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Prospective Cohort Study

Significant factors influencing chronic postoperative inguinal pain: A conditional time-dependent observational cohort study

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ABSTRACT

Background: Inguinal hernia (IH) repair is a common surgical procedure. Focus has shifted from recurrences to chronic postoperative inguinal pain (CPIP). To assess the natural course of CPIP and identify patient factors influencing the onset of CPIP, an observational registry-based study was performed.

Materials and methods: Data prospectively collected from the Club-Hernie national database was retrieved from 2011 until 2021. Patients who underwent elective surgery for inguinal hernia were divided in an irrelevant pain group and relevant pain group. Relevant pain at one year and two years were compared with patients with irrelevant pain at all-time points (preoperatively, one month, one year and two years). Quality of life questions were compared between relevant pain at one year and two years.

Results: 4.016 patients were included in the analysis. Mean age was 65.1 years, 90.3% of patients was male. Factors correlated with CPIP onset were age, gender, ASA, recurrent surgery, surgical technique, nerve handling and fixation type. Relevant pain at one month was a greater risk for CPIP than preoperative pain (12.3% vs 3.6%). In the majority of patients (83.2%) CPIP was ameliorated at two years. Hernia related complaints differed significantly between CPIP at one year and two years.

Conclusion: Postoperative pain after one month was a greater risk factor for CPIP development than preoperative pain. CPIP at one year seems to have a different pain etiology than CPIP at two years. Patient and surgical factors influence the onset of CPIP at one year, however the natural course of these complaints shows great decline at two years, largely without reinterventions.

1. Introduction

Inguinal hernia (IH) repair is one of the most ubiquitous procedures in daily surgical practice. In The Netherlands alone, approximately 20.000 inguinal hernia repairs are performed annually [1]. With the use of prosthetic meshes, focus has shifted from the incidence of recurrence to the development of chronic postoperative inguinal pain (CPIP). Chronic pain has been identified by the International Association for the Study of PAIN (IASP) as pain lasting longer than three months [2]. Due to differences in definitions of CPIP, the incidences range from 1 to 60% [3]. It is estimated that CPIP affects the daily life of 5–10% of patients [1].

In open IH repair, reasons for developing CPIP have been attributable to nerve injury, nerve entrapment in the mesh, meshoma formation (i.e.

shrinkage by fibrosis, followed by folding or balling up of the mesh) and non-absorbable sutures for mesh fixation [4]. Although the nerve handling considerations apply less for the laparoendoscopic approach, CPIP is also reported in this technique [5].

Intra-operative nerve transection for the prevention of CPIP has been thoroughly investigated by many studies, and also in a meta-analysis by Cirocchi and colleagues [6–8]. Although decrease in pain in the early postoperative period is observed, this difference is not observed anymore one year postoperatively. Conversely, more groin paresthesia is found when comparing neurectomy with nerve preservation after six months.

The type of fixation used has also been suggested to interfere with the onset of CPIP [9]. Many types of fixation can be used to hold the mesh in place (e.g. resorbable and non-resorbable sutures/staples, glue,

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self-adhesive). While glue in the form of fibrin or cyanoacrylate has been proven to reduce short-term postoperative pain, doubt still exists whether this will be significant for the onset of inguinal pain in the long run [9,10].

While many studies focus on the factors that influence the onset of CPIP [4,11-13], the natural course of CPIP has not been investigated

thoroughly. There is some information that CPIP dissipates over time, but no information is given about the patient and surgical factors that may come into play [14]. Surgeons can inform patients about the chances of developing CPIP, which is about ten percent depending on open or endoscopic techniques, but information about the long-term course of CPIP and chances of CPIP persisting for over one year with

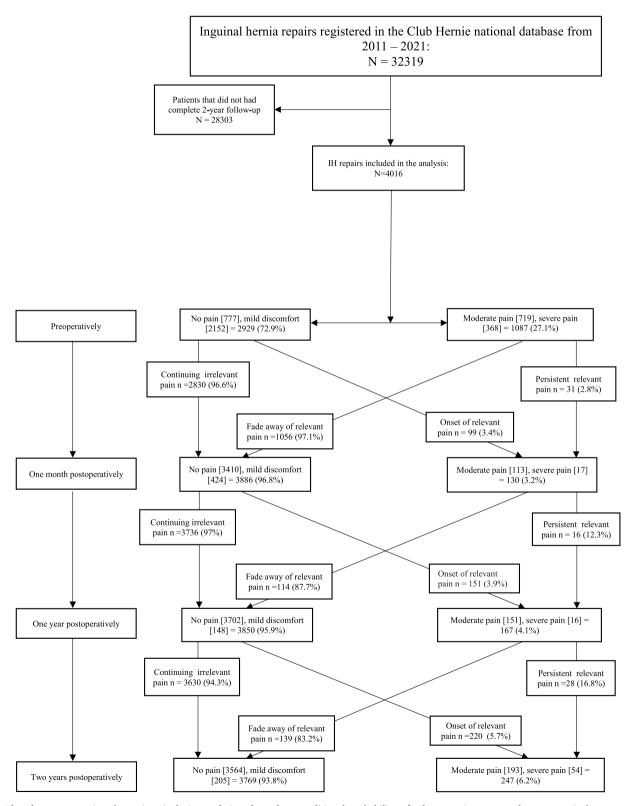


Fig. 1. Flowchart representing the patient inclusion and time-dependent conditional probability of relevant pain one month postoperatively, one year post-operatively and two years postoperatively.

respect to their patient and surgical characteristics is lacking. This would be valuable information for patients experiencing CPIP.

In order to provide an outlook on the course of CPIP and quantitate quality of life deterioration, the aim of this study is to assess the conditional probability of continuous pain and discomfort, depending on the earlier status of pain and discomfort, and identifying patient and/or surgical factors contributing to pain and/or discomfort with a complete follow-up of two years.

2. Methods

This prospectively collected observational study was registered at researchregistry.com (UIN: researchregistry7671) and conducted according to the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) and STROCSS (Strengthening the Reporting of Cohort Studies in Surgery) statements [15].

Data utilized in this study was prospectively collected by the members of the Hernia-Club Registry [16] and retrospectively reviewed. This registry functions as a prospectively compiled online database of surgical procedures for all ventral abdominal wall hernias. The Hernia-Club (club-hernie-mesh.com) is a society of French surgeons with an interest in parietal surgery, and who have been gathering the prospective anonymised data for all ventral abdominal wall hernia patients since 2011.

2.1. Data collection

Surgeons from all over France enlisted patients consecutively and unselectively in close-ended boxes. Patients gave their formal consent for auditing of the original medical records in the case of discrepancies between the database and patient reported outcomes during the follow-up visit, independent of the attending surgeon.

Data collection for follow-up was performed by a clinical research assistant (CRA) by telephone calls. This included validated Quality of Life (QoL) questionnaires in the form of Patient Reported Outcome Measurements (PROMs).

Patients were informed that their data was registered in a pseudonymized manner, and only the CRA and operating surgeon were able to relate the pseudonymized number with the patient. Data was stored in a protected databank in Switzerland. This registry is abiding to the requirements of the French 'Commission Nationale de l'Informatique et des Libertés' (CNIL; registration number 1993959v0).

Additional information regarding registration in the Hernia-Club database can be found in the articles by Romain et al. and De Smet et al. [13,17].

2.2. Patients and methods

All patients undergoing elective inguinal hernia repair from 2011 to 2021 were identified from the Hernia-Club registry. Only patients with minimum two years of follow-up were included in the study (Fig. 1).

2.3. Outcomes

Data derived from the registry included patient demographics such as age, gender, body mass index (BMI), American association of Anesthesiologists (ASA) classification, smoking, comorbidities such as diabetes, preoperative pain and physical activity.

Hernia characteristics identified were whether the hernia was primary or recurrent and classified according to the EHS classification of inguinal hernias [18].

Surgical characteristics included surgical techniques: Lichtenstein, transabdominal preperitoneal (TAPP) repair, transinguinal preperitoneal (TIPP) repair, totally extraperitoneal (TEP) repair, use of prosthetics, fixation of these prosthetics (e.g. resorbable and non-resorbable sutures, resorbable and non-resorbable staples, glue, self-adhesive), type of anaesthesia (i.e. general, spinal or local) and intra-operative nerve

handling (i.e. not seen, preservation or resection) of the iliohypogastric nerve (IHN) and the ilioinguinal nerve (IIN).

To measure preoperative and postoperative pain the Verbal Rating Scale (VRS) was used. This scale is divided in four scores (i.e. no pain, mild pain, moderate pain, severe pain). For present comparison, these groups are clustered in irrelevant pain (no pain, mild pain) and relevant pain (moderate and severe pain).

Patients who reported relevant pain at one year and two years were compared to patients that reported no pain at one month, one year and two years with respect to baseline, hernia and surgical characteristics.

Quality of Life was assessed with the use of a validated telephone questionnaire in the form of a PROM concept. Patients were asked a self-assessment of their complaints in a simple manner and understandable for everyone with capacity of the French language. QoL was compared to the patient group that reported relevant pain at one year and two year to distinguish possible differences in experienced afflictions.

2.4. Statistical analysis

Baseline characteristics are presented as means with standard deviation, medians with inter-quartile range or as numbers of patients and percentages, as appropriate. Patients who had no pain at any measured time point (one month, one year and two years postoperatively) were compared to patients with relevant pain at one year and to patients with relevant pain at and two years postoperatively, using multivariable binary logistic regression, including the variables age, gender, ASA classification, smoking status, activity level, diabetes, primary/recurrent hernia, EHS hernia classification, and mesh fixation, presenting odds ratios (OR) with 95% confidence intervals (95% CI). Surgical approach and nerve handling were excluded from multivariable analysis, as these variables correlate heavily to the mesh fixation that was used. This correlation was discovered by Cross-Tabulation. Univariable binary logistic regression was used for surgical approach, iliohypogastric nerve handling and ilioinguinal nerve handling. For iliohypogastric nerve handling, only patients undergoing the Lichtenstein procedure were considered. For ilioinguinal nerve handling only patients undergoing the Lichtenstein and TIPP procedures were considered. Model fitting was assessed with the Log-Likelihood statistic. QoL outcomes were compared using Pearson's Chi-Square test. Correction for multiple testing was not performed.

3. Results

In total, 4.016 repairs were extracted from the Club-Hernie database that completed the full two-year follow-up between 2011 and 2021, and were included in the analysis.

3.1. Patient, hernia and surgical characteristics

Baseline characteristics of the included patients is shown in Table 1. Mean age of patients was 65.1 years and patients were predominantly male (90.3%). Generally, patients had good physical health with only 7.7% of patients having a BMI higher than 30, only 9.9% of patients had an ASA classification exceeding two, 52.8% was active (i.e. doing exercise), and 4.1% of patients had diabetes.

Primary hernias were the main type of hernia (92.8%), with lateral and medial inguinal types representing the majority of hernia types.

The surgical techniques were clustered into two groups: open and laparoendoscopic techniques.

Most procedures encompassed an open technique (55.2%). Meshes or other prosthetics were used in 96.7% repairs, and most prosthetics if fixated, were fixated by resorbable staples (46.0%). Almost all surgeries were performed under general anaesthesia, and many surgeons did not undertake nerve identification, 54.0% of the IHNs and 38.8% of the IINs the course was not recognized during open surgery.

Table 1Baseline characteristics of patients with 2-year follow-up.

| Patient characteristics Age Male sex BMI Patients with BMI > 30 | N = 4016 (%) 65.1 (14.3) |
|--|-----------------------------|
| Age Male sex BMI Patients with BMI > 30 | |
| Male sex BMI Patients with BMI > 30 | |
| BMI Patients with BMI > 30 | |
| Patients with BMI > 30 | 3628 (90.3) |
| | 25.1 (3.6) |
| | 311 (7.7) |
| ASA classification | 0006 (50.5) |
| 1 2 | 2036 (50.7) |
| 3 | 1574 (39.2) 397 (9.9) |
| Smoking | 357 (5.5) |
| Never smoked | 2134 (53.1) |
| Ex-smoker > 12 months | 1029 (25.6) |
| Occasional smoker | 177 (4.4) |
| Daily smoker | 653 (16.3) |
| Activities | |
| None | 1894 (47.2) |
| Sporadic (<1 time a week) Moderate (1 time a week | 593 (14.8) 646 (16.1) |
| Intense (>1 time a week) | 860 (21.4) |
| Work | 000 (21.1) |
| Unemployed | 1472 (36.7) |
| Administrative work | 883 (22.0) |
| Moderate physical work | 643 (16.0) |
| Physical work | 911 (22.7) |
| Diabetes | 163 (4.1) |
| Preoperative pain | 777 |
| None Mild | 777 2099 |
| Moderate | 53 |
| Severe | 1087 |
| Hernia characteristics | |
| Primary hernia | 3725 (92.8) |
| Lateral (total) | 2855 |
| L1 | 602 |
| L2 | 1499 |
| L3 | 754 |
| Medial (total) M1 | 1518 261 |
| M2 | 747 |
| M3 | 510 |
| Femoral (total) | 260 |
| F1 | 124 |
| F2 | 108 |
| F3 | 28 |
| Surgical characteristics | 0010 (55.0) |
| Open Lichtenstein | 2219 (55.2) 932 (23.2) |
| TIPP | 1287 (32.0) |
| Laparoendoscopic | 1786 (44.0) |
| TAPP | 992 (24.7) |
| TEP | 776 (19.3) |
| Received prosthetics | 3883 (96.7) |
| Fixation | |
| No fixation | 2700 |
| Sutures (resorbable/not resorbable) | 134/204 |
| Staples (resorbable/not resorbable) Glue | 578/183 27 |
| Self-adhesive | 132 |
| Type of anaesthesia | 102 |
| General | 3786 |
| Spinal or TAP Block | 122 |
| Local anaesthesia | 75 |
| Iliohypogastric nerve: | |
| Not applicable/not seen | 2889 |
| Preserved | 998 |
| Resected | 104 |
| Ilioinguinal nerve: | 2584 |
| Not applicable/not seen | 2584 1272 |
| Preserved | 14/4 |

3.2. Conditional probability of CPIP

Fig. 1 shows the development and evolution of CPIP in the study population. Preoperatively, 2.929 (72.9%) patients had irrelevant pain and 1.087 (27.1%) patients had relevant pain.

At one month postoperatively, the large majority of patients: 96.8% (n =3.886) had irrelevant pain and 3.2% (n =130) had relevant pain. Ninety-nine patients (3.4%) who did not have pain preoperatively, had pain at one month. One-thousand-and-fifty-six patients (97.1%) who had pain preoperatively, did not have pain at one month.

At one year postoperatively, 3.850 (95.9%) patients had irrelevant pain and 167 (4.1%) patients had relevant pain. One-hundred-and-fifty-two (4.0%) patients who did not have pain at one month, had pain at one year. One-hundred-and-twelve (86.8%) patients who had pain at one month, did not perceive their pain as relevant at one year.

At two years postoperatively, 3.769 patients (93.8%) had irrelevant pain and 247 (6.2%) patients had relevant pain. Two-hundred-and-nineteen (5.8%) patients who did not have pain at one year, had pain at two years. One-hundred-and-thirty-nine (83.2%) patients who had pain at one year, did not have pain at two years.

Of the patients that experienced relevant pain preoperatively, 30 (2.8%) continued to have relevant pain at one month. Sixteen (12.3%) patients experiencing pain at one month, continued developing CPIP at one year, while only 39 (3.6%) of the patients experiencing preoperative pain but who were pain free at one month, developed CPIP at one year.

3.3. No pain at any point versus relevant pain at one year postoperatively

Patients who reported no pain at one month, one year and two years postoperatively were compared to patients who reported relevant pain at one year postoperatively. These results are presented in Table 2.

Patients of ages 60 and below were more likely to have relevant pain (OR 1.763; 95% CI 1.150–2.703; p=0.009) than patients over 60 years old. Males were at a significantly lower odds of having relevant pain (OR 0.466; 95% CI 0.258–0.840; p=0.011). This difference is also present in ASA 2 patients, when compared to ASA 1 patients (OR 1.976; 95% CI 1.284–3.040; p=0.002). Additionally, fewer ASA 1 patients were present in the relevant pain group (p=0.002). Recurrent IHs were at significantly higher risk of relevant pain group than patients operated for a primary IH (OR 2.125; 95% CI 1.015–4.450; p=0.046).

Lichtenstein repair was performed more often in the relevant pain group (p = 0.004). TIPP repair, when compared to Lichtenstein repair, resulted in lower odds of relevant pain (OR 0.485; 95% CI 0.312–0.752; p = 0.001). Not fixating the mesh was more prevalent in the no pain group (p = 0.016). The opposite is true for fixation of the mesh with non-resorbable staples (OR 2.445; 95% CI 1.120–4.940; p = 0.013) and for self-adhesive mesh (OR 5.550; 95% CI 1.773–17.376; p = 0.003), both of which resulted in pain more often. Any type of nerve handling of the IHN was not statistically significant correlated with severe pain at one year (p = 0.246, p = 0.194, p = 0.953). When the IIN was preserved instead of not identified, pain occurred more often (OR 1.713; 95% CI 1.062–2.763; p = 0.027).

3.4. No pain at any point versus relevant pain at two years postoperatively

Patients who reported no pain at one month, one year and two years postoperatively were compared to patients who reported relevant pain at two years postoperatively. These results are presented in Table 3.

Younger patients (\leq 60 years old) were observed in the group with relevant pain at two-years (OR 1.450; 95% CI 1.052–1.999; p = 0.023). Males were less likely than females to have relevant pain (OR 0.490; 95% CI 0.310–0.773; p = 0.002). More patients in the relevant pain group were occasional smokers (OR 2.566; 95% CI 1.490–4.417; p < 0.001). More patients in relevant pain group were operated for a F1 femoral hernia (p = 0.036).

Table 2
Patients with no pain at 1 month, 1 year and 2 years versus patients with relevant pain at 1 year. Missing values were omitted from analyses. 1: only Lichtenstein repairs considered in analysis. 2: only Lichtenstein and TIPP repairs considered in analysis. 1: too few (<10) patients in group in order to interpret logistic regression. 1: chi-squared test. OR: odds ratio. UV: univariable logistic regression, MV: multivariable logistic regression.

| | No pain N = 2796 (%) | Relevant pain $N = 167$ (%) | OR (UV, 95% CI) | OR (MV, 95% CI) | P-value |
|--|--------------------------|-----------------------------|---------------------|------------------------------|----------------|
| Patient characteristics | | | | | |
| Age | | | | | |
| <60 years | 842 (30.1) | 56 (33.5) | | 1.763 (1.150–2.703) | 0.009 |
| >60 years | 1952 (69.8) | 111 (66.5) | | (ref) | |
| Male sex | 2552 (91.3) | 142 (85.0) | | 0.466 (0.258–0.840) | 0.011 |
| BMI at year 1 | 24.7 (5.3) | 24.3 (4.54) | | 1.013 (0.966–1.062) | 0.598 |
| ASA classification | 4.00 (=0.0) | () (00 0) | | | |
| 1 | 1423 (50.9) | 64 (38.3) | | (ref) | 0.002** |
| 2 | 1088 (38.9) | 76 (45.5) | | 1.976 (1.284–3.040) | 0.002 |
| 3 | 280 (10.0) | 27 (16.2) | | 1.870 (0.799–4.375) | 0.149 |
| Smoking | 1407 (50.0) | 00 (50 0) | | (0 | 0.074** |
| Never smoked | 1497 (53.8) | 90 (53.9) | | (ref) | 0.974** |
| Ex-smoker > 12 months Occasional smoker | 735 (26.4) 111 (4.0) | 40 (24.2) | | 0.844 (0.511–1.395) * | 0.508 |
| | ' ' | 7 (4.2) | | | 0.577 |
| Daily smoker Activities | 439 (15.8) | 29 (17.6) | | 0.987 (0.583–1.672) | 0.961 |
| None | 1212 (47.2) | 07 (E9 9) | | (rof) | 0.004** |
| | 1312 (47.2) | 97 (58.8) | | (ref) | |
| Sporadic (<1 time a week) | 415 (14.9) | 21 (12.7) | | 0.715 (0.405–1.261) | 0.246 0.291 |
| Moderate (1 time a week | 469 (16.9) | 22 (13.3) | | 0.736 (0.417–1.299) | |
| Intense (>1 a week) | 586 (21.1) | 25 (15.2) | | 0.739 (0.435–1.257) | 0.265 |
| Diabetes No | 2246 (80.3) | 127 (76.0) | | (ref) | 0.965** |
| Yes | 126 (4.5) | 7 (4.2) | | (lel) * | 0.385 |
| Hernia characteristics | 120 (4.3) | 7 (4.2) | | | 0.363 |
| Primary hernia | 2617 (93.6) | 153 (91.6) | | (ref) | 0.314** |
| First recurrence | 137 (4.9) | 11 (6.6) | | 2.125 (1.015–4.450) | 0.046 |
| Second recurrence | 16 (0.6) | 3 (1.8) | | 2.123 (1.013–4.430) | 0.040 |
| Lateral (total) | | | | | |
| | 1965 (70.2) | 124 (74.2) | | (400) | 0.116** |
| L1 L2 | 411 (14.7) | 32 (19.2) | | (ref) 0.850 (0.488–1.479) | 0.116 |
| L3 | 1034 (37.0) | 64 (38.3) 28 (16.8) | | 0.534 (0.258–1.102) | 0.090 |
| | 520 (18.6) | | | 0.334 (0.236–1.102) | 0.090 |
| Medial (total) | 1044 (37.3) | 68 (40.7) | | (400) | 0.198** |
| M1 | 180 (6.4) | 15 (9.0) | | (ref) | |
| M2 | 521 (18.6) | 28 (16.8) | | 0.726 (0.339–1.553) | 0.409 |
| M3 | 343 (12.3) | 25 (15.0) | | 0.708 (0.309–1.624) | 0.415 |
| Femoral (total) F1 | 163 (5.8) 72 (2.6) | 20 (12.0) 8 (4.8) | | * | * |
| F2 | | | | * | * |
| F3 | 78 (2.8) 13 (0.5) | 7 (4.2) 5 (3.0) | | * | * |
| Surgical characteristics | 13 (0.3) | 3 (3.0) | | | |
| Open | | | | | |
| Lichtenstein | 612 (22.0) | 53 (31.7) | (ref) | | 0.004** |
| TIPP | 834 (30.0) | 35 (21.0) | 0.485 (0.312–0.752) | | 0.004 |
| Laparoendoscopic | 634 (30.0) | 33 (21.0) | 0.463 (0.312-0.732) | | 0.001 |
| TAPP | 767 (27.6) | 44 (26.3) | 0.662 (0.438-1.002) | | 0.051 |
| TEP | 563 (20.2) | 35 (21.0) | 0.718 (0.461–1.117) | | 0.142 |
| Received prosthetics | 2719 (92.7) | 164 (98.2) | 0.718 (0.401–1.117) | | 0.142 |
| Fixation | 2/19 (92.7) | 104 (38.2) | | | |
| No fixation | 1877 (67.1) | 97 (58.1) | | (ref) | 0.016** |
| Sutures | 18// (0/.1) | 97 (36.1) | | (IeI) | 0.010 |
| Resorbable | 98 (3.5) | 2 (1.2) | | * | 0.997 |
| Not resorbable | 127 (4.5) | 8 (4.8) | | * | 0.997 |
| Staples | 127 (4.3) | 8 (4.8) | | | 0.2/1 |
| Resorbable | 439 (15.7) | 28 (16.8) | | 0.897 (0.515-1.563) | 0.702 |
| Not resorbable | | | | | 0.702 |
| Glue | 129 (4.6) 19 (0.7) | 17 (10.2) 2 (1.2) | | 2.445 (1.210–4.940) | 0.627 |
| Self-adhesive | 68 (2.4) | 10 (6.0) | | 5.550 (1.773-17.376) | 0.027 |
| Iliohypogastric nerve ¹ : | 00 (2.7) | 10 (0.0) | | 3.330 (1.//3-1/.3/0) | 0.003 |
| Not identified | 781 (54.0) | 27 (30.7) | (ref) | | 0.246** |
| Preserved | 781 (54.0) 593 (41.0) | 57 (64.8) | 1.642 (0.777–3.466) | | 0.246*** |
| Resected | 68 (4.7) | 4 (4.5) | 1.642 (0.777–3.466) | | 0.194 |
| Ilioinguinal nerve ² : | 00 (4./) | 7 (4.3) | | | 0.953 |
| | E41 (20 0) | 25 (29.4) | (rof) | | 0.050** |
| Not identified | 561 (38.8) 799 (55.2) | 25 (28.4) | (ref) | | 0.052** |
| Preserved Resected | | 61 (69.3) | 1.713 (1.062–2.763) | | 0.027 |
| | 80 (5.5) | 2 (2.3) | * | | 0.438 |
| Reoperations | 12 (0.4) | 3 (1.8) | | | |

TEP repair showed a lower odds of having relevant pain when compared to Lichtenstein repair (OR 0.616; 95% CI 0.398–0.953; p=0.029). In the no pain group, the prosthetic mesh was not fixated more often than in the relevant pain group (p<0.001). Self-adhesive

prosthetic meshes resulted in more relevant pain when compared to no fixation (OR 2.948; 95% CI 1.233–7.049; p=0.015).

A proportionally higher number of resections of the IHN was performed in the relevant pain group (OR 2.800; 95% CI 1.150–6.816; p=

Table 3
Patients with no pain at 1 month, 1 year and 2 years versus patients with relevant pain at 2 years. Missing values were omitted from analyses. 1: only Lichtenstein repairs considered in analysis. 2: only Lichtenstein and TIPP repairs considered in analysis. *: too few (<10) patients in group in order to interpret logistic regression. **: Chi-squared test. OR: odds ratio. UV: univariable logistic regression. MV: multivariable logistic regression.

| | No pain N = 2796 (%) | Relevant pain N = 247 (%) | OR (UV, 95% CI) | OR (MV, 95% CI) | P-value |
|--|----------------------------|---------------------------|---------------------|--|----------------|
| Patient characteristics | | | | | |
| Age | 040 (00.1) | 100 (41 7) | | 1 450 (1 050 1 000) | 0.000 |
| ≤60 years | 842 (30.1) | 103 (41.7) | | 1.450 (1.052–1.999) | 0.023 |
| >60 years Male sex | 1952 (69.8) 2552 (91.3) | 144 (58.3) 204 (82.6) | | (ref) 0.490 (0.310-0.773) | 0.002 |
| ASA classification | 2332 (91.3) | 204 (82.0) | | 0.490 (0.310-0.773) | 0.002 |
| 1 | 1423 (50.9) | 135 (54.7) | | (ref) | 0.257** |
| 2 | 1088 (38.9) | 91 (36.8) | | 1.004 (0.717–1.407) | 0.980 |
| 3 | 280 (10.0) | 20 (8.1) | | 0.626 (0.255–1.536) | 0.306 |
| Smoking | | | | | |
| Never smoked | 1497 (53.8) | 130 (52.8) | | (ref) | 0.771** |
| Ex-smoker > 12 months | 735 (26.4) | 51 (20.7) | | 1.085 (0.733–1.606) | 0.682 |
| Occasional smoker | 111 (4.0) | 21 (8.5) | | 2.566 (1.490–4.417) | < 0.001 |
| Daily smoker | 439 (15.8) | 44 (17.9) | | 1.221 (0.811–1.838) | 0.338 |
| Activities | 1010 (47.0) | 101 (40.0) | | (0 | 0.540** |
| None | 1312 (47.2) | 121 (49.2) | | (ref) | 0.542** |
| Sporadic (<1 time a week) | 415 (14.9) | 34 (13.8) | | 0.783 (0.496–1.237) | 0.295 0.276 |
| Moderate (1 time a week Intense (>1 a week) | 469 (16.9) 586 (21.1) | 40 (16.3) 51 (20.7) | | 0.786 (0.509–1.212) 0.989 (0.673–1.452) | 0.276 |
| Diabetes | 586 (21.1) | 51 (20.7) | | 0.989 (0.673–1.452) | 0.953 |
| No | 2246 (80.3) | 214 (86.9) | | (ref) | 0.050** |
| Yes | 126 (4.5) | 5 (2.0) | | * | 0.050 |
| Hernia characteristics | 120 (1.5) | 3 (2.0) | | | 0.005 |
| Primary hernia | 2617 (93.6) | 224 (90.7) | | (ref) | 0.139 |
| First recurrence | 137 (4.8) | 17 (6.9) | | 1.635 (0.875–3.053) | 0.159 |
| Second recurrence | 16 (0.57) | 2 (0.81) | | * | 0.573 |
| Lateral (total) | 1965 (70.2) | 180 (72.8) | | | |
| L1 | 411 (14.7) | 48 (26.3) | | (ref) | 0.293 |
| L2 | 1034 (37.0) | 94 (38.1) | | 0.965 (0.629–1.482) | 0.871 |
| L3 | 520 (18.6) | 38 (15.4) | | 0.725 (0.423–1.243) | 0.242 |
| Medial (total) | 1044 (37.3) | 83 (33.6) | | | |
| M1 | 180 (6.4) | 18 (7.3) | | (ref) | 0.850 |
| M2 | 521 (18.6) | 37 (15.0) | | 1.018 (0.509–2.039) | 0.959 |
| M3 | 343 (12.3) | 28 (11.3) | | 0.895 (0.416–1.925) | 0.777 |
| Femoral (total) | 163 (5.8) | 26 (10.5) | | (406) | 0.036** |
| F1 F2 | 72 (2.6) 78 (2.8) | 12 (4.9) 9 (3.6) | | (ref) | 0.421 |
| F3 | 13 (0.5) | 5 (2.0) | | * | 0.084 |
| Surgical characteristics | 15 (0.5) | 3 (2.0) | | | 0.001 |
| Open | | | | | |
| Lichtenstein | 612 (22.0) | 60 (24.4) | (ref) | | 0.325** |
| TIPP | 834 (30.0) | 69 (28.0) | 0.844 (0.588–1.211) | | 0.357 |
| Laparoendoscopic | | | | | |
| TAPP | 767 (27.6) | 79 (32.1) | 1.051 (0.739-1.494) | | 0.784 |
| TEP | 563 (20.2) | 34 (13.8) | 0.616 (0.398-0.953) | | 0.029 |
| Received prosthetics | 2719 (97.2) | 238 (97.2) | | | |
| Fixation | | | | | |
| No fixation | 1877 (67.1) | 140 (56.7) | | (ref) | < 0.001** |
| Sutures | 00 (0.5) | F (0.0) | | * | 0.001 |
| Resorbable | 98 (3.5) | 5 (2.0) | | | 0.221 |
| Non-resorbable | 127 (4.5) | 18 (7.3) | | 0.983 (0.471–2.051) | 0.963 |
| Staples Resorbable | 439 (15.7) | 39 (19.8) | | 1.357 (0.908–2.027) | 0.136 |
| Non-resorbable | 129 (4.6) | 11 (4.5) | | 1.008 (0.460–2.210) | 0.130 |
| Glue | 19 (0.7) | 1 (0.4) | | * | 0.998 |
| Self-adhesive | 68 (2.4) | 19 (7.7) | | 2.948 (1.233-7.049) | 0.015 |
| Iliohypogastric nerve ¹ : | () | - 0.17 | | (/ / / / / / / / / | |
| Not identified | 781 (54.0) | 56 (43.4) | (ref) | | 0.199** |
| Preserved | 593 (41.0) | 59 (45.7) | 1.404 (0.682–2.889) | | 0.357 |
| Resected | 68 (4.7) | 14 (10.9) | 2.800 (1.150–6.816) | | 0.023 |
| Ilioinguinal nerve ² : | | | | | |
| Not identified | 561 (38.8) | 36 (27.9) | (ref) | | 0.015** |
| Preserved | 799 (55.3) | 80 (62.0) | 1.560 (1.038–2.346) | | 0.033 |
| Resected | 80 (5.5) | 13 (10.1) | 2.532 (1.288-4.979) | | 0.007 |
| Reoperations | 6 (0.2) | 2 (0.8) | | | |

0.023). Non-identification of the IIN occurred more often in the relevant pain group (p = 0.015). The IIN being preserved resulted in a higher odds of relevant pain, compared to not identifying the IIN (OR 1.560; 95% CI 1.038–2.346; p = 0.033). More relevant pain resulted from IIN resections when compared to non-identification of the IIN (OR 2.532;

95% CI 1.288–4.979; p = 0.007).

3.5. Quality of life assessment

Table 4 shows outcomes of QoL questionnaires of patients who had

Table 4 Quality of life compared between severe pain at 1 year and 2 years post-operatively. Differences in answers between the groups were calculated with the ${\rm Chi}^2$ test. Missing answers were excluded in statistical analyses.

| | Severe pain at year 1 n = 167 (%) | Severe pain at year 2 N = 219 (%) | p- value |
|--------------------------------------|-----------------------------------|---|-------------|
| Quality of Life | | | |
| Questionnaire | | | |
| Q1: Does your abdominal wall | | | 0.435 |
| seem firm? | | | |
| Firm | 154 (92.2) | 196 (89.5) | |
| Not firm | 13 (7.8) | 22 (10) | |
| Missing | 0 (0) | 1 (0.5) | |
| Q2: Do you feel a swelling or a | | | 0.137 |
| lump in your groin? | | | |
| Yes | 11 (6.6) | 29 (13.2) | |
| No | 156 (93.4) | 189 (86.3) | |
| Missing | 0 (0) | 1 (0.5) | |
| Q3: Where are your symptoms located? | | | 0.125 |
| Side of surgery | 133 (79.6) | 196 (89.5) | |
| Median | 9 (5.4) | 6 (2.7) | |
| Contralateral | 4 (2.4) | 8 (3.7) | |
| Bilateral | 5 (3.0) | 1 (0.5) | |
| Other locations | 6 (3.6) | 6 (2.7) | |
| Missing | 10 (6) | 2 (1) | 0.001 |
| Q4: When do you feel these | | | 0.001 |
| symptoms? | 00 (10 0) | 0 (0.7) | |
| During coughing, lifting | 20 (12.0) | 8 (3.7) | |
| After exertion or at the end | 18 (10.8) | 48 (21.9) | |
| of the day | 121 (72.4) | 163 (74.4) | |
| During other activities Missing | 121 (72.4) 8 (4.8) | 0 (0) | |
| Q5: How often do you feel | 0 (4.0) | 0 (0) | 0.001 |
| these symptoms? | | | 0.001 |
| Rarely | 56 (33.5) | 127 (58.0) | |
| A few times per week | 76 (45.5) | 62 (28.3) | |
| A few times per day | 17 (10.2) | 14 (6.4) | |
| Often per day | 8 (4.8) | 4 (1.8) | |
| All the time | 4 (2.4) | 12 (5.5) | |
| Missing | 6 (3.6) | 0 (0) | |
| Q6: Do these symptoms: | | | 0.003 |
| Not hinder your activities? | 142 (85.1) | 192 (87.7) | |
| Cause temporary | 4 (2.4) | 6 (2.7) | |
| interruption of your | | | |
| activities? | | | |
| Prevent you from doing | 2 (1.2) | 18 (8.2) | |
| specific activities? | | | |
| Missing | 19 (11.4) | 3 (1.4) | |
| Q7: The nuisance/pain | | | 0.011 |
| discomfort is: | 100 (=0 = | · | |
| Less of a nuisance than my | 123 (73.7) | 185 (84.5) | |
| hernia was | 00 (17 4) | 00 (0.1) | |
| More of a nuisance than my | 29 (17.4) | 20 (9.1) | |
| hernia was | 15 (0) | 14 (6.4) | |
| Missing | 15 (9) | 14 (6.4) | 0.001 |
| Q8: How would you assess | | | 0.001 |
| your surgery? Bad or medium | 71 (42.5) | 45 (20.6) | |
| Good or excellent | 71 (42.5) 93 (55.7) | 45 (20.6) 172 (78.5) | |
| Missing | 3 (1.8) | 2 (1.6) | |
| | - (2.0) | _ (2.0) | |

relevant pain at one year postoperatively, compared to patients who had relevant pain at two years postoperatively.

Firmness of the abdominal wall (Question 1) was similar in either group (p = 0.435). Feeling a lump or swelling in the groin region and the location of any present symptoms (Question 2 and Question 3) were also answered similarly (p = 0.137 and p = 0.125, respectively).

Significant differences were present in the moment symptoms were experienced (Question 4), the frequency of symptoms (Question 5) and the amount of hindrance in activities experienced from symptoms (Question 6, p=0.001, p=0.001 and p=0.003, respectively). When asked how their current symptoms compare to their preoperative hernia-related symptoms (Question 7), patients with relevant pain at

two years postoperatively found their current symptoms significantly less bothering than their preoperative hernia-related symptoms, compared to patients with relevant pain at one year postoperatively (p = 0.011).

Satisfaction with the surgery (Question 8) was significantly higher in patients with relevant pain at two years postoperatively (p = 0.001).

4. Discussion

This observational, registry-based study demonstrated that overall, chances on developing CPIP are low, even if patients experienced preoperative relevant pain. Patient and surgical characteristics such as gender, age, ASA, type of surgery, recurrent surgery, type of fixation and nerve handling are significantly associated with influencing CPIP onset.

Remarkably, patients experiencing pain at one month, had relatively higher risks of developing CPIP than patients that experienced preoperative pain (12.3% versus 3.6%). Patients who perceived relevant pain at one year, had high chances of alleviating their complaints at two years, without need of reintervention. There was a small chance of developing new CPIP complaints at two years.

Previous studies showed significant differences in baseline characteristics for patients developing CPIP [11]. In accordance with literature, the present study also showed significant differences in gender and ASA classification for patients developing CPIP at one year [19]. Occasional smokers seem to be at an higher risk of being in the relevant pain at two year group. Femoral hernias seemed to lead to more CPIP complaints after one and two years, which is congruent with literature [20]. This may be due to the difference in pathophysiology of femoral hernias compared to inguinal hernias.

There seems to be a difference in patient groups when comparing patients experiencing relevant pain at one year and two years. For instance, the ASA classification is no longer significantly different between the groups at two years, whereas frequency of smoking is. These results suggest that during the longer follow up period other factors (affections) than the local inguinal postoperative anatomical conditions started to play a role. Laparoendoscopic techniques do differ in the sense that TEP is seemingly protective for CPIP at two years. This could be due to the fact that by avoiding the neural planes less nerve handling considerations apply, and could therefore limits the chances on inguinodynia. Not fixating the prosthetic mesh, possibly interfering with any nerves, seems to be favorable at one year and two years.

Many studies have been conducted on CPIP and surgical techniques. In accordance with literature, more CPIP complaints are observed when patients received an open repair for their IH (with the highest grade in the Lichtenstein group), when compared to laparoendoscopic techniques [21]. While the evidence is apparent, many surgeons still practice the Lichtenstein procedure in high numbers, perhaps due to the fact that the anterior approach can be performed without general anaesthesia and has long been one of the first procedures that trainees are taught. Patients with IH opting for surgery should be informed about the CPIP percentages after Lichtenstein's procedure. Surgical residents should be made aware of the fact that the open Lichtenstein technique is simple but not easy, considering the large amount of patients experiencing CPIP.

The difference between relevant pain and irrelevant pain is based on four different "levels" of pain. In studying pain, arbitrary cut-off points for pain have to be chosen. It is known that patients experience pain in a multitude of different ways and that pain is not merely physical, but psychological and social factors play a large role in how pain is experienced. Patients might tolerate a high amount of pain if they are still able to perform certain daily tasks and it is up to their interpretation how severely they are affected. Judgement of pain in this study is determined by the patients themselves, and might therefor be subjective with regard difference in relevant and irrelevant pain.

Fixation of prosthetics meshes in IH repair can be done in many ways. Fixation types included in this study were non-resorbable sutures and staples, resorbarble sutures and staples, glue and self-adhesive prosthetics not requiring fixation. Significantly more relevant pain was observed at one year and two years when fixation was used, although due to small numbers of patients, analyses on resorbable and non-resorbable sutures are incomplete. This effect was most apparent when non-resorbable staples or self-adhesive prosthetics were used. This could be due to the fact that staples that were non-resorbable entrapped a nerve. Results from this study might indicate that the use of non-resorbable staples should be avoided in IH repair, as other types of fixations are available.

Cirocchi et al. [6] wrote an extensive review with respect to prophylactic nerve transection to prevent CPIP. As results varied between studies, the authors made it clear that no conclusions could be drawn from their meta-analysis. It is appreciable however, that pain on the short postoperative period (i.e. six months postoperatively) declined after neurectomy. However, at one year, the advantage of the neurectomy was no longer present. This could be attributed to neuroma formation of the IIN or IHN, beginning at postoperative periods exceeding three months [22]. Difference should be made however, in the interpretation of the 'not identified' group. In TIPP repair, the recommendation of identification of all three nerves is not standard recommendation as it is with Lichtenstein's repair [23]. Only the IIN should be identified and preserved in TIPP repair, while the IHN is not at risk due to absence of extensive pre-muscular dissection, and no fixation is performed. This could be the main reason for the paradoxical CPIP outcome in unidentified nerves. Next to this, it was not clear whether the surgeons merely identified the nerves or actively searched for the nerve. In 'digging up' the nerve, unintentional lesions to the nerve could have taken place. Resection of both nerves seemed to lead to more CPIP complaints at two years, which could be due to neuroma formation and the fact that resection of the nerve could require dissection locally around it.

Differences in PROM answers between pain at one year and to year were present in time-dependent questions, while localization-specific answers were equal. As prior results suggest other factors to play a role in the long-term pain perception, the same could be true for the PROM answers. To underline this, patients experiencing pain at two years judge their CPIP as less of a nuisance compared to the pain they experienced from their hernia, compared to patients experiencing pain at one year (9.1% versus 17.4%, respectively). Furthermore, patients experiencing pain at two years predominantly (78.5%) assess their surgery as good or excellent while patients experiencing pain at one year asses their surgery as good or excellent in a mere 55.7%.

5. Limitations

The present study is based on retrospective data from a prospectively maintained cohort. As patient inclusion into this database is not randomized, although the experienced surgeons that include patients attempt to minimize selection, there will undoubtedly be some form of selection bias present in the selected sample of patients.

Surgeons that participate in the Hernia Club database are experienced hernia surgeons. Inguinal hernia surgery is not only performed by hernia surgeons, but also by most other types of surgeons around the world. This inhibits the ability to generalize the outcomes of the Hernia Club database to the broader surgeon community.

Identifying the characteristics that make one group different from another in a non-randomized setting, using their baseline and surgical characteristics, can be done by statistical analysis, which can bring forth correlations between these characteristics and the outcomes that are assessed. However, this does not directly mean that there is a direct causal connection between these characteristics and the patients' outcomes. Results from this study should therefore be taken with caution.

6. Conclusion

There is a low risk of developing CPIP after IH surgery. CPIP was relatively more apparent in patients with younger age, higher ASA classification, female gender, open surgery, and if fixation of prosthetic meshes was used. The present study found that postoperative pain at one month is a relatively higher risk for later onset of CPIP, when compared to preoperative pain. Patients could be informed if they experience CPIP at one year that they are likely to ameliorate their complaints at two-year follow-up. Patients presenting CPIP after two years seem to have a different pain etiology than patients presenting CPIP at one year. The present study could aid surgeons when informing patients about the onset and course of CPIP after IH surgery.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Ethical approval

All patients agreed to their data being stored in a pseudonymized manner in a protected databank in Switzerland. This registry is abiding to the requirements of the French 'Commission Nationale de l'Informatique et des Libertés' (CNIL; registration number 1993959v0).

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Author contribution

L.M. van den Dop, MD: Study design, data analysis, writing F.P.J. den Hartog, MD: Data analysis, writing D. Sneiders, MD: Data analysis, writing G. Kleinrensink, PhD: Study design, writing J.F Lange, MD, PhD: Study design, writing J.F. Gillon, MD⁴: Study design, writing Hernia-Club Members: Data collection

Conflicts of interest

None.

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Guarantor

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Appendix A. Supplementary data

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