Original article

Recurrence rate after absorbable tack fixation of mesh in laparoscopic incisional hernia repair

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Background: The mesh fixation technique in laparoscopic incisional hernia repair may influence the rates of hernia recurrence and chronic pain. This study investigated the long-term risk of recurrence and chronic pain in patients undergoing laparoscopic incisional hernia repair with either absorbable or non-absorbable tacks for mesh fixation.

Methods: This was a nationwide consecutive cohort study based on data collected prospectively concerning perioperative information and clinical follow-up. Patients undergoing primary, elective, laparoscopic incisional hernia repair with absorbable or non-absorbable tack fixation during a 4-year interval were included. Follow-up was by a structured questionnaire regarding recurrence and chronic pain, supplemented by clinical examination, and CT when indicated. Recurrence was defined as either reoperation for recurrence or clinical/radiological recurrence.

Results: Of 1037 eligible patients, 84·9 per cent responded to the questionnaire, and 816 were included for analysis. The median observation time for the cohort was 40 (range 0–72) months. The cumulative recurrence-free survival rate was 71·5 and 82·0 per cent after absorbable and non-absorbable tack fixation respectively ($P = 0·007$). In multivariable analysis, the use of absorbable tacks was an independent risk factor for recurrence (hazard ratio 1·53, 95 per cent c.i. 1·11 to 2·09; $P = 0·008$). The rate of moderate or severe chronic pain was 15·3 and 16·1 per cent after absorbable and non-absorbable tack fixation respectively ($P = 0·765$).

Conclusion: Absorbable tack fixation of the mesh was associated with a higher risk of recurrence than non-absorbable tacks for laparoscopic mesh repair of incisional hernia, but did not influence chronic pain.

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Introduction

Laparoscopic incisional hernia repair is routine in many surgical departments[1–4]. The reinforcing mesh can be secured using tacks (non-absorbable or absorbable), transfascial sutures, fibrin glue, or a combination of fixation techniques. Tack fixation is often preferred because it is easy and effective[2,5]. The fixation technique may influence main outcomes such as hernia recurrence, chronic pain and other long-term surgical complications[6–9]. Evidence for the ideal fixation technique is limited[2,5,10–14].

This prospective, nationwide, registry-based study investigated the long-term risk of recurrence (clinical/radiological recurrence or reoperation) and chronic pain in patients who had laparoscopic incisional hernia repair with mesh fixation using absorbable or non-absorbable tacks.

Methods

The present nationwide cohort study included consecutive patients registered prospectively during a 4-year interval in the Danish Ventral Hernia Database (DVHD)[15]. Some of the patients included in the present study have been described in a previous report[4] on surgical risk factors for 30-day readmission, mortality and reoperation for recurrence.

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The DVHD is a national surgical database including more than 80 per cent of all ventral hernia repairs in Denmark[15,16]; it is mandatory by law to register all patients undergoing ventral hernia repair. Patients registered in the DVHD between 1 January 2008 and 31 January 2012 were recruited for the present study. Inclusion criteria were: primary laparoscopic repair for an incisional hernia with intraperitoneal onlay mesh, and mesh fixation by either absorbable or non-absorbable tacks. Patients whose mesh was fixed with only transfascial sutures or fibrin glue were not included. To achieve maximum information on reoperation for recurrence, data from the DVHD were supplemented with data from the Danish National Patient Register (DNPR). Patients who had emigrated, died or were lost to follow-up (no response to several mailed questionnaires or several telephone calls) were excluded. Furthermore, responders who had undergone a subsequent abdominal operation after incisional hernia repair, or declined clinical examination, were also excluded.

According to the information in the database all patients had a minimum mesh overlap of 4–5 cm. Information about the type of mesh was not reported consistently; however, all meshes were synthetic. Fixation of the mesh was performed with tacks (either absorbable or non-absorbable) without the support of sutures (registered in the DVHD). The number or product name of tacks used was not registered in the DNPR, but a double-crown technique with a distance of 0·5–1 cm between the tacks is recommended. The size of the hernia defect was recorded as the widest diameter (width and length) measured during surgery. The DNPR does not include information on patients' medication or co-morbidity, or grade of operating surgeon.

The primary endpoint of the present study was the cumulative recurrence rate. Recurrence was defined as reoperation for recurrence or clinical/radiological recurrence (as defined below). Secondary endpoints were moderate or severe chronic pain at the site of hernia/previous hernia, and predetermined risk factors for recurrence and chronic pain. The study was approved by the Danish Data Protection Agency (SN-33-2012) and the local ethics committee (no. SJ-315), and registered at ClinicalTrials.gov (NCT01740882).

Questionnaire and clinical follow-up

During November 2013 patients were sent a validated questionnaire concerning the possibility of hernia recurrence[17], supplemented with questions regarding chronic pain. The questionnaire was resent twice to non-responders, who were then contacted by telephone for up to three attempts. When indicated by the questionnaire response (suspicion or doubt of recurrence), patients were invited for clinical examination during December 2013 and January 2014. Body mass index (BMI) and smoking status was derived from patients' self-reported weight, height and smoking history.

Recurrence

The questionnaire employed had been validated previously, and had sufficient sensitivity (86 per cent) and specificity (78 per cent) to identify recurrence in Danish patients who underwent ventral hernia repair[17]. Patients were asked to register smoking status, height and weight at the time of hernia repair. Patients who reported suspicion of recurrence, but were unable to come to the hospital for review, were offered examination in their own home. These follow-up visits were done by one experienced surgeon. All patients gave written informed consent before clinical examination. CT was performed if the clinical examination was inconclusive. Recurrence was either clinically palpable or verified on CT as a fascial defect with protrusion of intra-abdominal contents[17].

Chronic pain

Patients were asked to rate the average degree of pain during the previous month using a verbal rating scale (VRS) (none, light, moderate or severe chronic pain). Chronic pain was defined as persisting moderate or severe pain during the previous month at the site of hernia repair. Patients were also asked to rate the impact of chronic pain on daily living, defined as leisure and work (rated as none, mild, moderate or severe impact).

Statistical analysis

This study was descriptive and exploratory in nature. A sample size calculation was therefore not possible. Data are presented as median (range) and percentages with 95 per cent c.i., unless stated otherwise. Observation time-adjusted estimates of hernia recurrence were calculated using the Kaplan–Meier method, presented as a survival function showing cumulative recurrence-free survival, and compared by means of the log rank test. Non-parametric Mann–Whitney *U* test was used to compare continuous variables, and Pearson χ^2 test for categorical variables. VRS data on chronic pain and impact on daily living were dichotomized into no chronic pain

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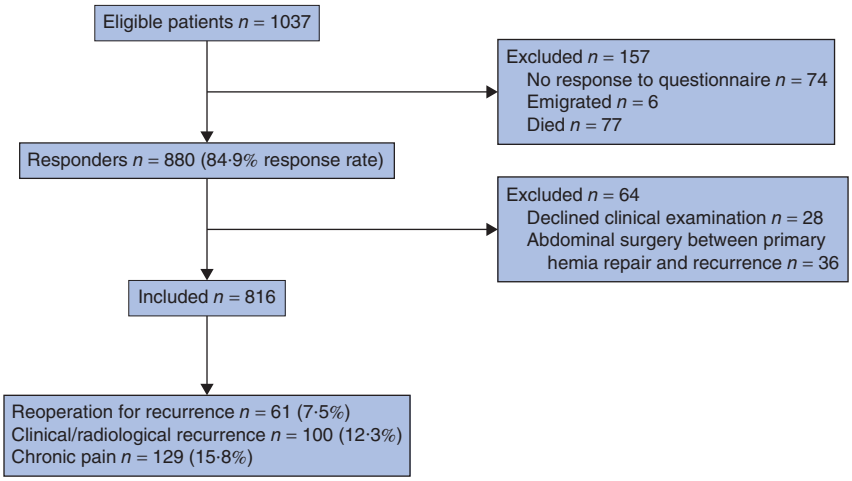

Fig. 1 Study profile

(none or mild) or chronic pain (moderate or severe). The potential association between chronic pain and reoperation for hernia recurrence or clinical recurrence was analysed by χ^2 testing. The log rank test was used for univariable analysis of risk factors for recurrence, and risk factors for chronic pain were evaluated using the χ^2 test. Univariable co-variables with $P < 0{\cdot}200$ were entered simultaneously into a multiple logistic regression or Cox regression model, as appropriate[18], with results expressed as odds ratios (ORs) and hazard ratios (HRs) respectively. Calibration of the logistic regression model was tested by means of the Hosmer–Lemeshow goodness-of-fit test. For the statistical analysis, age was divided into quartiles (18–50, 51–60, 61–70, more than 70 years), hernia size into tertiles (0–7, 8–15, more than 15 cm) and BMI into tertiles (15–25, 26–30, more than 30 kg/m^2). $P < 0{\cdot}050$ was considered significant.

Results

During the 4 years of inclusion, 1037 patients were eligible; 880 patients responded to the questionnaire (response rate 84·9 per cent), and 816 patients (275 who had hernia repair with absorbable tacks and 541 with non-absorbable

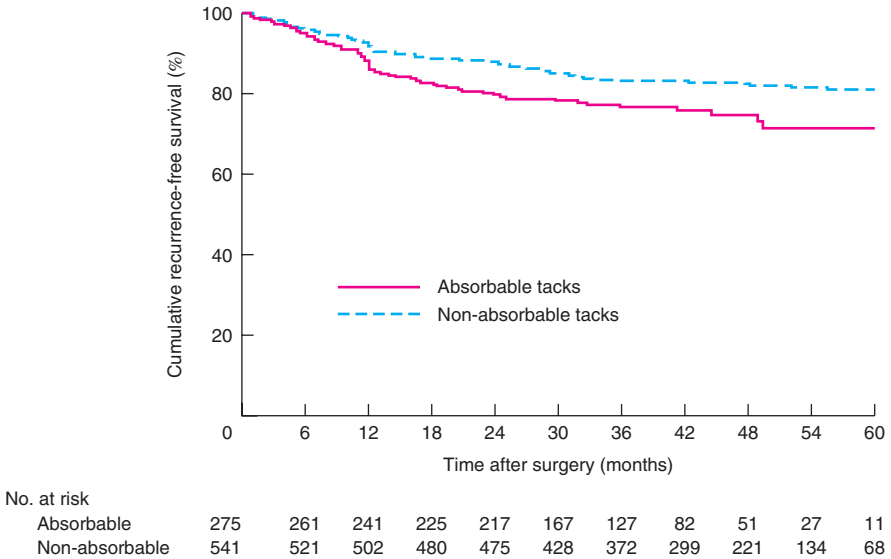

Fig. 2 Kaplan–Meier survival plot illustrating the cumulative recurrence-free survival rate (reoperation and clinical recurrence) after laparoscopic incisional hernia repair with mesh fixation using absorbable or non-absorbable tacks. $P = 0{\cdot}007$ (log rank test)

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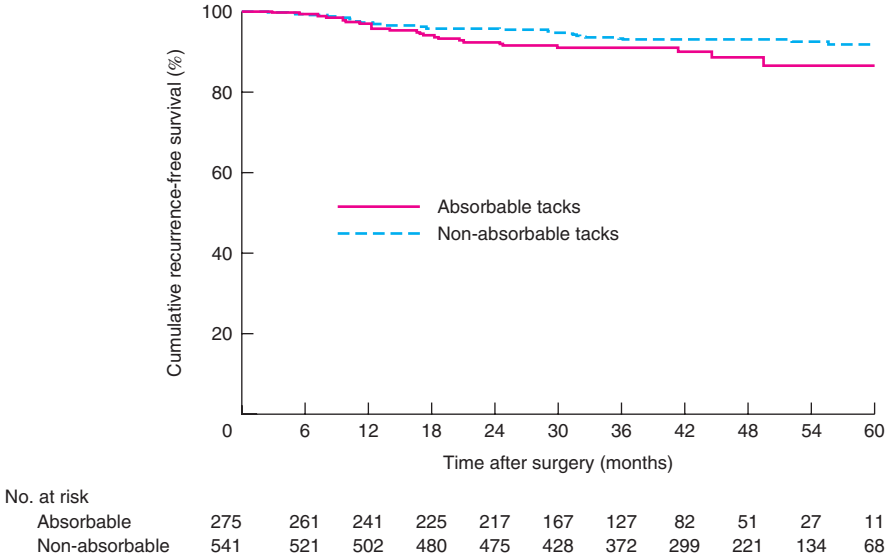

Fig. 3 Kaplan–Meier survival plot illustrating the cumulative reoperation for recurrence-free survival rate for laparoscopic incisional hernia repair with mesh fixation using absorbable or non-absorbable tacks. $P = 0{\cdot}072$ (log rank test)

tacks) completed follow-up, and were available for analysis (*Fig. 1*). Of these, 174 patients indicated suspicion of recurrence and were examined (18 in their own home and 156 in a local hospital). The overall median observation time for the cohort was 40 (range 0–72) months.

Recurrence

A total of 100 patients had hernia recurrence (diagnosed by clinical examination in 85 and CT in 15). The total cumulative recurrence-free survival rate in the cohort was 78·1 per cent. Recurrence-free survival rates were 71·5 and 82·0 per cent after repair with absorbable and non-absorbable tacks respectively ($P = 0{\cdot}007$) (*Fig. 2*). The intergroup difference became evident after the first year of follow-up.

Sixty-one patients had reoperation for recurrence alone (recurrence-free survival rates 86·5 and 92·5 per cent for patients with absorbable and non-absorbable tacks respectively; $P = 0{\cdot}072$) (*Fig. 3*). Follow-up was significantly shorter for the absorbable tack fixation group (median 34 *versus* 44 months; $P < 0{\cdot}001$); hernia size was significantly larger in the non-absorbable fixation group (largest median diameter 7 *versus* 9 cm; $P < 0{\cdot}001$) (*Table 1*).

Risk factors for recurrence

Smoking status, BMI, age, defect size and tack type were all tested for association with recurrence. The following co-variables ($P < 0{\cdot}200$) were included in the multivariable analysis: type of mesh fixation (absorbable *versus* non-absorbable tacks; $P = 0{\cdot}007$) and smoking status ($P = 0{\cdot}090$). In the multivariable analysis, the type of mesh fixation was the only independent risk factor, with a 53 per cent increased risk of recurrence when absorbable tacks were employed (HR 1·53, 95 per cent c.i. 1·11 to 2·09; $P = 0{\cdot}008$).

Table 1 Characteristics of patients undergoing laparoscopic incisional hernia repair

	Absorbable tacks ($n = 275$)	Non-absorbable tacks ($n = 541$)	All ($n = 816$)
Age (years)*†	61 (23–85)	61 (21–86)	61 (21–86)
Men	112 (40·7; 34·9, 46·5)	246 (45·5; 41·3, 49·7)	358 (43·9; 40·4, 47·2)
Hernia size (cm)*‡	7 (1–40)	9 (1–34)§	8 (1–40)
Body mass index (kg/m^2)*	28 (17–70)	28 (17–49)	28 (17–70)
Smoking status†	95 (34·5; 28·9, 40·1)	168 (31·1; 27·2, 35·0)	263 (32·2; 29·0, 35·4)
Duration of follow-up (months)*	34 (0–63)	44 (1–72)§	40 (0–72)

Values in parentheses are percentages with 95 per cent c.i. unless indicated otherwise; *values are median (range). †At time of primary hernia repair. ‡Longest diameter of hernia defect. §$P < 0{\cdot}001$ *versus* absorbable tacks (Mann–Whitney *U* test).

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Chronic pain

A total of 129 patients (15·8 per cent) reported chronic pain (90 reported moderate pain, and 39 severe pain) with no significant difference between the absorbable and non-absorbable fixation groups (15·3 *versus* 16·1 per cent; $P = 0·765$). Chronic pain affected daily work or leisure activity in 28 patients (10·2 per cent) in the absorbable tack group and 65 (12·0 per cent) in the non-absorbable tack group ($P = 0·753$). There were no significant differences in the rates of chronic pain between patients who had reoperation for recurrence or clinical recurrence among patients who had absorbable tack fixation (7 had chronic pain with reoperation for recurrence, 14 had chronic pain with clinical recurrence; $P = 0·603$) or non-absorbable tacks (15 *versus* 18 patients; $P = 0·268$).

Risk factors for chronic pain

Age, sex, defect size, tack type and recurrence/no recurrence were all tested for association with chronic pain. The following co-variables ($P < 0·200$) were included in the multivariable analysis: recurrence ($P < 0·001$) and age ($P = 0·010$). In the multivariable analysis, both recurrence and young age (18–50 *versus* 61–70 years) were independent risk factors for chronic pain. The risk of chronic pain was 52 per cent lower in patients aged 61–70 years than in those aged 18–50 years (OR 0·48, 95 per cent c.i. 0·28 to 0·84; $P = 0·010$). There was no difference in the rate of chronic pain between patients aged 18–50 years and the other age groups (51–60, and over 70 years). Recurrence increased the risk of chronic pain by threefold (OR 3·93, 2·59 to 5·94; $P < 0·001$).

Discussion

In the present study the overall recurrence-free survival rate was 78·1 per cent a median of 40 months after laparoscopic incisional hernia repair. Recurrence-free survival was significantly increased from 71·5 to 82·0 per cent when non-absorbable tacks were used to secure the mesh compared with absorbable tacks. However, the type of tack had no effect on chronic pain: 15·3 *versus* 16·1 per cent. Chronic pain had an impact on daily living in 11·4 per cent of the patients.

There are no previous large or long-term follow-up studies comparing absorbable with non-absorbable tacks. The recurrence-free survival rate in the present study was relatively low (78·1 per cent) compared with that in other studies[4,6,19–22] of laparoscopic incisional hernia repair (recurrence rates 0·8–16 per cent after 3–49 months). The fact that both reoperation and clinical/radiological recurrences were included may explain the high recurrence rate. This corresponds well with previous reports of a 4–5-fold underestimation of recurrence rates when reporting reoperation for recurrence alone[17]. Previous studies were often from hernia centres or hernia specialists, whereas the present study used nationwide data, covering all levels of surgical expertise. One retrospective study[21] described the use of non-absorbable tacks for mesh fixation in 159 patients with clinical or radiological follow-up and, after a median of 49 months, reported a similar recurrence rate of 20 per cent[21].

The present study investigated independent risk factors for recurrence; the type of mesh fixation (absorbable tacks) was the only independent risk factor here. The ideal fixation device should be strong and durable enough to prevent mesh migration and recurrence, without increasing the risk of chronic pain. Transfascial sutures and non-absorbable titanium tacks are equivalent in terms of hernia recurrence, but transfascial sutures are more time-consuming and may cause more postoperative pain[6,23–25]. Two systematic reviews[5,23], including four and 25 clinical studies respectively, found shorter operating time, less postoperative pain, and equal rates of recurrence and complications with use of non-absorbable tacks compared with transfascial sutures. Absorbable tacks and fibrin glue were developed in an attempt to decrease the risk of chronic pain and adhesions[7,11,26]. *In vitro* studies[11–13] suggested that non-absorbable tacks are significantly stronger (tensile strength) than absorbable tacks. Only one retrospective clinical study[10] compared the strength of absorbable *versus* non-absorbable tacks in a clinical setting. The study had short follow-up (10–14 months) and, as absorbable tacks disappear within 12–18 months[7,10,27], evaluation of recurrence after their use should extend beyond 1 year. In the present study, differences in recurrence rates between the two methods of tack fixation became evident after 12 months. Possible reasons why absorbable tacks are less effective could include less penetration. Furthermore, absorbable tacks are more expensive, which may limit the number of tacks used in each repair.

Few studies have investigated chronic pain after incisional hernia repair, and chronic pain was usually poorly defined[6,10,28–30]. The rate of moderate or severe chronic pain in the present study was high (15·3–16·1 per cent), with no significant difference between absorbable and non-absorbable tacks. The finding of no differences in chronic pain between patients who had reoperation for recurrence or clinical recurrence may be due to the small number of patients with moderate or severe pain. The rate of chronic pain after laparoscopic incisional hernia repair was roughly 7–8 per cent in other small-scale

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studies[6,28–30]. In the present study, hernia recurrence and young age (18–50 *versus* 61–70 years) were independent risk factors for chronic pain after incisional hernia repair, similar to chronic pain after umbilical and epigastric hernia repair[31], and inguinal hernia repair[32]. The present study had no information on preoperative pain levels, which could have influenced subsequent chronic pain[33], but there is no apparent reason to believe that the two mesh fixation groups should be different.

In the present study, follow-up was 10 months shorter in the absorbable tack group than in the non-absorbable tack group (34 *versus* 44 months). In addition, the absorbable tack group had significantly smaller hernia defects (7 *versus* 9 cm). Larger hernia defects tend to increase the risk of recurrence[4], and longer follow-up allows more recurrences to be detected[4,34]. Accordingly, if defect size and follow-up had been equally distributed in the two groups, the recurrence-free survival rate in the absorbable group may have been even lower.

Other potential limitations include that only patients who responded to the questionnaire (84·9 per cent) and only those who thought they had a recurrence were examined. However, the questionnaire has been validated previously for the purpose of hernia detection with a high sensitivity (86 per cent) and specificity (78 per cent)[17]. The present study was not a randomized trial, but it was based on data from a nationwide clinical database, enhancing its external validity[35]. There is no reason to believe that less experienced surgeons would be more likely to use absorbable tacks.

Definitive recommendations on the type of tack for optimal mesh fixation await large-scale controlled studies with a minimum of 2 years' clinical follow-up. Other potential early and late complications, such as ileus, mesh migration and infection, should be included in the evaluation.

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