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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, hypoesthesia), 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, hyperesthesia, 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, suprapubic), if applicable lateral defect location lateral (subcostal, flank, iliac, lumbar) and width of the defect according to EHS width classification [18].

Surgical characteristics comprised of emergency procedure, incarceration, 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-quare 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 overfitting 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.

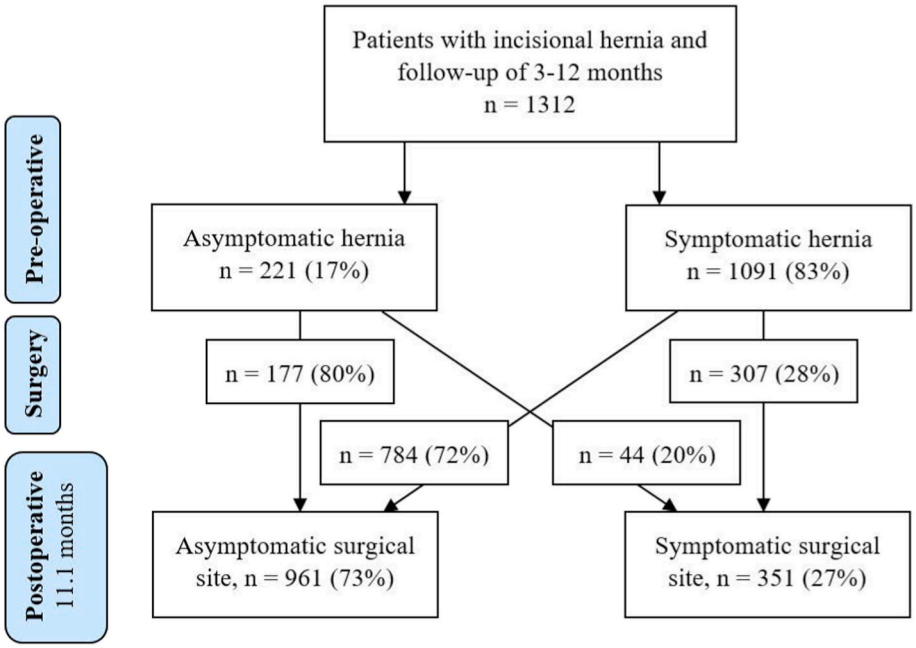

Fig. 1. Flowchart representing initially asymptomatic and symptomatic patients undergoing hernia repair.

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		
Age (years)	65 SD 13.6	65.8 SD 13.5	64.9 SD 13.6	0.369	3
Sex					0
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/m^2)	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)	8 (3.6)	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					9
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	18
Chronic cough	182 (14.1)	17 (7.9)	165 (15.3)	< **0.001**	18
Constipation	93 (7.2)	9 (4.2)	84 (7.8)	0.06	18
Heavy lifting	90 (7)	11 (5.1)	79 (7.3)	0.24	18

BMI: body mass index; AAA abdominal aortic aneurysm; ASA American Society of Anesthesiologists. 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 X^2test as appropriate.

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 = 1091) reported no pain or discomfort after a mean of 11.3 ± 4.5 months. When considering the severity of postoperative symptoms, the majority of patients reported only minor complaints. Mild pain was reported by 22 out of 44 patients (50%) of initially asymptomatic patients and by 160 out of 307 patients (52%) of initially symptomatic patients. Moderate pain or severe pain was reported in 14 out of 44 patients (30%) of initially asymptomatic patients and in 80 out of 307 (26%) of initially symptomatic patients. Only sensitive complaints (dysesthesia, hyperesthesia, hyperpathia or hypoesthesia) were reported in a minority of patients with postoperative pain or discomfort (30 out of 351 patients (8.5%)).

3.5. Long-term follow-up questionnaire

A total of 841 patients completed a follow-up questionnaire by telephone or by mail after a mean follow-up of 24.7 ± 11.4 months. Results of this questionnaire are summarized in Table 5. Overall, the incidence of patients experiencing any postoperative complaints including pain or discomfort was lower as compared to 12 months follow-up. 196 out of 841 patients (23.7%) of patients who returned the questionnaire experienced any complaints. Only 144 patients (17.1%) experienced pain or discomfort. Of those patients experiencing pain or discomfort, the initially symptomatic patients (n = 706) appeared to experience more severe symptoms, as compared to the initially asymptomatic (n = 135) patients (discomfort: 9.2% asymptomatic *versus* 18.7% symptomatic, p = 0.01). 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 (R^2: 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: 1.74, 95%CI:1.19–2.54), constipation, (OR: 1.61, 95%CI: 1.02–2.55), mesh fixation with use of tackers or staplers (OR: 1.79, 95%CI: 1.28–2.5), and use of a self-adhesive mesh (OR: 2.07, 95%CI: 1.14–3.15).

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

Table 2
Hernia characteristics for asymptomatic and symptomatic patients with an incisional hernia.

	Overall patients	Asymptomatic	Symptomatic	P	N missing
N	1312	221	1091		
Recurrent hernia	318 (24.8)	41 (19)	277 (26)	0.03	29
Previous surgery with mesh[a]					14
No mesh	867 (66.8)	159 (71.9)	708 (65.7)	0.07	
Prefascial (onlay)	19 (1.5)	3 (1.4)	16 (1.5)	0.89	
At the bangs (inlay)	13 (1)	3 (1.4)	10 (0.9)	0.56	
Retromuscular (sublay)	120 (9.2)	19 (8.6)	101 (9.4)	0.72	
Preperitoneal (sublay)	58 (4.5)	10 (4.5)	48 (4.5)	0.96	
Intraperitoneal (onlay)	201 (15.5)	21 (9.5)	180 (16.7)	**0.01**	
Not specified	20 (1.5)	6 (2.7)	14 (1.3)	0.12	
Defect location midline					17
Subxiphoid	46 (3.6)	7 (3.2)	39 (3.6)	0.79	
Epigastric	196 (15.1)	45 (20.8)	151 (14)	**0.01**	
Peri-umbilical	474 (36.6)	88 (40.7)	386 (35.8)	0.17	
Infra-umbilical	239 (18.5)	31 (14.4)	208 (19.3)	0.09	
Suprapubic	104 (8)	8 (3.7)	96 (8.9)	**0.01**	
Only lateral location	236 (18.2)	37 (17.1)	199 (18.4)	0.65	
Defect location lateral					17
Subcostal	73 (5.6)	6 (2.8)	67 (6.2)	**0.05**	
Flank	77 (5.9)	8 (3.7)	69 (6.4)	0.13	
Iliac	149 (11.5)	34 (15.7)	115 (10.7)	**0.03**	
Lumbar	18 (1.4)	0 (0)	18 (1.7)	0.06	
Only medial	978 (75.5)	168 (77.8)	810 (75.1)	0.40	
EHS width classification					51
W1: ≥ 4 cm	575 (45.6)	112 (54.9)	463 (43.8)	**0.004**	
W2: ≥ *4*–10 cm	500 (39.7)	73 (35.8)	427 (40.4)	0.22	
W3: > 10 cm	186 (14.8)	19 (9.3)	167 (15.8)	**0.02**	

EHS: European Hernia Society. 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 X^2test as appropriate.

[a] Not directly a recurrent hernia.

postoperative chronic pain [17,20].

To the best of our knowledge, this is the first study based on prospectively 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 experience complaints. Moreover, the initially symptomatic patients experience 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 patients, 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 interesting differences between pre-operative symptomatic and asymptomatic 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 comorbidities with regard to pre-operative pain were previously reported and warrant further investigation [21].

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 mortality 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 substantiate any meaningful recommendations. Considering the observational 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 incisional 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

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					19
Prefascial onlay	33 (2.6)	2 (0.9)	31 (2.9)	0.10	
Sublay (retro-muscular/pre-peritoneal)	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					134
Suture	749 (63.6)	109 (54)	640 (65.6)	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	93SD 55	0.09	49
Altemeier wound classification					7
Clean	1161 (89)	188 (85.8)	973 (89.6)	0.11	
Clean contaminated	91 (7)	17 (7.8)	74 (6.8)	0.62	
Contaminated	37 (2.8)	12 (5.5)	25 (2.3)	0.01	
Dirty	16 (1.2)	2 (0.9)	14 (1.3)	0.64	
Antibiotic treatment					15
None	140 (10.8)	39 (18.1)	101 (9.3)	<0.001	
Prophylactic	1023 (78.9)	166 (76.9)	857 (79.3)	0.43	
Therapeutic	134 (10.3)	11 (5.1)	123 (11.4)	0.01	

IPOM: Intraperitoneal Onlay Mesh. 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 X^2test as appropriate.

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	10.5 SD 4.0	11.3 SD 4.5	0.016	62
Any discomfort	351 (26.8)	44 (19.9)	307 (28.1)	0.01	0
Discomfort specified				0.05	
Sensitive scar only	32 (2.4)	4 (1.8)	28 (2.6)		
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 X^2test as appropriate.

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 hernia repair. One retrospective single-arm cohort study of Kroese et al. [35] 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. [36] six months after using self-adhesive ProGrip™ mesh in Rives-Stoppa 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 5
Questionnaire results in incisional hernia patients after hernia repair.

	Overall patients	Asymptomatic	Symptomatic	P	N missing
N	841	135	706		
Written questionnaire	484 (57.6)	91 (67.4)	393 (55.7)	**0.01**	0
Phone questionnaire	357 (42.4)	44 (32.6)	313 (44.3)	**0.01**	0
Follow-up (months after surgery)	24.7 SD 11.4	24.1 SD 11.9	24.8 SD 11.3	0.513	0
Any complaints	196 (23.7)	21 (16.3)	175 (25.1)	**0.03**	15
Bulging	108 (12.9)	12 (9.2)	96 (13.6)	0.17	14
Sensation of non-solid scar	88 (10.7)	11 (8.7)	77 (11.1)	0.42	20
Discomfort	144 (17.1)	12 (9.2)	132 (18.7)	**0.01**	15
Discomfort specified (n)	144	12	132	**0.006**	0
Sensitive scar only	6 (4.2)	0 (0)	6 (4.5)		
VRS mild pain/discomfort	68 (47.2)	8 (66.7)	60 (45.5)		
VRS moderate pain	37 (25.7)	3 (25)	34 (25.8)		
VRS severe pain	15 (10.4)	0 (0)	15 (11.4)		
Less sensitivity	14 (9.7)	1 (8.3)	13 (9.8)		
Other discomfort	7 (4.9)	0 (0)	7 (5.3)		
Frequency of discomfort (n)	144	12	132	0.057	23
Rarely	32 (22.2)	6 (50)	26 (19.7)		
Weekly	37 (25.7)	1 (8.3)	36 (27.3)		
Daily	52 (36.1)	2 (16.7)	50 (37.9)		
Not specified	23 (16.0)	3 (25)	20 (15.2)		
Functional limitations due to discomfort (n)	144	12	132	0.052	23
No limitations of general activities	63 (44.4)	8 (66.7)	55 (42.3)		
Some limitations of general activities	30 (21.1)	1 (8.3)	29 (22.3)		
Severe limitations of general activities	26 (18.3)	0 (0)	26 (20)		
Not specified	23 (16.0)	3 (25)	20 (15.2)		

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 X^2test as appropriate.

Table 6
Multivariable logistic regression, factors associated with long-term post-operative pain and discomfort.

N = 1298	OR (95%CI)	P	N missing
Age			3
1st quartile	reference		
2nd quartile	1.14 (0.8–1.62)	0.47	
3rd quartile	0.77 (0.53–1.11)	0.16	
4th quartile	0.77 (0.53–1.11)	0.16	
Smoking			96
Never	reference		
Ex-smoker > 1 year	0.86 (0.61–1.2)	0.36	
Incidental	0.71 (0.3–1.65)	0.42	
Daily	1.46 (1.01–2.1)	**0.04**	
Constipation	1.61 (1.02–2.55)	**0.04**	
EHS width			50
< 4 cm	Reference		
4 – 9 cm	1.22 (0.92–1.16)	0.17	
≥ 10 cm	1.22 (0.83–1.81)	0.31	
Any pre-operative discomfort	1.74 (1.19–2.54)	< **0.001**	0
Mesh position			19
Sublay (retro-muscular/pre-peritoneal)	reference		
Prefascial onlay	0.51 (0.21–1.25)	0.14	
Intraperitoneal onlay	0.85 (0.63–1.16)	0.30	
No mesh	1.77 (0.54–5.85)	0.34	
Mesh fixation			108
Suture	reference		
Tacker/stapler	1.79 (1.28–2.5)	< **0.001**	
Self-adhesive	2.07 (1.14–3.77)	**0.02**	
No mesh	0.96 (0.29–3.15)	0.94	

EHS: European Hernia Society. Cases with glue fixation (n = 9) and inlay mesh placement (n = 5) were excluded from multivariable analysis.

should be interpreted with caution. Nevertheless, the sample at hand may represent the general patient population undergoing surgical incisional hernia repair, as seen in every day clinical practice. Although this introduces some heterogeneity, this sample is not limited to one technique or a certain subset of complex patients. However, it is important to realize that all surgical procedures were performed by dedicated abdominal wall surgeons. This introduces some selection bias as 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: 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.

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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/5ea6ae7a4868bd001527e305/

Guarantor

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Provenance and peer review

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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

Gijs H.J. de Smet: Conceptualization, Methodology, Formal analysis, Data curation, Investigation, Writing - original draft, Visualization. **Dimitri Sneiders:** Conceptualization, Methodology, Formal analysis, Data curation, Investigation, Writing - original draft, Visualization. **Yagmur Yurtkap:** Conceptualization, Methodology, Data curation, Investigation, Writing - original draft. **Anand G. Menon:** Supervision, Writing - review & editing. **Johannes Jeekel:** Supervision, Writing - review & editing. **Gert-Jan Kleinrensink:** Supervision, Writing - review & editing. **Johan F. Lange:** Conceptualization, Investigation, Supervision, Writing - review & editing. **Jean-François Gillion:** Conceptualization, Validation, Resources, Data curation, 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.ijsu.2020.07.054.

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