Prospective Cohort Study

Functional outcomes in symptomatic versus asymptomatic patients undergoing incisional hernia repair: Replacing one problem with another? A prospective cohort study in 1312 patients

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ABSTRACT

Background: Incisional hernias can be associated with pain or discomfort. Surgical repair especially mesh reinforcement, may likewise induce pain. The primary objective was to assess the incidence of pain after hernia repair in patients with and without pre-operative pain or discomfort. The secondary objectives were to determine the preferred mesh type, mesh location and surgical technique in minimizing postoperative pain or discomfort.

Materials and methods: A registry-based prospective cohort study was performed, including patients undergoing incisional hernia repair between September 2011 and May 2019. Patients with a minimum follow-up of 3–6 months were included. The incidence of hernia related pain and discomfort was recorded perioperatively.

Results: A total of 1312 patients were included. Pre-operatively, 1091 (83%) patients reported pain or discomfort. After hernia repair, 961 (73%) patients did not report pain or discomfort (mean follow-up = 11.1 months). Of the pre-operative asymptomatic patients (n = 221), 44 (20%, moderate or severe pain: n = 14, 32%) reported pain or discomfort after mean follow-up of 10.5 months. Of those patients initially reporting pain or discomfort (n = 1091), 307 (28%, moderate or severe pain: n = 80, 26%) still reported pain or discomfort after a mean follow-up of 11.3 months postoperatively.

Conclusion: In symptomatic incisional hernia patients, hernia related complaints may be resolved in the majority of cases undergoing surgical repair. In asymptomatic incisional hernia patients, pain or discomfort may be induced in a considerable number of patients due to surgical repair and one should be aware if this postoperative complication.

1. Introduction

Incisional hernia is a common complication after abdominal surgery with incidence rates of more than 30% in high-risk patients, such as patients with abdominal aortic aneurysms and obese patients [1–4]. Incisional hernias may cause discomfort, pain, and an impaired quality of life [5]. Nowadays, mesh reinforcement is the preferred treatment for incisional hernia repair and for prevention in patients with a high risk for developing an incisional hernia [6,7]. However, mesh reinforcement has also been associated with chronic pain [8]. Moreover, among patients there is an increased resistance for the use of surgical meshes in general, due to negative reports in media (including social media). Is this negative view of the media on incisional hernia repair causing postoperative chronic pain justified? And, do we replace incisional hernia related pain with pain caused by hernia repair?

Several previous studies reported on the long-term incidence of pain or discomfort after primary and incisional hernia repair, reported incidences varying widely from 3% to over 61% [9–12]. These differences

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are likely explained by multiple factors, such as differences in assessment and different surgical techniques [12–14]. Additionally, pain is usually assessed as secondary outcome in studies with varying objectives. Therefore, the patient population may vary greatly in comparison to the general population of patients presenting with an incisional hernia.

Incisional hernia research mostly emphasizes on reducing recurrence rates, usually in relation to different mesh types and different surgical approaches. However, in contrast to inguinal hernia, the functional outcomes of patients who underwent incisional hernia repair are studied less frequently. Nevertheless, both outcomes are equally important to the individual and may aide in clinical decision-making, functional outcomes especially being of importance to patients with smaller incisional hernias who are either asymptomatic or have only minor complaints.

The primary objective of this registry-based study, was to assess the incidence of pain after incisional hernia repair in patients with and without pre-operative pain or discomfort.

2. Material and methods

This prospective cohort study was performed within the French Hernia-Club registry. The French Hernia-Club registry is approved by the French ‘Commission Nationale de l’Informatique et des Libertés’ (CNIL, registration number: 1993959v0) and complies to the General Data Protection Regulation. Because this study is registry-based and guarantees completely anonymized data, additional participant consent and approval were not required according to the French and Dutch national ethical standards. This study was conducted following the STROBE (Strengthening the Reporting of Observational studies in Epidemiology), STROCSS (Strengthening the Reporting of Cohort Studies in Surgery) statements, and the European Registry of Abdominal Wall Hernias (EuraHS) recommendations [15–17].

2.1. Study design

A registry-based, prospective cohort study was performed. Adult patients undergoing incisional hernia repair registered in the French Hernia-Club registry, between September 1, 2011 and May 22, 2019 were eligible for inclusion. For this study, patients were selected with a minimum follow-up of 3–6 months with available data on pre- and postoperative pain and discomfort. Two groups were defined:

- Patients without pre-operative discomfort or pain: asymptomatic patients.
- Patients with pre-operative discomfort or pain: symptomatic patients.

Patients were considered symptomatic if they experienced either pain, sensitive complaints (dysesthesia, hypesthesia), incarceration of the bowel, or discomfort not otherwise specified. At the end of follow-up, the incidence of postoperative pain or discomfort was compared in these groups.

2.2. Hernia-Club registry

The Hernia-Club registry is a collaborative, prospective, anonymized online database of all surgical procedures for primary and incisional hernias. French surgeons specialized in abdominal wall surgery performed all surgical procedures. Each participating surgeon must accept and sign the Charter of Quality, which states that: ‘all input must be registered in a consecutive, unselected and exhaustive manner and in real time.’ A total of 191 parameters were collected by the operating surgeon and the blinded, independent, clinical research associates, using online forms. Parameters comprise data from screening, pre-, peri-, and postoperative periods. Participants consent to random peer review of original medical charts to ensure high-quality data. The medical records were also checked in the case of any discrepancies. In case of discrepancy between what the patient reported and what is registered in the database, the original medical chart is reviewed with the operating surgeon and the last author (J.F. Gillion). All collected parameters in this database were fully compatible with the EuraHS international online platform, as well as the European Hernia Society (EHS) classification incisional abdominal wall hernias [17,18].

2.3. Data collection

Baseline patient characteristics extracted from the registry comprised age, sex, body mass index (BMI), smoking, diabetes mellitus, recent corticosteroid use, recent radiotherapy, recent chemotherapy, history of abdominal aortic aneurysm (AAA), connective tissue disorder, anticoagulant use or coagulopathy, history of ventral hernia, family history of hernia, American Society of Anesthesiologists (ASA) classification, presence of ascites, chronic cough, constipation and heavy lifting. With reference to pre-operative symptoms, the presence of pain, sensitive complaints (dysesthesia, hypesthesia, hyperpathia, hypoesthesia) or other (non-specified) discomfort were extracted.

Baseline hernia characteristics comprised presence of recurrent hernia, previous surgery with mesh, location of previous mesh (onlay, inlay, retromuscular sublay, preperitoneal sublay, intraperitoneal onlay), defect location in the midline (subxiphoid, epigastric, peri-umbilical, infra-umbilical, supraumbilicus), if applicable lateral defect location (subcostal, flank, iliac, lumbar) and width of the defect according to EHS width classification [18].

Surgical characteristics comprised of emergency procedure, incarc-eration, open or laparoscopic procedure, mesh position (onlay, inlay, retromuscular sublay, preperitoneal sublay, intraperitoneal, component separation, no mesh/suture closure), mesh fixation (suture, tacker/stapler, self-adhesive mesh), duration of surgery, Altemeier wound classification [19] and antibiotic treatment.

2.4. Outcomes

The primary outcome was the incidence of pain or discomfort after hernia repair. Pain was assessed at the outpatient clinic at two time points, between 3 and 6 months postoperatively and approximately 12 months postoperatively. If repeated measurements were present the last observation available was carried forward. If patients were willing to participate, a long-term follow-up questionnaire was performed after approximately two years. Patients received the questionnaire by telephone which was performed by an independent clinical research associate who was blinded for the used technique.

In this questionnaire, symptoms were specified with use of the 4 scales Verbal Rating Scale (VRS) (no pain, mild pain/discomfort, moderate pain, severe pain), presence of a sensitive scar, less sensitivity of the skin and other discomfort. Additionally, the presence of bulging, sensation of non-solid scar, the frequency of discomfort (rarely, weekly, daily), and functional limitations due to discomfort (no limitations, some limitations, severe limitations of general activities) were assessed.

2.5. Statistical analysis

Statistical analysis was performed with SPSS version 25 (IBM SPSS Statistics for Windows, version 25.0.0.1, IBM Corp, Armonk, New York). Continuous variables are presented as mean and standard deviation (SD). Discrete variables are presented as absolute numbers and percentages. Continuous variables were compared with a Student’s T-test or Mann Whitney U test, as appropriate. Discrete variables were compared with a chi-square test. The primary outcome, the incidence of pain and discomfort postoperatively, was compared between the pre-operatively asymptomatic and symptomatic patients, was reported as absolute numbers and percentages. Additionally, these proportions were
compared with a $X^2$ test.

Secondarily, to assess factors potentially associated with long-term postoperative pain and discomfort, uni- and multivariable logistic regression was used. For univariable logistic regression a complete case analysis was performed, including all variables of interest. To ensure maximized use of available data, multiple imputations were performed to compensate for missing data (0–8.3%), in advance of multivariable logistic regression. Multiple imputations were performed with ten imputations. Variables potentially associated with pain or discomfort after univariable analysis ($p < 0.2$) and variables of clinical interest were considered for multivariable analysis. Backward elimination was used to reduce the model. The saturated model was compared to the reduced model with likelihood ratio chi-square test. Variables with a strong mutual correlation were not fitted simultaneously. To prevent over-fitting a maximum of one variable was fitted for each ten events. Age appeared not linearly associated to the outcome, therefore age was fitted in 4 quartiles. Glue ($n = 8$) fixation and inlay mesh ($n = 5$) placement were rarely applied, therefore these cases were excluded from multivariable analysis. The $R^2$-value was used to assess the overall variance that could be predicted. A $p$-value of $< 0.05$ was considered statistically significant.

3. Results

A total of 1312 included patients underwent surgery for incisional hernia repair (Fig. 1). Pre-operatively, 1091 (83%) patients reported pain or discomfort (symptomatic patients). A total of 221 (17%) patients reported no pre-operative pain or discomfort (asymptomatic patients).

3.1. Patient baseline characteristics

All baseline patient characteristics are presented in Table 1. Patients who presented with a symptomatic incisional hernia were more likely to be female and had a slightly higher BMI, compared to asymptomatic patients (sex, male/female: 60.2/39.8% asymptomatic versus 45.2/54.8% symptomatic, $p < 0.001$; BMI: 27.9 kg/m$^2$ asymptomatic versus 29.5 kg/m$^2$ symptomatic, $p < 0.001$). Additionally, those patients who presented with a symptomatic incisional hernia more often had a recurrent hernia (31.1% asymptomatic versus 40.1% symptomatic, $p = 0.012$). Factors related to an increased intra-abdominal pressure such as chronic cough and constipation were more frequently reported by symptomatic patients, compared to asymptomatic patients (chronic cough: 7.9% asymptomatic versus 15.3% symptomatic, $p < 0.001$; constipation: 4.2% asymptomatic versus 7.8% symptomatic, $p = 0.06$).

3.2. Hernia characteristics

Hernia characteristics are presented in Table 2. Patients who presented with a symptomatic incisional hernia and who had received mesh surgery, slightly more often had received an intraperitoneal mesh (9.5% asymptomatic versus 16.7% symptomatic, $p = 0.01$). The proportion of patients who presented with a symptomatic hernia and who had received mesh surgery was equal for all other mesh locations, compared to the asymptomatic patients. With reference to hernia location the distribution of patients who presented with a symptomatic or asymptomatic incisional hernia appeared relatively equal. Slightly more symptomatic patients presented with a suprapubic hernia and slightly less with a epigastric hernia, compared to asymptomatic patients (suprapubic hernia: 3.8% asymptomatic versus 8.9% symptomatic, $p = 0.01$; epigastric hernia: 20.8% asymptomatic versus 14% symptomatic, $p = 0.01$). Of those patients who had a lateral hernia, patients with a subcostal lateral hernia more often reported pain or discomfort and patients with a iliac lateral hernia less often reported pain or discomfort at baseline (subcostal hernia: 2.8% asymptomatic versus 6.2% symptomatic, $p = 0.05$; iliac hernia: 15.7% asymptomatic versus 10.7% symptomatic, $p = 0.03$). With reference to the EHS width classification, slightly more symptomatic patients presented with a grade W3 hernia ($\geq 10$ cm), and slightly less with a grade W1 hernia ($< 4$ cm), compared to asymptomatic patients (W1 hernia: 54.9% asymptomatic versus 43.8% symptomatic, $p = 0.004$; W3 hernia: 9.3% asymptomatic versus 15.8% symptomatic, $p = 0.02$).

3.3. Surgical characteristics

Surgical characteristics are presented in Table 3. Almost all patients who received an emergency procedure were symptomatic incisional hernia patients. By definition, patients with a non-reducible incarceration were considered symptomatic, this occurred in 30 (2.3%) patients.

![Flowchart](image)

Fig. 1. Flowchart representing initially asymptomatic and symptomatic patients undergoing hernia repair.
In general, different surgical treatments, were evenly distributed among symptomatic and asymptomatic patients. In symptomatic patients undergoing mesh repair, suture fixation appeared to be used slightly more often, compared to asymptomatic patients (54% asymptomatic versus 65.6% symptomatic, p = 0.002).

### 3.4. Long-term postoperative pain and discomfort

The incidence of postoperative pain in relation to pre-operative symptoms is graphically summarized in Fig. 1. Detailed data on long-term postoperative pain and discomfort are presented in Table 4. Data on postoperative pain and discomfort was recorded after a mean of 11.1 ± 4.5 months. In initially asymptomatic patients who had received hernia repair surgery, 44 patients (20%, total n = 221) reported pain or discomfort after a mean of 10.5 ± 4.0 months. In initially symptomatic patients who had received hernia repair surgery, 961 patients (72%, total n = 135) patients (discomfort: 9.2% asymptomatic versus 18.7% symptomatic, p = 0.001). The initially asymptomatic patients who experienced pain or discomfort (n = 12), reported mild pain in 66.7% of cases. In comparison, those patients who were initially symptomatic and who were still experiencing pain or discomfort (n = 132), reported moderate pain in 25.8% of cases, and severe pain in 11.4% of cases. Additionally, those patients who were initially symptomatic reported more limitations in daily life due to their symptoms, this was only rarely reported in the initially symptomatic patients who experienced pain or discomfort (Table 5).

### 3.6. Factors associated with postoperative pain and discomfort

Results of multivariable logistic regression are summarized in Table 6. Results of univariable logistic regression are summarized in the Supplementary. Current data only provided very limited predictive potential with reference to long-term pain and discomfort (R²: 0.06). Factors that appeared associated with an increased odds for long-term postoperative pain and discomfort included presence of pre-operative pain and discomfort (OR: 1.79, 95%CI:1.19–2.65), mesh fixation with use of tackers or staplers (OR: 2.07, 95%CI: 1.02–2.54), test as appropriate.

### 4. Discussion

Today, it is almost unthinkable to repair an incisional hernia without using a mesh. The mesh is necessary to reinforce the abdominal wall and, subsequently, to prevent incisional hernia recurrence. In spite of the inevitability of mesh reinforcement, resistance against surgical meshes is also present among patients due to potential complications including pain and discomfort. However, considering current literature, there is a lack of evidence concerning the incidences of induced, reduced or maintained pain or discomfort after incisional hernia repair. Additionally, according to several hernia guidelines no recommendation can be made with respect to mesh placement and mesh fixation in reducing

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**Table 1**

Patient baseline characteristics for asymptomatic and symptomatic patients with an incisional hernia.

| Overall patients | Asymptomatic | Symptomatic | P     | N missing |
|------------------|--------------|-------------|-------|-----------|
| N                | 1312         | 221         | 1091  | 0.369     | 3         |
| Age (years)      | 65 SD 13.6   | 65.8 SD 13.5| 64.9 SD 13.6|          |           |
| Sex              |              |             |       |           |           |
| Male             | 626 (47.7)   | 133 (60.2)  | 493 (45.2) | < 0.001  |           |
| Female           | 686 (52.3)   | 88 (39.8)   | 598 (54.8) | < 0.001  |           |
| BMI (kg/m²)      | 29.2 SD 6.2  | 27.9 SD 6.1 | 29.5 SD 6.1 | < 0.001  | 24        |
| Current smoking  | 215 (17.7)   | 31 (15.6)   | 184 (18.1) | 0.39      | 97        |
| Diabetes mellitus| 224 (17.3)   | 36 (16.4)   | 188 (17.5) | 0.69      | 17        |
| Corticosteroids  | 52 (4)       | 8 (3.6)     | 44 (4.1)  | 0.75      | 17        |
| Radiotherapy     | 28 (2.2)     | 3 (1.4)     | 20 (1.9)  | 0.10      | 17        |
| Chemotherapy     | 138 (10.7)   | 24 (10.9)   | 114 (10.6) | 0.89      | 17        |
| History of AAA   | 9 (0.7)      | 2 (0.9)     | 7 (0.6)   | 0.66      | 7         |
| Connective tissue disorder | 2 (0.2) | 0 (0) | 2 (0.2) | 0.53 | 7 |
| Anticoagulant use or coagulopathy | 207 (16) | 34 (15.5) | 173 (16.1) | 0.81 | 17 |
| History of ventral hernia | 503 (38.5) | 68 (31.1) | 435 (40.1) | 0.01 | 7 |
| Family history of hernia | 11 (0.8) | 3 (1.4) | 8 (0.7) | 0.35 | 7 |

ASA classification

| I/II              | 952 (73.1) | 167 (75.6) | 785 (72.6) | 0.36 |
| III-IV            | 351 (26.9) | 54 (24.4)  | 297 (27.4) | 0.36 |
| Ascites           | 5 (0.4)    | 0 (0)      | 5 (0.5)    | 0.32 |
| Chronic cough     | 182 (14.1) | 17 (7.9)   | 165 (15.3) | < 0.001 |
| Constipation      | 95 (7.2)   | 9 (4.2)    | 84 (7.8)   | 0.06 |
| Heavy lifting     | 90 (7)     | 11 (5.1)   | 79 (7.3)   | 0.24 |

BMI: body mass index; AAA abdominal aortic aneurysm; ASA American Society of Anesthesiologists. Continuous variables are presented as mean and SD, discrete variables are presented as absolute number and (percentage). P for student T-test,fishers exact test or X² test as appropriate.
patients, the cosmetic appearance of the abdominal wall hernia is a more
symptomatic patients. Up to 28% of the latter may continue to experi-
ence complaints. Moreover, the initially symptomatic patients experi-
ence more severe symptoms after hernia repair compared to the initially
symptomatic patients. 

Based on the sample at hand, mesh repair was not significantly
associated with long-term pain either. However, patients with an inci-
sional hernia (Table 2).

Another interesting finding is the relationship between pre-operative
pain complaints and hernia location. Subcostal or suprapubic located
incisional hernias more often caused complaints compared to the other
hernia sites. An explanation could be found in the distribution of sensory
nerve fibers in relation to the length of the incisions. Another hypothesis
could be that the edges of the costal and pubic bones might provoke
more pain complaints, especially when exercising, due to the more static
nature of the bone in contrast to the high mobility of the abdominal wall
muscles.

Considering severity of reported symptoms in the present cohort, the
absence of pain or discomfort may be considered a relative but probably
not an absolute contra-indication for surgical hernia repair. For
example, if during conservative management a continuous increase of
the diameter of the incisional hernia is noted, repair may be considered.
Although, pain and discomfort, may be induced in approximately
10–20% of asymptomatic patients, reported complaints were usually
minor, i.e. mild pain in 66.7% of patients (n = 12) after a mean follow-
up of 24.1 months postoperatively. Aesthetic complaints, leading to
functional limitations may very well outweigh this risk in selected
patients.

Another reason to repair a ventral hernia is the risk for incarceration.
Previous studies reported prevalence rates of incarceration between
approximately 3 and 10% [22–24]. Mostly defects of approximately
3–4 cm in width appeared prone for incarceration [25]. In this respect,
for asymptomatic patients with multiple potential risk factors for
incarceration, elective hernia repair could be beneficial as a preventive
measure. In other non-complex ventral hernia patients, watchful waiting
is mostly considered a safe strategy [26–28]. However, one previous
study reported high crossover rates with significantly greater incidences
of intraoperative perforations, fistulas, emergency surgery, and mor-
tality due to watchful waiting [29]. Nevertheless, according to the
Guidelines for laparoscopic treatment of primary ventral and incisional
abdominal wall hernias, watchful waiting is recommended in patients
with modifiable risk factors [20].

Hitherto, no recommendations in surgical technique or surgical
accessory as suture, tacker, glue or mesh type could be made regarding
the incidence of chronic pain [20]. Considering our current results,
predicting the occurrence of chronic pain based on patient and surgical
characteristics appears difficult indeed. Although detailed information
was available concerning patient and surgical characteristics, it was not
possible to construct a model with sufficient predictive power, to sub-
stantiate any meaningful recommendations. Considering the observa-
tional design of current study, these associations must be interpreted
with great caution.

To the best of our knowledge, this is the first study based on pro-
spectively collected data primary investigating these issues in a large
sample of patients undergoing various surgical treatments for incisional
hernia. Based on the data of the present study, initially asymptomatic
incisional hernia patients who undergo surgical repair may develop pain
or discomfort in up to 20% of cases. Additionally, pain and discomfort
may not always be resolved by incisional hernia repair in initially
symptomatic patients. Up to 28% of the latter may continue to experi-
ence complaints. Moreover, the initially symptomatic patients experi-
ence more severe symptoms after hernia repair compared to the initially
asymptomatic patients.

Although the absence of pain or discomfort is considered a relative or
even absolute contra-indication for surgical hernia repair, for some pa-
tients, the cosmetic appearance of the abdominal wall hernia is a more
prominent reason to undergo hernia repair than pain [5]. Nevertheless,
in this patient group with no or limited hernia complaints, the risk of
inducing pain or discomfort due to surgical repair should be considered
when deciding to operate or not. Similarly, in initially symptomatic
patients, one should consider that surgical repair will resolve complaints
in the majority, but not in all treated patients.

Baseline patient characteristics in this cohort showed some inter-
esting differences between pre-operative symptomatic and asymptom-
atic patients. Patient with a symptomatic incisional hernia were more
likely to be female and were more likely to have a slightly higher BMI.
Factors related to an increased intra-abdominal pressure, such as
chronic cough and constipation, were also more frequently reported in
symptomatic patients (Table 1). These differences in sex and comor-
bidity with regard to pre-operative pain were previously reported and
warrant further investigation [21].

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tional design of current study, these associations must be interpreted
with great caution.

Based on the sample at hand, mesh repair was not significantly
associated with long-term pain or discomfort, as compared to suture
repair. Additionally, the position of the surgical mesh appeared not
associated with long-term pain either. However, patients with an inci-
sional hernia, who received an intraperitoneal onlay mesh (IPOM),
appeared to present slightly more often with a symptomatic incisional
hernia (Table 2).

In contrast, the method of mesh fixation appeared associated with
long-term pain and discomfort. According to the data presented in this
study, both the use of tackers and self-adhesive meshes were associated
with increased odds for long-term postoperative pain and discomfort. These observations have been previously hypothesized and reported.

From performing abdominal surgery under local anesthesia in the late 19th and begin 20th century, the parietal peritoneum is known to be intensively sensitive to pain [30]. New studies confirmed these early observations. Additionally, the parietal peritoneum is sensitive to pressure, touch, friction, cutting and temperature through innervation by the phrenic and sensitive spinal (lower thoracic) viscero-somatic nerves [31]. Attaching a mesh to the peritoneum with tackers, might stimulate these nerve fibers leading to pain sensation.

The mesh must be fixated on the abdominal wall to prevent migration and to maintain good contact between abdominal wall and mesh. Bansal et al. [32] compared suture mesh fixation versus tacker mesh fixation for laparoscopic repair of ventral hernias in a prospective randomized study. This study found, similar to the current observational report, that the use of suture fixation was more beneficial with respect to postoperative pain [32]. The authors hypothesized that tackers may cause increased incidence of pain due to the screwing mechanism of the sharp tips penetrating the tissue and thereby causing compression and twisting of nerve fibers [32]. Additionally, tackers are approximately seven times more costly compared to conventional suture fixation [33].

Until now, no pathophysiologic mechanism of self-adhesive meshes inducing postoperative chronic pain is known. Possibly, self-adhesive meshes may cause a peritoneal tissue reaction [34]. Self-adhesive meshes are relatively new and not studied thoroughly for ventral hernias repair. One retrospective single-arm cohort study of Kroese et al. [36] found that 9 out of 39 patients (23%) reported pain complaints (mean VAS = 1.7) after open complex abdominal wall hernia repair with the self-adhesive ProGrip™ mesh after a median follow-up of 25 months. However, no pain was reported by Bueno-Lledó et al. [35] six months after using self-adhesive ProGrip™ mesh in Rives-Stoppani repair.

Considering current outcomes, incisional hernia research should emphasize more on functional outcomes, in addition to treatment success in terms of recurrence rates. Pain and discomfort after prophylactic mesh reinforcement warrants further evaluation.

5. Limitations

This cohort study has several limitations. Pain and discomfort, although collected by standardized scores and questionnaires, remain subjective measurements and probably differ over time. Additionally, data on functional limitations as a result of pain and discomfort were only available in a subset of patients. Although data was collected in a prospective manner, this study remains observational, therefore causality of found associations cannot be confirmed. Therefore, current data

### Table 3

Surgical characteristics for asymptomatic and symptomatic patients with an incisional hernia.

|                         | Overall patients | Asymptomatic | Symptomatic | P  | N missing |
|-------------------------|------------------|--------------|-------------|----|-----------|
| N                       | 1312             | 221          | 1091        |    |           |
| Emergency procedure     | 55 (4.2)         | 2 (0.9)      | 53 (4.9)    | 0.01 | 8         |
| Incarceration           | 30 (2.3)         | 0 (0)        | 30 (2.8)    | 0.01 | 10        |
| Open procedure          | 1134 (87.4)      | 190 (87.2)   | 944 (87.5)  | 0.89 | 15        |
| Laparoscopic procedure  | 163 (12.6)       | 28 (12.8)    | 135 (12.5)  | 0.89 | 15        |
| Mesh position           |                  |              |             |    |           |
| Prefacial onlay         | 33 (2.6)         | 2 (0.9)      | 31 (2.9)    | 0.10 |           |
| Sublay (combined muscle) | 596 (46.1) | 113 (52.1)   | 483 (44.9)  | 0.05 |           |
| Intraperitoneal onlay   | 548 (42.4)       | 81 (37.3)    | 467 (43.4)  | 0.09 |           |
| No mesh                 | 110 (8.5)        | 21 (9.7)     | 89 (8.3)    | 0.5  |           |
| Mesh fixation           |                  |              |             |    |           |
| Suture                 | 749 (63.6)       | 109 (54)     | 640 (55.6)  | 0.002 |           |
| Tacker/stapler         | 278 (23.6)       | 55 (27.2)    | 223 (22.8)  | 0.18 |           |
| Self-adhesive           | 59 (5)           | 13 (6.4)     | 46 (4.7)    | 0.30 |           |
| No mesh                 | 110 (9.3)        | 21 (10.4)    | 89 (9.2)    | 0.57 |           |
| Duration of surgery, min | 94 SD 60 | 102 SD 77    | 93 SD 55    | 0.09 | 49        |

### Table 4

Discomfort between 3 and 12 months after surgery.

|                         | Overall patients | Asymptomatic | Symptomatic | P  | N missing |
|-------------------------|------------------|--------------|-------------|----|-----------|
| N                       | 1312             | 221          | 1091        |    |           |
| Follow-up (months)      | 11.1 SD 4.5      | 11.3 SD 4.5  | 0.016       | 62 |
| Any discomfort          | 351 (26.8)       | 44 (19.9)    | 307 (28.1)  | 0.01 | 0         |
| Discomfort specified    |                  |              |             |    |           |
| Sensitive scar only     | 32 (2.4)         | 4 (1.8)      | 28 (2.6)    | 0.05 |           |
| VRS mild pain/discomfort | 182 (13.9) | 22 (10)      | 160 (14.7)  |      |           |
| VRS moderate pain       | 78 (5.9)         | 12 (5.4)     | 66 (6)      |      |           |
| VRS severe pain         | 16 (1.2)         | 2 (0.9)      | 14 (1.3)    |      |           |
| Less sensitivity only   | 30 (2.3)         | 1 (0.5)      | 29 (2.7)    |      |           |
| Other discomfort        | 13 (1)           | 3 (1.4)      | 10 (0.9)    |      |           |

VRS: Verbal Rating Scale; Continuous variables are presented a mean and SD, discrete variables are presented as absolute number and (percentage). P for student T-test, fishers exact test or X² test as appropriate.
may represent the general patient population undergoing surgical operations. However, the sample at hand should be interpreted with caution. Nevertheless, the sample may consist partly of secondarily referred patients. Therefore, these results mostly translate to the practice of a dedicated hernia surgeon.

6. Conclusion

Incisional hernia complaints may be resolved in the majority of cases after surgical repair. However, in asymptomatic incisional hernia patients, pain or discomfort may be induced in a considerable number of patients due to surgical repair and one should be aware if this post-operative complication. Symptomatic hernia patients should be informed that surgical repair may resolve pain or discomfort in the majority, but not all patients.

Ethical approval

This prospective cohort study was performed within the French Hernia-Club registry. The French Hernia-Club registry is approved by the French ‘Commission Nationale de l’Informatique et des Libertés’ (CNIL registration number: 1999359v0) and complies to the General Data Protection Regulation. Because this study is registry-based and guarantees completely anonymized data, additional participant consent and approval were not required according to the French and Dutch national ethical standards.

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Trial registry number
1. Name of the registry: Research Registry.
2. Unique Identifying number or registration ID: researchregistry5545.
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/browse-the-registry#home?registrationdetails=5ea6ae7a4686bd00008552e305/

Guarantor
G.H.J. de Smet. D. Sneiders. J.F. Gillion.

Provenance and peer review
Not commissioned, externally peer-reviewed.

Data statement
All data is derived from the Hernia-Club registry and raw data would remain confidential and would not be shared. More information about the Hernia-Club registry is found in the materials and method section and at https://www.club-hernie.com/.

CRediT authorship contribution statement

- Investigation, Writing - original draft, Visualization: Jean-François Gillion
- Conceptualization, Methodology, Formal analysis, Writing - review & editing: Johannes Jeekel: Supervision, Writing - review & editing: Gert-Jan Kleinepnink: Supervision, Writing - review & editing: Johan F. Lange: Conceptualization, Investigation, Supervision, Writing - review & editing: Jean-François Gillion: Conceptualization, Validation, Resources, Data collection, Investigation, Supervision, Writing - review & editing.

Declaration of competing interest
There are no conflicts of interest to declare.

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Appendix A. Supplementary data
Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijssu.2020.07.054.

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