ORIGINAL ARTICLE



Longitudinal cohort study on preoperative pain as a risk factor for chronic postoperative inguinal pain after groin hernia repair at 2-year follow-up

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Abstract

Purpose To assess the rate of late chronic postoperative inguinal pain (CPIP) after groin hernia repair in patients with different categories of preoperative VRS (Verbal Rating Scale) pain and to make a pragmatic evaluation of the rates of potentially surgery-related CPIP vs. postoperative continuation of preexisting preoperative pain.

Methods Groin pain of patients operated from 01/11/2011 to 01/04/2014 was assessed preoperatively, postoperatively and at 2-year follow-up using a VRS-4 in 5670 consecutive groin hernia repairs. A PROM (Patient Related Outcomes Measurement) questionnaire studied the impact of CPIP on the patients' daily life.

Results Relevant (moderate or severe VRS) pain was registered preoperatively in 1639 of 5670 (29%) cases vs. 197 of 4704 (4.2%) cases at the 2-year follow-up. Among the latter, 125 (3.7%) cases were found in 3353 cases with no-relevant preoperative pain and 72 (5.3%) in 1351 cases with relevant preoperative pain. Relevant CPIP consisted of 179 (3.8%) cases of moderate pain and 18 (0.4%) cases of severe pain. The rate of severe CPIP was independent of the preoperative VRS-pain category while the rate of moderate CPIP (3.1%, 3.4%, 4.1%, 6.8%) increased in line with the preoperative (none, mild, moderate, and severe) VRS-pain categories. The VRS probably overestimated pain since 71.6% of the relevant CPIP patients assessed their pain as less bothersome than the hernia.

Conclusion At the 2-year follow-up, relevant CPIP was registered in 4.2% cases, of which 63.5% were potentially surgery-related (no-relevant preoperative pain) and 36.5% possibly due to the postoperative persistence of preoperative pain. The rate of severe CPIP was constant around 0.4%.

Keywords Chronic postoperative inguinal pain \cdot Registry \cdot Inguinal hernia repair \cdot Lichtenstein \cdot Preoperative pain \cdot Postoperative pain

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Introduction

Preoperative and early postoperative pain are two important risk factors for chronic postoperative inguinal pain (CPIP) after groin hernia repair [1-7]. Although it has been widely investigated [1, 2, 8], the pathogenesis of CPIP is still not completely understood [9-13] and is probably multifactorial, including many potential parameters such as surgical technique, surgeon's experience, postoperative complications, pre- and postoperative pains [2-5,14–19]. In contrast, very few studies have been published on the rate and category of groin pain before and after groin hernia repair. Page et al. found that moderate (VAS 1-5) or severe (VAS > 5) pain on moving was present preoperatively in 133 (50.2%) of the 323 patients studied and postoperatively at 1-year in 46 (22.6%) of the 204 patients followed up [19]. Magnusson et al. [20] reported that 64% of 309 patients scheduled for surgery had groin pain (VAS 0.9-5.4), decreasing to 14%, 12% and 7% at 1, 2 and 3 years after surgery. Smeds et al. [21], in a longitudinal self-assessment study of 464 patients, observed that a significant proportion of the patients developed pain more than 3 months after the operation and a difference in pain evolution between moderate pain and severe postoperative pain at 3 months after surgery. Pain can increase in intensity from moderate to severe, both with and without the presence of clinical recurrence. The small number of patients with severe pain in their series impaired some subgroup analyses. Therefore, the evolution over time of groin pain in patients with each category of preoperative pain and the potential crossovers between pain categories need to be further analysed in larger series with a longer follow-up.

The main objective of this study was to evaluate, in a large series, the rate of CPIP in patients with different categories of VRS-4 (preoperative verbal rating scale) pain. The respective rates of possible surgery-related CPIP and postoperative continuation of preoperative groin pain (unchanged VRS-pain category at 2-year follow-up compared to baseline) were also analysed.

Methods

Study design

This retrospective study used the prospectively collected data of the Hernia-Club Registry [22]. The first step was a multivariate analysis to assess whether, in our series, preoperative pain was a risk factor for CPIP. The second step was a longitudinal cohort study of VRS-pain categories and a comparison between pain status at the 2-year followup vs. pain at baseline (preoperatively).

Endpoints

Our main endpoint was the rate of CPIP in patients suffering from different categories of preoperative VRS-4 pain.

The secondary endpoints were: (i) the respective rates of possible surgery-related CPIP (no or less pain at baseline than at 2-year follow-up) vs. postoperative continuation of preexisting preoperative pain (same VRS category for CPIP and preoperative pain); and (ii) the impact of CPIP on the patients' daily life evaluated using a PROM (Patient Related Outcomes Measurement) questionnaire.

Hernia-Club registry

The Hernia-Club registry is a collaborative, prospective, anonymised online database of all surgical procedures for primary and incisional hernias. Hernia-Club (club-hernie. com; club-hernie-mesh.com) is an association of French surgeons especially interested in parietal surgery, who have been gathering prospective anonymised data for all consecutive hernia patients in a dedicated registry since 2011. They comply with unselected consecutive patient inclusions and data entries (in close-ended boxes) and gave their formal consent for examination of the original medical chart in the case of a discrepancy between what was written in the database and what the patient said to the clinical research assistant (CRA) during follow-up, independent from the operating surgeon. More details on the methodology can be found in published international articles based on this database [23, 24]. All parameters collected in this database were fully compatible with the European Hernia Society (EHS) classification of inguinal hernias [25, 26].

Inclusions/exclusions

All consecutive groin hernia repairs registered in the Hernia-Club database between September 2011 and November 2016 were selected.

The inclusion criteria were: adult patients, treated for unior bilateral groin hernias using one of the four most frequent mesh repairs ('top four') in our registry: (i) open anterior inguinal mesh repair ('Lichtenstein'); (ii) transinguinal preperitoneal repair ('TIPP'); (iii) totally preperitoneal laparoscopic repair ('TEP') and (iv) transabdominal preperitoneal laparoscopic repair ('TAPP'). The choice of mesh was left to the operating surgeon's discretion. As, in bilateral hernias, the results may differ from one side to the other, the results were registered, studied and reported as hernia repairs or 'cases' rather than as patients. The exclusion criteria were: sportsman hernia syndrome, surgery too recent to allow for 2-year follow-up and lack of patient's contact address.

Studied pain subgroups

Preoperative and postoperative pains were categorised [19, 27] as: none, mild pain/discomfort, moderate pain and severe pain based on a VRS-4, and were grouped as relevant pain (moderate or severe pain) or no-relevant pain (no pain or mild pain) for subgroup analysis. The pain registered was the worst pain experienced during the studied time interval. CPIP was defined as pain lasting longer than 3 months in the inguinal region [28, 29].

Data collection

Data extracted from the registry included patient characteristics: age, sex, body mass index (BMI), physical activity, previous history of hernias and comorbidities, preoperative pain, hernia characteristics, EHS groin hernia classification [25], surgical technique, postoperative pain (at D0, D1, D8, M1) and postoperative complications. A clinical examination was performed by the surgeon at discharge and at the 1-month clinical visit. An evaluation by phone was performed on D8. In the case of any symptoms, an optional additional visit was scheduled between 3- and 6-months post-surgery. Recurrences were recorded in the database.

Two-year follow-up

VRS-pain experienced at 2-year follow-up was assessed during the systematic close-ended telephone questionnaire used in our studies since 1999 [23, 24] and performed by a dedicated CRA, independent from the surgical team. The wording of the VRS (identical to that used preoperatively) was in the common language: no pain, mild pain, moderate pain, and severe pain. The impact of pain on daily life was self-assessed by the patient him/herself, using the PROM questionnaire.

Answers were recorded verbatim, without any medical adjustment according to our PROM policy. The CRA was aware of avoiding any response bias. In the case of any reported event, the patient was strongly recommended to schedule a clinical visit. Patients were considered lost to follow-up after five failed attempts to contact them by phone at different times on different days.

Ethical approval

In this observational study, patients received a non-opposition form informing them that their anonymised data were registered in an electronic database and that they would be offered a telephone questionnaire at different steps of their follow-up. The patients' telephone details were not stored in the database. Only the surgeon and the CRA were able to link the randomly allocated identification numbers and the patients' details. The anonymised data were stored in a specialised data centre where they were protected against network intrusion. The database complies with the requirements of the General Data Protection Regulation (GDPR), the French 'Méthodologies de Référence de la Commission Nationale Informatique et Liberté' (MR003) and the different specific French ethics committees.

Statistical analysis

For the descriptive analysis, mean, median and standard deviation (SD) were used for continuous variables and frequency and percentage for categorical variables. To analyse which variables were statistically related to postoperative pain at 2 years, categorical variables were analysed with the Chi² test and continuous variables were analysed with the Chi² test and continuous variables with the Wilcoxon test. For the analysis of the PROM questionnaire, the Chi² or Fisher's tests were used depending on the application conditions. A logistic regression model was then used including variables known to be risk factors in the literature. An adjustment according to Bonferroni method was performed for PROM questionnaire analysis. The risk of the first species alpha was set at 5% for all analyses and R version 3.6 software was used.

Results

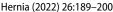
Study population

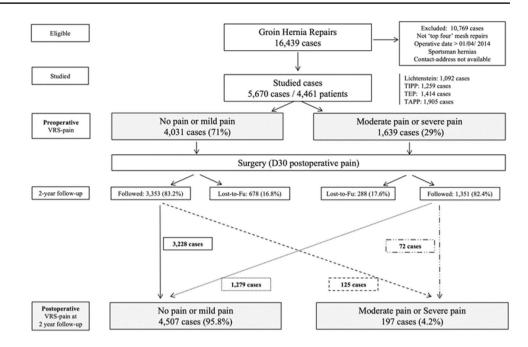
Among 16,439 consecutive groin hernia repairs registered from September 2011 to November 2016, 5670 cases in 4461 patients met the inclusion criteria (Fig. 1). As the results (especially pain) may differ on each side of a bilateral repair, the results were studied and reported for hernia repairs or 'cases' rather than for patients. In the cohort study, there were 90% males, mean (SD) age was 64.05 ± 1.9 years, mean (SD) BMI was 25.2 ± 0.25 kg/m² and ASA classification was: ASA1 (45%), ASA2 (39%), ASA3 (13.8%), and ASA4 (0.09%). The characteristics of the two populations with and without postoperative pain at the 2-year follow-up are summarised in Table 1.

Preoperative relevant (moderate or severe) VRS-pain was recorded in 1639 (29%) cases vs. no-relevant pain (mild pain/discomfort or no pain at all) in 4031 (71%) cases.

The correspondence between VRS-4 and NRS-11 (median; IQR) in our series was as follows: no pain (0; 0–0), mild (1; 0–2), moderate (3; 1–4), and severe (5; 3–7).

The 2-year follow-up rates were similar (82.4% vs. 83.2%) in both preoperative painful and pain-free groups.





Postoperative relevant VRS-pain (CPIP) was recorded in 197 cases (4.2%): moderate in 179 (3.8%) and severe in 18 (0.4%) cases, while no-relevant pain was recorded in 4507 (95.8%) cases.

Uni- and multivariate analyses

In univariate analysis, preoperative VRS-pain was confirmed as a significant risk factor for relevant CPIP (Table 1). In multivariate analysis, severe preoperative pain (OR = 2.3 [95% CI 1.1–4.6]; p = 0.02), was an independent significant risk factor for CPIP (Supplementary Table 1). The surgical technique used (open mesh repair, TIPP, TAPP, and TEP) was not a risk factor for CPIP (OR = 1.3; 95% CI [0.6–2.7]; p = 0.4).

Some other potential risk factors, such as nerve management, mesh fixation and additional local ropivacaine infiltration were also registered (Supplementary Tables 2, 3, 4) but were not studied because they were not included in the endpoints of the present study.

Proportion of CPIP in each preoperative VRS-pain category

Among the 1639 cases with relevant preoperative pain, 1351 (82.4%) cases were followed up at 2 years (Fig. 1). Among the 4031 cases with no or mild preoperative pain, 3353 (83.2%) were followed up at 2 years. In 1279 (95%) of the 1351 cases with relevant preoperative pain, the pain disappeared after the groin hernia repair, while in 72 (5%) cases the pain did not disappear. In 95% of the cases with pain (1279/1351 cases followed) and 96% of the pain-free cases

(3228/3353 cases followed), the pain present preoperatively disappeared or did not appear after the groin hernia repair. In 5% of cases with relevant preoperative pain (72/1351 cases followed), moderate or severe pain persisted after the groin hernia repair. In 4% of cases with no-relevant pain (125/3353 cases followed), moderate or severe pain occurred after the groin hernia repair.

When comparing pre- and postoperative pains at 2 years, VRS-pain decreased significantly in all pain categories: mild (51% vs. 2.9%; *p* < 0.001), moderate (19% vs. 4.1%; p < 0.001) and severe (10% vs. 0.4%; p < 0.001) (Table 2). Moderate CPIP (Table 2) increased linearly (3.1%, 3.4%, 4.1%, and 6.8%) with preoperative (no, mild, moderate, and severe, respectively) VRS categories (r=0.99; p<0.001), while severe CPIP, stable around 0.4%, was not significantly correlated with preoperative VRS categories (p = 0.8). Relevant CPIP was registered in 1639 (29%) preoperative cases vs. 197 (4.2%) postoperative cases: moderate in 179 (3.8%) and severe in 18 (0.4%) cases (Table 1). Seventy-two (37%) of the 197 CPIP cases had relevant preoperative pain, while 125 (63%) had no-relevant preoperative pain. Among 18 severe CPIP cases, 14 (77.8%) did not have pain or only had mild pain preoperatively. Among 179 moderate CPIP cases, 111 (62%) did not have pain or only had mild pain preoperatively.

Impact of CPIP on the patients' daily life at 2-year follow-up

The PROM questionnaire (Table 3) was completed in 4704 (83%) of the 5670 cases: 4507 cases in Group 1 (no-relevant CPIP) and 197 cases in Group 2 (relevant CPIP). In Group

Table 1 Characteristics of the study population (univariate analysis)

> Total L1 L2

L3

	Group 1 No or mild pain at 2-year follow-up (N=4507)	Group 2 Moderate or severe pain at 2-year follow-up (N=197)	p value	
Sex				
Male	4087 (91)	177 (89.8)	0.524	
Female	420 (8.9)	20 (10.2)		
Age (years)	66.6 ± 1.4	61.9 ± 1.1	0.432	
BMI (kg/m ²)	25.2 ± 6.0	25.3 ± 3.8	0.058	
Work				
Unemployed	1901 (42.2)	84 (42.9)	0.751	
Sedentary work	877 (19.4)	38 (19.4)		
Moderately physical work	649 (14.3)	27 (13.8)		
Highly physical work	878 (19.4)	38 (19.4)		
Not known	202 (4)	10 (5)		
Sport				
None	2199 (48.7)	115 (58.3)	0.011	
Occasional	691 (15.3)	18 (9.1)		
Moderate (1 time per week)	684 (15.1)	31 (15.7)		
Intense (several times per week)	840 (19)	27 (13.7)		
Not known	93 (2)	6 (3)		
Smoking				
None	2273 (50.4)	108 (54.8)	0.789	
Stopped for > 12 months	1173 (26)	50 (25.3)		
Occasional	237 (4.7)	8 (4.1)		
Daily	726 (16.1)	30 (15.2)		
Not known	98 (1.3)	1 (0.5)		
Primary or recurrent hernia				
Primary	4190 (94.6)	179 (91.3)	0.135	
First recurrence	211 (4.8)	14 (7.1)		
Second recurrence	28 (0.6)	3 (1.5)		
Third recurrence	2 (0)	0 (0)		
Not known	76 (1.7)	1 (0.5)		
Bilateral localisation				
No	2922 (65)	118 (60)	0.15	
Yes	1585 (35)	79 (40)		
General anaesthesia				
No	241(5.3)	11 (5.6)	0.871	
Yes	4266 (94.7)	186 (94.4)		
Additional local ropivacaine infiltration				
No	2407 (53.3)	98 (49.7)	0.3	
Yes	2100 (46.6)	99 (50.2)		
Hernia EHS classification ^a				
Lateral				
Total	3051(68)	132 (67)	0.791	
Ll	610	29		
1.0	505	71		

595

846

1, 4381 cases were pain free and 126 cases reported mild pain, detailed in questions Q4-Q7 and compared with the corresponding answers of Group 2.

Episodes of pain occurred more frequently (several times a week or several times a day) in Group 2 than in Group 1 (64.5% vs. 37.3%, respectively; *p* < 0.001),

71

32

Table 1 (continued)

	Group 1 No or mild pain at 2-year follow-up (<i>N</i> =4507)	Group 2 Moderate or severe pain at 2-year follow-up (<i>N</i> =197)	<i>p</i> value	
Medial				
Total	1886 (41.4)	97 (49)	0.094	
M1	361	25		
M2	864	38		
M3	524	25		
Mx	137	9		
Femoral				
Total	368 (8.1)	27 (14)	< 0.001	
F1	128	9		
F2	88	5		
F3	8	5		
Fx	144	8		
Surgical technique				
Lichtenstein	818 (18.1)	43 (21.8)	0.117	
TIPP	1050 (23.3)	35 (17.8)		
Laparoscopic TEP	1112 (24.7)	43 (21.8)		
Laparoscopic TAPP	1527 (34)	76 (38.6)		
Mesh fixation				
No fixation	3080 (68.3)	123 (62.4)	0.105	
Fixation	1259 (27.9)	61 (31)		
Auto adhesive mesh	168 (3.7)	13 (6.6)	0.054	
Postoperative complications				
Medical	79 (1.7)	5 (2.5)	0.4	
SSO	195 (4.3)	12 (6)	0.2	
Surgical non-SSO	38 (0.8)	2(1)	0.8	
Preoperative pain (VRS)				
None	911 (20.2)	33 (16.7)	0.01	
Mild	2317 (51.4)	92 (46.7)		
Moderate	857 (19)	39 (19.8)		
Severe	422 (9.3)	33(16.8)		

Data shown are mean \pm standard deviation, or n (%)

BMI: body mass index; EHS: European Hernia Society; TIPP: transinguinal preperitoneal repair; TEP: totally preperitoneal laparoscopic repair; TAPP: transabdominal preperitoneal laparoscopic repair; SSO: surgical site occurrence; SSI: surgical site infection, VRS: verbal rating scale; D0: day of the procedure ^aTotal > 100% due to combined hernias

Table 2	Distribution of VRS-
pain ove	er time

Preoperative	Total	No. of patients at follow-up	CPIP at 2-year follow-up			
VRS-pain			No CPIP	Mild CPIP	Moderate CPIP	Severe CPIP
No pain	1140 (20)	944 (82.8)	897 (95)	14 (1.5)	29 (3.1)	4 (0.4)
Mild pain	2891 (51)	2409 (83.3)	2248 (93.3)	69 (2.9)	82 (3.4)	10 (0.4)
Moderate pain	1083 (19)	896 (82.7)	830 (92.7)	27 (3.0)	37 (4.1)	2 (0.2)
Severe pain	556 (10)	455 (81.8)	406 (89.3)	16 (3.5)	31 (6.8)	2 (0.4)
Total	5670 (100)	4704 (83.0)	4381 (93.0)	126 (2.6)	179 (4.0)	18 (0.4)

All data shown are n (%)

CPIP: chronic postoperative inguinal pain

	Group 1 No or mild CPIP (N=4507)	Group 2 Moderate or severe CPIP (N=197)	<i>p</i> value
Q1. Since your operation does your abdominal wall s	seem		
Solid	4475 (99.3)	183 (93)	< 0.00
Not solid	22 (0.5)	13 ^a (7)	
Missing data	10	1	
Q2. Do you have a new hernia or bulge in the operate	ed groin?		
No	4396 (97.5)	187 (95)	< 0.001
Yes	77 (1.7)	10 ^b (5)	
Missing data	34	0	
Q3. Do you currently feel any pain or local discomfo	rt?		
No (asymptomatic)	4381 (97.2)	0 (0)	< 0.001
Yes	126 (2.8)	197 (100)	
Missing data	0	0	
If 'No' go to Q8			
Q4. When exactly do you feel these symptoms?			
Not specified	25 (19.8)	12 (6)	
During lifting, coughing, or pushing	20 (15.9)	28 (14)	0.003
During other types of effort (please specify)	33 (26.2)	72 (36.5)	
After physical effort or at the end of the day	11 (8.7)	17 (9)	
At any other specified moment (please specify)	1 (0.8)	0 (0)	
At any time	36 (28.6)	68 (34.5)	
Missing data	0	0	
Q5. How often do you feel them?			
Not specified	18 (14.3)	8 (4.1)	< 0.00
Rarely	60 (47.7)	60 (30.5)	
Several time a week	41 (32.5)	97 (49.2)	
Several time a day	6 (4.8)	30 (15.2)	
24/24 h	1 (0.7)	2(1)	
Missing data	0	0	
Q6. These symptoms:			
Have no impact	24 (19.1)	21 (10.7)	< 0.00
Do not interfere with your daily life	91 (72.2)	118 (60)	
Allow you to pursue the ongoing activity	11 (8.7)	52 (26.3)	
Cause a temporary interruption of your activity	0 (0)	4 (2)	
Prevent certain activities (impairment)	0 (0)	2 (1)	
Missing data	0	0	
Q7. These symptoms are:			
No impact	19 (15)	23 (11.7)	0.002
Less bothersome than the hernia	102 (81)	141 (71.6)	
More bothersome than the hernia	5 (4)	33 (16.8)	
Missing data	0	0	
Q8. Have you had any further operations on your abo	lominal wall?		
No	4490 (99.6)	192 (97)	0.0001
Yes (please specify)	17 ^c (0.4)	5 ^d (3)	
Missing data	0	0	

Table 3Patient RelatedOutcomes Measurement(PROM) questionnaire assessedat the 2-year follow-up

caused an interruption in the ongoing activity or prevented specific activities more frequently in Group 2 than in Group 1 (2% vs. 0%, respectively), and were assessed as more bothersome than the hernia itself more frequently in Group 2 than in Group 1 (16.8% vs. 4%, respectively; p = 0.002).

Table 3 (continued)

	Group 1 No or mild CPIP (N=4507)	Group 2 Moderate or severe CPIP (N=197)	<i>p</i> value
Q9. How do you assess the result of your he	ernia operation		
Excellent	1464 (32.6)	8 (4)	< 0.001
Good	2943 (65.2)	107 (54.4)	
Medium	52 (1.2)	61 (31)	
Bad	8 (0.1) ^e	21 (10.6) ^f	
Missing data	40 (0.9)	0 (0)	

All data shown are n (%). CPIP: chronic postoperative inguinal pain

^aReoperations (3) (2 for recurrence, 1 for infection); others with unclear symptoms did not attend the proposed clinical visit; 1 medium result changed to good at 5 years

^bReoperation for recurrence, solid so far (1); no re-operated recurrence (1); others with unclear symptoms did not attend the proposed clinical visit

^cRecurrences (7), infections (2), chronic pain (2), unrelated cause (1), not specified (5)

^dInfections (2), chronic pain (1), not specified (1)

^e Recurrences (4) (2 not re-operated, 1 solid after reoperation, 1 re-recurrence after reoperation), 3 for constant discomfort including hypoesthesia (3), not specified (1)

^fRecurrence (1), infection (2), pain (15), not specified (3)

In Group 1, 81% of cases assessed their postoperative pain as less bothersome than the hernia itself and having no impact at all (15%) on their daily life. In Group 2, when reporting relevant pain, 71.6% assessed their pain as less bothersome than the hernia itself or having no impact at all (11.7%). No regular use of analgesia was registered by the CRA. This distortion in the patients' assessments between self-reported pain and relative impact on their daily life must be noted. Similarly, the patients' global assessments of their surgery did not appear to be completely linked to their pain status as surgery was assessed as excellent (4%) or good (54.4%) in the 'painful' Group 2 patients. The result of surgery was assessed as bad in 8 cases in Group 1: recurrence (4 cases), discomfort and/or numbness (3 cases) and not specified (1 case); the result was assessed as bad in 21 cases in Group 2: recurrence (1 case), infection (2 cases), pain (15 cases) and not specified (3 cases).

Reoperation (in the same or another hospital) was recorded in 17 cases in Group 1: recurrence (7 cases), infection (2 cases), chronic pain (2 cases), unrelated cause (1 case) and not specified (5 cases). Reoperation was also recorded in six cases in Group 2: infection (two cases), chronic pain (one case) and not specified (three cases). In Group 2, patients assessed their abdominal wall as not solid in 13 cases: reoperation (3 cases: 2 for recurrence and 1 for infection) and others with unclear symptoms did not attend the scheduled visit; in one of these, the result changed from medium to good at the 2-year control.

Finally, the global result of surgery was assessed as good or excellent in 98% of cases in Group 1 vs. 58% of cases in Group 2.

Discussion

In this large multicentre, registry-based, prospective study of groin hernia repairs, relevant (moderate or severe) preoperative VRS-pain was registered in 1639 of 5670 (29%) cases vs. 197 of 4704 (4.2%) cases followed up at 2 years, of which 125 (63.5%) could be potentially surgery-related (no preoperative relevant pain) and 72 (36.5%) due to the postoperative persistence of preoperative pain. Relevant CPIP was moderate in 179 (3.8%) cases and severe in 18 (0.4%). The rate of severe CPIP, stable around 0.4%, appeared to be independent from the preoperative VRS-pain category while the rate of moderate CPIP (3.1%, 3.4%, 4.1%, and 6.8%) increased along with the preoperative (none, mild, moderate, and severe) VRS-pain category. The VRS probably overestimated the pain since, in the PROM, 71.6% of the relevant CPIP patients assessed their pain as less bothersome than the hernia.

Preoperative groin pain rates (either relevant pain or overall pain) higher than 29% have already been published [19, 20, 30, 31], depending on the cutoff in pain levels used and the local implementation of guidelines, which suggest mainly operating on symptomatic patients [26]. Unlike many of the above-mentioned studies, almost 60% of our cases were laparoscopic and 35% were bilateral repairs (Table 1). The contralateral side of those repairs was frequently less symptomatic than the main one. Globally, pain decreases over time after surgery. In the series of Magnusson et al. [20], groin pain (VAS 0.9–5.4) registered preoperatively in 64% of patients decreased to 14%, 12% and 7% of patients at 1, 2 and 3 years after surgery. In the

present series, 94.7% (1279/1351 cases followed) of the relevant preoperative pain cases moved to the no-relevant postoperative pain subgroup (Fig. 1). This suggests that patients operated on in this series were mainly symptomatic. This also suggests that an important part of the preoperative pain was directly related to the hernia and dramatically decreased after the groin hernia repair [20]. This finding must be interpreted very cautiously because, frequently, the groin pain accompanying the hernia is not related to the hernia itself but is referred pain [13] from pubic, hip, sacroiliac, dorsal-lumbar disorders, urinary or pelvic diseases [32, 33], etc., and/or related to psychosocial or general conditions such as an individual pain susceptibility [34, 35]. Such pain persists or reappears after groin hernia repair and may result in clinical and sometimes medico-legal issues if not documented preoperatively. In the present study, relevant preoperative pain persisted in 72 (5.3%) of the 1351 cases followed (Fig. 1). The number of painful patients who had not undergone surgery was unknown because those cases were not registered in the database. Surgery on an inguinal hernia in adult male patients is not an emergency [26] and 'watchful waiting' is a good option [26, 31, 36-38], not only for asymptomatic patients.

In the present study, relevant CPIP occurred in 125 (3.7%) of the 3353 no-relevant (mild pain or no pain) preoperative pain cases followed. A potential surgery-related cause may be considered. The aim of this study was not to analyse surgical technical issues and their prevention (nerve preservation, mesh fixation, etc.), already widely discussed [39–41], nor to study CPIP prophylaxis using early infiltrations or regional blocks (Table 1). Our secondary endpoint was only an evaluation of the rate of continuation of preexisting pain vs. possible surgery-related CPIP.

These 125 cases accounted for 65% of the 197 relevant CPIP cases (179 (3.8%) moderate and 18 (0.4%) severe pain cases) (Fig. 1). The rate of severe CPIP, stable around 0.4%, appeared to be independent from the preoperative VRS-pain category (Table 2) while the rate of moderate CPIP (3.1%, 3.4%, 4.1%, and 6.8%) increased in line with the preoperative (none, mild, moderate, and severe) VRS-pain category (r=0.99; p < 0.001). These results suggest that severe CPIP, independent from the preoperative pain status, could be mainly surgery-related, while moderate CPIP could be correlated with the preoperative pain status.

Groin hernia repair not only restored the anatomy but also significantly reduced groin pain or groin discomfort in all VRS categories. When comparing (Table 2) pre- and postoperative pains at 2 years, VRS-pain decreased significantly in all pain categories: mild (51% vs. 2.9%; p < 0.001), moderate (19% vs. 4.1%; p < 0.001) and severe (10% vs. 0.4%; p < 0.001). The ratio no-relevant vs. relevant pain changed from 71% vs. 29% preoperatively to 95.8% vs. 4.2% postoperatively at 2-year follow-up (Fig. 1). The present results confirm those of previous studies [19, 20].

Our final endpoint was an evaluation, using a PROM questionnaire, of the impact of CPIP on the patients' daily life (Table 3). In the 197 relevant (moderate or severe) CPIP cases (Group 2), only 16.8% assessed their pain as more troublesome than the hernia itself (Q7), while 71.6% assessed their pain as less bothersome than the hernia and 11.7% said it had no impact on their daily life (Q7; Q6). These results suggest that the VRS probably overestimates pain. Patients who describe a simple discomfort or "a feeling different than before", not necessarily pain, are classified as mild pain. This is an important issue, especially in our series in which 2891 cases preoperatively (64% of the 4530 VRS-pain cases) and 126 cases postoperatively (39% of the 323 VRS-pain cases) were classified as mild pain or discomfort. At the opposite end of the VRS-pain spectrum, severe pain was not defined precisely. For example, in our series, none of the patients reporting severe pain regularly used analgesics or consulted a pain centre. Postoperatively, the pain was assessed as more bothersome than the hernia itself in only 33/197 (17%) of the CPIP cases. This is why, in our PROM questionnaire, VRS-pain, recorded verbatim, was amended with questions Q5, Q6 and Q7 assessing its impact on daily life. Moreover, Magnusson et al. reported that the improvement in quality of life was mainly observed in patients with preoperative pain [20]. Unlike many of the above-mentioned studies, our study included not only open mesh repairs, but also TIPP, TAPP and TEP. In the uni- and multivariate analyses (Table 1, Supplementary Table 2), the type of surgical technique used was not identified as a risk factor for CPIP. Moreover, in a previous study from the same database [42], the 2-year PROM was similar amongst these four techniques.

The impact of pain on daily activities [43] and psychological considerations are of major relevance. There is a need for a uniform and validated assessment of CPIP. In a recent systematic review [1], 33 different instruments were individualised to quantify CPIP. Some of them are dedicated to hernia repair such as the Carolina Comfort Scale [44] or the Inguinal Pain Questionnaire and some others are too sophisticated to be used in daily practice [45], which suggests that simplified versions such as the short form Inguinal Pain Questionnaire SF-IPQ [46] should be proposed.

This study has several limitations. Although using prospectively collected data, the design of the present study is retrospective. Surgeries selected for assessment were performed 10–7 years ago, allowing for a late follow-up. Only 2-year follow-up data are presented in the present study. The 5-year follow-up data will be analysed in a further study. PROM used in this study, although non-formally validated, is the PROM we have been using in all our published studies since 1999 [47]. The weakness of any pain study is the subjective dimension of pain evaluation by the patient. What is relevant is not the absolute value of the pain evaluated but its evolution over time for a given patient or for a category of pain patients. This is why we studied the evolution of pain over time looking at crossovers between pain categories and comparing preoperative with postoperative pain using the same tools. The 2-year delay between the assessment of discomfort due to CPIP and that due to the hernia could introduce a recall bias. Asking direct questions in a pain questionnaire, required for VRS assessment, could introduce a response bias. However, other tools, which are more complex and demanding, are difficult to use in large cohorts such as the present series. The patients did not undergo a medical visit at the 2-year follow-up, but the VRS-pain assessment does not require a visit to the surgeon's office. Dealing with bilateral repairs is an issue as the pain at one side could bias the evaluation of the contralateral pain. In our registry, many procedures are bilateral repairs and exclusion of these cases could have introduced a selection bias. The bias seems light, as the distribution of bilateral repairs was similar at around 35% in both the relevant and no-relevant CPIP subgroups (Table 1).

Conclusion

In this series of patients operated from 01/11/2011 to 01/04/2014, at the 2-year follow-up, relevant CPIP was registered in 4.2% cases, of which 63.5% could be potentially surgery related and 36.5% due to the postoperative persistence of preoperative pain. The rate of severe CPIP, stable around 0.4%, appeared to be independent from the preoperative VRS-pain category, while the rate of moderate CPIP (3.1%, 3.4%, 4.1%, and 6.8%) increased in line with the preoperative (none, mild, moderate, and severe) VRSpain category. Thus, groin hernia repairs not only restored the anatomy but also significantly reduced groin pain or groin discomfort in all VRS categories. When comparing pre- and postoperative pains at 2 years, VRS-pain decreased significantly across all pain categories: mild (51% vs. 2.9%; p < 0.001), moderate (19% vs. 4.1%; p < 0.001) and severe (10% vs. 0.4%; p < 0.001). The ratio no-relevant vs. relevant pain changed from 71% vs. 29% preoperatively to 95.8% vs. 4.2% postoperatively at 2-year follow-up.

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Availability of data and materials Anonymised data are accessible on request.

Declarations

Conflict of interest The authors declare that they have no conflicts of interest to declare regarding this study.

Consent to participate In this registry-based study, patients were informed ('Non-opposition' form) that their completely anonymised data could be further used for scientific studies and that they could ask for a withdrawal of their own data whenever they wanted.

Consent for publication All the patients gave their informed consent for publication their data.

Ethics approval This prospective cohort study was performed within the French Hernia-Club registry. The Hernia-Club registry complies with the requirements of the 'Commission Nationale de l'Informatique et des Libertés' (CNIL) and of the General Data Protection Regulation (GDPR). Human and animal rights Statement All procedures performed in this study were in accordance with the ethical standards of the French researchcommittee and with the 1964 Helsinki Declaration and its later amends.

Informed consent All the patients gave their informed consent for publication their data.

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