to postoperative symptoms.

Dysesthesia was also rated on a numerical analog scale (NAS) from 0 (no dysesthesia) to 10 (greatest dysesthesia imaginable). Participants were asked to evaluate discomfort in the surgical area as postoperatively reduced, unchanged, or increased. Incisional hernia recurrences and mesh removals were determined. Satisfaction with the cosmetic result was rated on a scale from 0 (dissatisfied) to 10 (extremely satisfied).

Statistics

Continuous variables were expressed as means with standard deviations. Chi-square and Wilcoxon tests were used to detect possible differences between groups. A p value <0.05 was defined as significant. Statistical analysis was done using SPSS 18.0® for Windows® (SPSS, Chicago, Illinois, USA).

Results

Patient characteristics

Ninety patients, 45 females and 45 males, were prospectively enrolled in the study between December 2006 and April 2009. Their average age was 59.0 years (range 29–81, SD ± 12.0). Table 1 shows the characteristics of all patients divided into oligosymptomatic ($n = 43$) and symptomatic ($n = 47$) groups. A total of 49 incisional hernias occurred after median laparotomy (54.4 %), 15 after transverse laparotomy (16.7 %), 13 after pararectal incision (14.4 %), and 13 after costal margin incision (14.4 %). There were no significant differences between the prior surgery in both groups. 23.3 % of the oligosymptomatic and 25.5 % of the symptomatic patients had a hernia size less than 4 cm. The average hernia size was 8.0 cm in the oligosymptomatic and 7.3 cm in the symptomatic group.

Preoperative symptom status

The study population comprised 43 oligosymptomatic (47.8 %, NAS 0–3) and 47 symptomatic patients (52.2 %, NAS 4–10). Occasional pain was reported by 25.6 % in the oligosymptomatic and 36.2 % ($p > 0.05$) in the symptomatic group. Six (14.0 %) oligosymptomatic and seventeen (36.2 %) symptomatic patients experienced dysesthesia ($p = 0.016$).

Surgery and early postoperative outcome

The average operating time was 121 ± 50 min, and patients were hospitalized for 9.0 ± 4.3 days on the average. Early postoperative complications did not differ significantly between the two groups [13].

Patient response rate

Responses to the postoperative questionnaires were obtained from 87 of the 90 patients after 6 months and from 83 patients (92.2 %) after 18 months. Three patients died during follow-up, and four were lost to follow-up.

Postoperative pain and dysesthesia

Clinically relevant pain (NAS >3) was reported by 33.3 % of the oligosymptomatic and 35.4 % of the symptomatic patients 6 months postoperatively ($p > 0.05$). Three out of 40 (7.5 %) of the oligosymptomatic, and six out of 43 (14.0 %) of the symptomatic patients suffered from relevant pain 18 months after surgery. The percentage of patients with clinically relevant pain did not differ significantly between the two groups ($p > 0.05$) (Fig. 1). We found no correlation between pain intensity and hernia size.

The rate of clinically relevant pain remained unchanged in the oligosymptomatic group after 18 months (0 %

Table 1 Patient characteristics of all 90 patients included in the study (oligosymptomatic preoperatively: $n = 43$; symptomatic preoperatively: $n = 47$)

Patient characteristics	Oligosymptomatic	Symptomatic	Total
Males (*n*)	24 (55.8 %)	21 (44.7 %)	45 (50.0 %)
Age (years; Mean ± SD)	59.7 (±11.9)	58.3 (±12.0)	59.0 (±12.0)
Intraoperative hernia size <4 cm (*n*)	10 (23.3 %)	12 (25.5 %)	22 (24.4 %)
Intraoperative hernia size (cm; mean ± SD)	8.0 ± 5.2	7.3 ± 5.6	7.6 ± 5.5
ASA score 1 + 2	34 (79.1 %)	37 (78.7 %)	71 (79.7 %)
Obesity (BMI >30 kg/m^2) [*n*]	11 (25.6 %)	15 (31.9 %)	26 (28.9 %)
Diabetes mellitus (*n*)	9 (20.9 %)	10 (21.3 %)	19 (21.1 %)
Corticoid intake (*n*)	13 (30.2 %)	4 (8.5 %)*	17 (18.9 %)
Nicotine abuse >5 pack years (*n*)	28 (65.1 %)	38 (80.9 %)	66 (73.3 %)
Alcohol abuse (*n*)	7 (16.3 %)	2 (4.3 %)*	9 (10.0 %)
Liver cirrhosis (*n*)	2 (4.7 %)	2 (4.3 %)	4 (4.4 %)
Wound infection after primary surgery (*n*)	20 (46.5 %)	20 (42.6 %)	40 (44.4 %)
Chemotherapy after primary surgery (*n*)	5 (11.6 %)	7 (14.9 %)	12 (13.3 %)
Constipation (*n*)	13 (30.2 %)	11 (23.4 %)	24 (26.7 %)
COPD (*n*)	13 (30.2 %)	20 (42.6 %)	33 (36.7 %)
Malignant disease (*n*)	14 (32.6 %)	12 (25.5 %)	26 (28.9 %)

* $p < 0.05$ (oligosymptomatic vs. symptomatic)

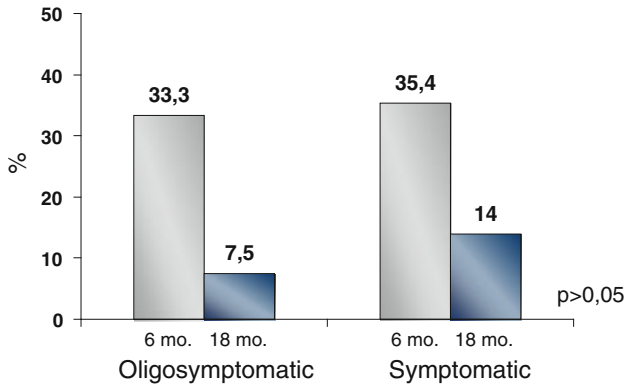

Fig. 1 Percentages of oligosymptomatic and symptomatic patients with clinically relevant pain (NAS 4–10) 6 and 18 months after surgery

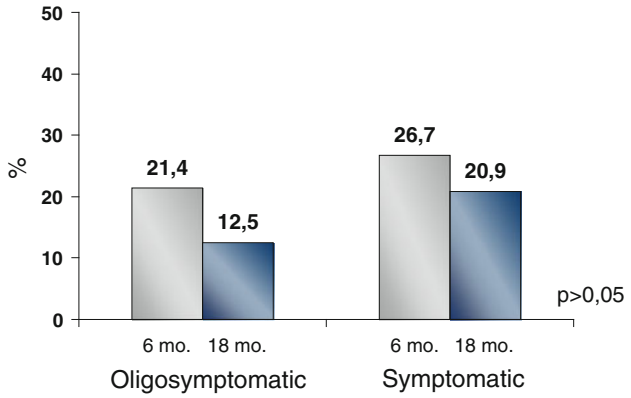

Fig. 2 Percentages of oligosymptomatic and symptomatic patients with clinically relevant dysesthesia (NAS 4–10) 6 and 18 months after surgery

before and 7.5 % after surgery) ($p > 0.05$), whereas the symptomatic group showed a significant reduction from 100 to 14.0 % ($p < 0.001$). In the long-term course, the rate of clinically relevant pain was significantly reduced in both groups: from 33.3 to 7.5 % in the oligosymptomatic group ($p = 0.01$) and from 35.4 to 14.0 % in the symptomatic group ($p = 0.013$).

Clinically relevant dysesthesia was reported by 21.4 % of the oligosymptomatic and 26.7 % of the symptomatic patients after 6 months. Five out of 40 (12.5 %) of the oligosymptomatic and nine out of 43 (20.9 %) of the symptomatic patients had dysesthesia after 18 months ($p > 0.05$). The rate of dysesthesia did not change significantly in either group (oligosymptomatic, 14.0 % preoperatively and 12.5 % postoperatively; symptomatic, 36.2 % preoperatively and 20.9 % postoperatively) (Fig. 2).

Subjective parameters

Discomfort was reduced in 77.5 and 79.1 %, unchanged in 7.5 and 2.3 %, and increased in 15.0 and 18.6 % of the

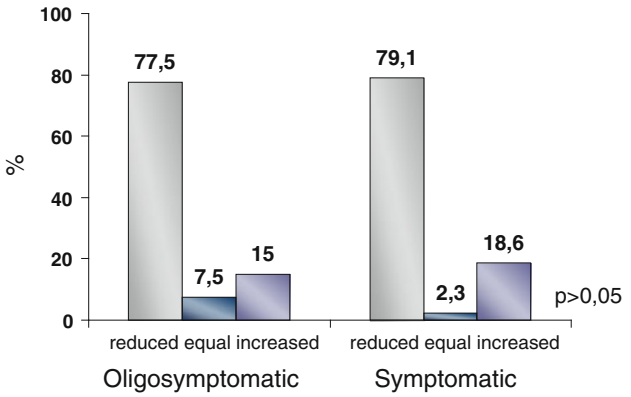

Fig. 3 Percentage of oligosymptomatic and symptomatic patients who rated their discomfort in the operated region as reduced, unchanged or increased 18 months after surgery versus before surgery

oligosymptomatic and symptomatic patients 18 months after surgery (Fig. 3). Satisfaction with the cosmetic result was given a median rating of 8 by both groups.

Recurrences and mesh removals

There were 5 recurrences (12.5 %) in oligosymptomatic and 6 recurrences (14.0 %) in symptomatic patients. Recurrence rate was seven out of 60 (11.7 %) with mesh augmentation (closure of the anterior fascia) and four out of 23 (17.4 %) with bridging (no closure of the anterior fascia) ($p > 0.05$). There was a correlation between hernia recurrence and long-term pain: four out of 11 patients (36.4 %) with hernia recurrence suffered from long-term pain and five out of 72 patients (6.9 %) without hernia recurrence suffered from long-term pain ($p < 0.05$). One mesh had to be explanted in each group, the reason being dislocation in the oligosymptomatic and mesh infection in the symptomatic group.

Discussion

Incisional hernias are among the most frequent postoperative complications in abdominal surgery [1–4] and pose a significant surgical and socioeconomic challenge. According to current literature, surgical treatment is indicated for all incisional hernias regardless of the patient's symptoms. This recommendation is based on the potential risk of incarceration. However, data are lacking on the incarceration risk of incisional hernias. There is no systematic trial available that has observed a population with incisional hernia and assessed its risk of incarceration. Our study group found that 3.2 % of acute incarcerated incisional hernias required emergency repair [13].

A recent Cochrane analysis disclosed a high recurrence rate even after mesh implantation and showed that postoperative pain is quite common [19]. The low incarceration risk, the high risk of recurrence, and the relevant rate of postoperative pain and discomfort suggest that the general indication for surgical treatment of incisional hernias should be critically reconsidered.

Our evaluation of this patient population 6 months after surgery demonstrated that symptomatic patients definitely benefited from surgical repair. Oligosymptomatic patients, however, reported even more pain 6 months after repair, and the benefit from surgical repair was doubtful [13]. Since wound healing and remodeling processes are not finished after 6 months, and postoperative pain tends to decrease in the long-term follow-up [20], we performed a follow-up to evaluate the development of objective and subjective parameters after 18 months.

Thus, the purpose of this prospective study was to assess whether surgical repair really benefits oligosymptomatic and symptomatic patients.

Postoperative pain and dysesthesia

After 6 months, one-third of oligosymptomatic and symptomatic patients reported clinically relevant pain. After 18 months, the proportion of patients with clinically relevant pain decreased significantly to less than 10 % in the oligosymptomatic group and 14 % in the symptomatic group. The significant decrease in pain in both groups is probably due to remodeling and healing processes and part of the normal long-term postoperative development.

We found a similar result in inguinal hernia surgery. In patients who underwent minimally invasive inguinal hernia repair (TEP), we detected a significant drop in the rate of clinically relevant pain (NAS 4–10) from 10.3 % after 12–36 months to less than 3 % after more than 36 months [20]. Van Veen also found that pain interfering with daily activities was significantly decreased in the long-term course after open inguinal hernia repair with or without mesh. Pain was reported by more than 10 % of patients after 6 months and by 6 % after 24 months, and no patient had pain interfering with daily activities after more than 10 years [21]. These findings support the hypothesis that remodeling and healing are still in progress and that observation for more than one year is necessary to obtain reliable results and rule out "normal postoperative pain."

This study does not attempt to explain the factors that lead to a relevant change in pain levels. Chronic postoperative pain is a complex and multifactorial process. A systematic review identified depression, psychological vulnerability, stress, and late return to work as factors that negatively influence the occurrence of postoperative pain [22].

Interestingly, the development of pain is different in both groups. The oligosymptomatic patients experience an early postoperative peak of their pain level and a significant drop in the long-term course. Still, one out of 13 patients suffered from relevant pain after 18 months, and none of them had clinically relevant pain before surgery. The benefit of surgical repair might be doubtful in oligosymptomatic patients in terms of pain.

Symptomatic patients show a significant drop in relevant pain. There is no difference in pain level between both groups postoperatively. Hence, there is no doubt that the symptomatic patients benefited from surgical repair.

Dysesthesia remained unchanged in oligosymptomatic patients after 6 and 18 months. Moreover, the rate of dysesthesia did not decrease in the long-term course. A notable percentage of patients (oligosymptomatic, 12.5 %; symptomatic, 20.9 %) suffered from clinically relevant dysesthesia after 18 months.

These findings are similar to those we obtained after endoscopic inguinal hernia repair in the long-term course. Dysesthesia was reported by 19.6 % after 12–36 months and by 19.2 % after 61–96 months [20]. Hallén et al. also found that the rate of dysesthesia in patients who underwent inguinal hernia repair with mesh was not lower after 7 years than after 1 year [23]. Data are lacking on dysesthesia after incisional hernia repair. Results obtained in this trial support the assumption that dysesthesia and pain should be regarded as separate phenomena. In contrast to pain, dysesthesia seems to be rather stable in the long-term course.

Discomfort and cosmetic results

The vast majority of patients in both groups reported a reduction in their discomfort after 18 months (oligosymptomatic, 77.5 %; symptomatic, 79.1 %). Satisfaction with the cosmetic result was also rated favorably with a median of 8 in both groups.

Surprisingly, both groups had the same subjective impression of the benefit derived from surgical repair. One could assume that patients' evaluations are more modest in the long-term postoperative course. In an older patient population with high co-morbidity and open repair, the high level of satisfaction with the cosmetic results may be attributed to the fact that appearance does not seem to play a major role. Still, the subjective satisfaction of patients with the operative result favors surgical repair.

Recurrences and mesh removals

As demonstrated by our 6-month follow-up results, the early postoperative complication rate was low in both

groups [13]. However, the recurrence rate after 18 months was clinically relevant at 13.3 % and did not differ between oligosymptomatic and symptomatic patients. Furthermore, one mesh had to be explanted in each group. This could be attributed to the high comorbidity of the patients. As shown in Table 1, a relevant percentage of patients had risk factors for hernia recurrence. Three out of four patients had a nicotine abuse of at least 5 pack years. More than one out of three patients suffered from COPD, nearly 30 % were obese, more than 20 % had diabetes, nearly 20 % took corticoids, and 10 % had alcohol abuse.

A recent Cochrane review reported a recurrence rate of only 4.2 % after open repair (15/326 cases) [24]. However, this review included both ventral and incisional hernias, which are separate entities and have different recurrence rates. The follow-up period was rather short (<2 years in 4 out of 9 trials included).

A Spanish study group found a comparable recurrence rate of 9.7 % after a 1-year follow-up in patients who underwent open incisional hernia repair [25]. Luijendijk et al. reported a 23 % recurrence rate following mesh repair after a follow-up period of 3 years [26].

All these results show that, even with mesh, the problem of recurrence after incisional hernia repair has not yet been solved.

Summary

The main objective of this trial was to compare the pre- and postoperative proportion of incisional hernia patients with clinically relevant pain in order to identify those that benefit from surgical repair. We ruled out "normal postoperative pain" by conducting an interview 18 months after surgery.

Not surprisingly, symptomatic patients profit from surgical repair. They have a significantly lower rate of clinically relevant pain and less discomfort in the surgical area, and they are highly satisfied with the cosmetic result.

The trial focused particularly on oligosymptomatic patients. Here, the objective findings are less satisfactory. Although clinically relevant pain is experienced by fewer patients in the long-term course, it was entirely absent in these patients before surgery but still persists in 7.5 % of them even after 18 months. This group of patients had a 12.5 % rate of persistent dysesthesia; a recurrence rate of 12.5 %, and one mesh removal. Promising results were obtained using subjective criteria: More than three out of four patients reported less discomfort in the surgical area, and the majority were also satisfied with the cosmetic result.

The findings obtained in this study suggest that the general indication for surgery should be critically reconsidered in patients with oligosymptomatic incisional hernias. However, the patient population is too small to draw definitive conclusions regarding the benefit of surgical repair. Moreover, the outcome of the alternative to surgical repair—watchful waiting—has yet to be studied in a prospective setting.

To compare watchful waiting with surgical repair for treatment of oligosymptomatic incisional hernias, we have initiated a large randomized controlled multicenter trial this year [27].

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