Original article

Patient-reported rates of chronic pain and recurrence after groin hernia repair

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Background: **The effectiveness of different procedures in routine surgical practice for hernia repair with respect to chronic postoperative pain and reoperation rates is not clear.**

Methods: **This was prospective cohort study based on a unique combination of patient-reported outcomes and national registry data. Virtually all patients with a groin hernia repair in Sweden between September 2012 and April 2015 were sent a questionnaire 1 year after surgery. Persistent pain, defined as at least 'pain present, cannot be ignored, and interferes with concentration on everyday activities' in the past week was the primary outcome. Reoperation for recurrence recorded in the register was the secondary outcome.**

Results: **In total, 22 917 patients (response rate 75·5 per cent) who had an elective unilateral groin hernia repair were analysed. Persistent pain present 1 year after hernia repair was reported by 15·2 per cent of patients. The risk was least for endoscopic total extraperitoneal (TEP) repair (adjusted odds ratio (OR) 0·84, 95 per cent c.i. 0·74 to 0·96), compared with open anterior mesh repair. TEP repair had an increased risk of reoperation for recurrence (adjusted OR 2·14, 1·52 to 2·98), as did open preperitoneal mesh repair (adjusted OR 2·34, 1·42 to 3·71) at 2·5-year follow-up. No other methods of repair differed significantly from open anterior mesh repair.**

Conclusion: **The risk of significant pain 1 year after groin hernia repair in routine surgical practice was 15·2 per cent. This figure was lower in patients who had surgery by an endoscopic technique, but at the price of a significantly higher risk of reoperation for recurrence.**

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Introduction

The main goals of groin hernia repair are a successful procedure, without the development of recurrence or persistent pain[1] . The rate of hernia recurrence has decreased substantially since the introduction of mesh techniques[1,2]. The reported incidence of long-lasting pain, however, varies between 2 and 35 per cent, depending on surgical technique, method of pain evaluation and definition, and time after surgery[3–5]. The method of hernia repair is of interest when evaluating persistent pain, as this may be chosen according to surgeon or patient preference. Results from randomized studies[5–7] have shown that endoscopic repair is the least painful at long-term follow-up.

European guidelines[1] concluded that the overall rate of moderate to severe persistent pain after hernia surgery is around 10–12 per cent and that recurrence rates are similar when a large mesh is used, regardless of surgical technique[1].

Patient satisfaction, that is whether or not the operation/technique has met expectations, ultimately defines the success of a procedure. Patient-reported outcome measures (PROMs) are considered to be a relevant and objective way of evaluating the success of an intervention[8]. The drawback of PROMs assessment is that it is costly and time-consuming.

The aim of this study was to compare the rate of persistent pain 1 year after hernia repair in routine surgical practice, and also the rate of reoperation for recurrence, for different surgical methods. This study combined PROMs and national registry data.

Methods

This nationwide study, based on registry data and PROMs, followed STROBE guidelines[9]. Chronic pain was evaluated 1 year after hernia repair and reoperation for recurrence was recorded throughout the whole study interval. Approval was obtained from the Regional Ethics Board in Umeå (DNR 08-144 M). All procedures in this study involving human participants were undertaken in accordance with the ethical standards of the institutional and national research committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Swedish Hernia Register

The Swedish Hernia Register (SHR) covers almost 98 per cent of all groin hernia repairs in Sweden[10]. Approximately 16 000 hernia repairs are registered annually. All variables in the SHR are recorded online by the surgeon in real time on a secure database.

Data analysed at follow-up included: age, sex, method of repair, hernia anatomy, primary or recurrent hernia repair, annual surgeon volume, type of anaesthesia and reoperation for recurrence.

Patients are registered more than once if a recurrent or contralateral hernia is repaired, and all operations are easily traced using the personal identity number. The SHR is validated by an annual check of 10 per cent of participating centres. Once a year, recorded data are also checked manually against notes from a random sample of patients and units (unpublished).

Definitions

Chronic pain was defined as pain persisting for more than 3 months, affecting everyday activities[11,12]. Reoperation for recurrence was defined as a groin hernia repair in a groin that had been treated previously.

Pain questionnaire

Patients were sent a specific question extracted from the Inguinal Pain Questionnaire, a validated pain questionnaire developed specifically for groin hernia repair[13]. The questionnaire was sent 1 year after the index hernia surgery, plus up to 30 days, because the questionnaires were sent in monthly batches. The question put to the patient was: grade the worst pain you have felt in the operated groin during the past week. The seven possible scores were: 1, no pain; 2, pain present, but easily ignored; 3, pain present, cannot be ignored, but does not interfere with everyday activities; 4, pain present, cannot be ignored, and interferes with concentration on everyday activities; 5, pain present, interferes with most activities; 6, pain present, necessitating bed rest; and 7, pain present, prompt medical advice sought.

Scores of 1–3 were defined as no pain, and scores of 4–7 as chronic pain.

Data collection

All patients who had groin hernia repair between 1 September 2012 and 1 April 2015 were identified in the SHR. The first procedure during the study interval was considered the index procedure, irrespective of whether it was for primary or recurrent hernia. Postal addresses were obtained through the Swedish population register. Answers to the questionnaire were either returned by post or completed in an internet-based program. A reminder was sent if no response had been received within 1 month.

Patients and surgery

All patients in Sweden may be identified by their personal identity number[14]. This provides the opportunity to follow patients over time, regardless of where in Sweden they have primary or recurrent hernia repairs.

Inclusion criteria were: age at least 15 years, and elective surgery comprising unilateral primary or recurrent groin hernia repair. Sutured repairs were excluded as there were very few recorded in the register. Each patient was included only once; if a patient had a contralateral hernia repair during the study, that operation was not included. This led to the number of patients included being equal to the number of hernia repairs analysed.

Surgical methods included: open anterior mesh (OAM) repair (Lichtenstein), endoscopic total extraperitoneal (TEP) repair, laparoscopic transabdominal preperitoneal (TAPP) repair, combined anterior and posterior (CAP) techniques (plug; Prolene Hernia System® (Ethicon; Somerville, New Jersey, USA); open new simplified totally extraperitoneal hernia repair), and open preperitoneal mesh (OPPM) techniques.

Outcome measures

The primary endpoint was the rate of pain (according to the definition) present in the operated groin 1 year after the index repair in relation to the surgical method used. The secondary endpoint was the rate of reoperation for recurrence in the same groin after the index repair during the study interval.

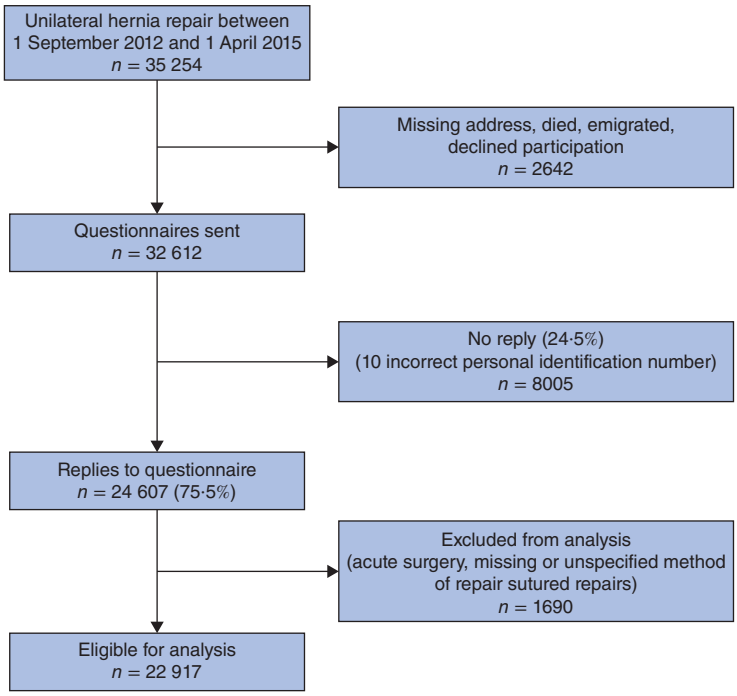

Fig. 1 Patients with hernia repair in the Swedish Hernia Register included in the study

Analysis of loss to follow-up

To account for loss to follow-up, a telephone interview was planned for a random sample of patients who did not reply to the questionnaire or the reminder. Elderly patients aged over 85 years were not contacted. Comparisons were made to detect any differences between responders and the sample of non-responders.

Reliability test

A test–retest was performed in October 2014. A sample of patients who had answered the first questionnaire were sent a second questionnaire 1 month later (in November 2014). The answers were dichotomized between no pain and pain.

Statistical analysis

Using data from the SHR, logistic regression analysis was done, with surgical method as the independent variable. Adjustments were made for confounders such as age (above or below median), sex, primary or recurrent hernia, surgeon's annual volume (above or below median), type of anaesthesia (local, regional or general) and intraoperative surgical anatomy (femoral *versus* non-femoral hernia). Starting with a full-sized model that included all confounders defined *a priori* to be clinically relevant, a

Table 1 Baseline characteristics of patients who had unilateral groin hernia repair registered in the Swedish Hernia Register between 1 September 2012 and 1 April 2015

	Responders (*n* = 22 917)	Non-responders (*n* = 8005)
Median age (years)*	65·5 (63·0)	58·8 (57·6)
Women	1872 (8·2)	819 (10·2)
Recurrent hernia	1666 (7·3)	541 (6·8)
Low-volume surgeon†	11 004 (48·0)	4121 (51·5)
Femoral hernia	566 (2·5)	327 (4·1)
Type of repair		
Open anterior mesh repair	18 034 (78·7)	5954 (74·4)
Endoscopic total extraperitoneal repair	2688 (11·7)	945 (11·8)
Laparoscopic transabdominal preperitoneal repair	380 (1·7)	138 (1·7)
Combined anterior and posterior techniques‡	1022 (4·5)	176 (2·2)
Open preperitoneal mesh techniques	793 (3·5)	344 (4·3)
Unspecified or sutured repair	–	448 (5·6)
Pain score 4 or more	3492 (15·2)	3 of 119 (2·5)§
Pain score 5 or more	2329 (10·2)	1 of 119 (0·8)§
Reoperation for recurrence	332 (1·4)	156 (1·9)

Values in parentheses are percentages unless indicated otherwise; *values in parentheses are means. †Fewer than 26 hernia repairs in the year that index operation was performed. ‡Plug, Prolene Hernia System®, open new simplified totally extraperitoneal hernia repair. §Telephone interview; 119 replies from 444 randomly selected patients.

Table 2 Baseline characteristics by type of repair

	Open anterior mesh repair ($n = 18\,034$)	Endoscopic total extraperitoneal repair ($n = 2688$)	Laparoscopic transabdominal preperitoneal repair ($n = 380$)	Combined anterior and posterior techniques ($n = 1022$)	Open preperitoneal mesh techniques ($n = 793$)
Age (years)*	66·1 (63·8)	60·0 (57·6)	64·5 (61·4)	65·0 (62·4)	67·1 (64·7)
Women	393 (2·2)	898 (33·4)	162 (42·6)	88 (8·6)	331 (41·7)
BMI (kg/m^2)*	25·0 (25·3)	24·3 (24·5)	24·5 (25·0)	24·8 (25·0)	24·5 (24·7)
Recurrent hernia	615 (3·4)	627 (23·3)	110 (28·9)	75 (7·3)	239 (30·1)
Low-volume surgeon†	9806 (54·4)	636 (23·7)	113 (29·7)	100 (9·8)	349 (44·0)
Performed by consultant	10 586 (58·7)	2574 (95·8)	375 (98·7)	934 (91·4)	737 (92·9)
Pain score 4 or more	2726 (15·1)	401 (14·9)	70 (18·4)	153 (15·0)	142 (17·9)
Pain score 5 or more	1829 (10·1)	246 (9·2)	56 (14·7)	106 (10·4)	92 (11·6)
Reoperation for recurrence	232 (1·3)	66 (2·5)	3 (0·8)	7 (0·7)	24 (3·0)

Values in parentheses are percentages unless indicated otherwise; *values in parentheses are means. †Fewer than 26 hernia repairs in the year that index operation was performed.

backward elimination process was used to reduce the size of the model by eliminating the variables contributing least to its explanatory power, such as form of anaesthesia and hernia anatomy. When two variables competed as candidates for elimination, the one with the least clinical importance was removed. Hernia anatomy, for example, is beyond the control of a surgeon and would therefore be excluded before method of hernia repair. Cohen's κ was calculated to test reliability. A sensitivity test of the results was carried by changing the definition of pain from a score of 4 or more to a score of 5 or more. A separate analysis excluded recurrent hernias, as the proportions of these differed between the surgical methods. Statistical significance was set at $P < 0{\cdot}050$.

Results

A total of 35 254 patients who underwent unilateral hernia repair were identified in the register, of whom 2642 had died, emigrated or had a private address (*Fig. 1*). Of the remaining 32 612 patients, 24 607 answered the questionnaire, a response rate of 75·5 per cent. Of these, 1690 were excluded based on prespecified criteria, leaving 22 917 patients and procedures eligible for analysis. A total of 3492 patients (15·2 per cent) reported having pain 1 year after hernia repair (*Table 1*).

Persistent pain

The proportion of patients reporting pain 1 year after surgery was 15·1 per cent after OAM repair (2726 patients), 14·9 per cent after TEP repair (401), 18·4 per cent after TAPP repair (70), 15·0 per cent after CAP procedures (153) and 17·9 per cent after open OPPM techniques (142) (*Table 2*).

Multivariable logistic regression analysis revealed TEP repair to be an independent factor for not developing persistent pain, compared with OAM repair. There were no significant differences between other techniques and OAM repair (*Table 3*).

Reoperation for recurrence

Reoperation for recurrence in the cohort during the study interval was necessary in 232 patients (1·3 per cent) after OAM repair, 66 (2·5 per cent) following TEP repair, three (0·8 per cent) after TAPP repair, seven (0·7 per cent) after a CAP procedure and 24 (3·0 per cent) for OPPM techniques (*Table 2*), at a median follow-up of 897 days (approximately 2·5 years) after the index repair. In multivariable analysis, the TEP repair showed a significantly increased risk of reoperation for recurrence compared with OAM repair, as did OPPM techniques (*Table 3*).

Analysis of loss to follow-up

The analysis of loss to follow-up included a random sample of 444 patients who did not reply to the questionnaire or the reminder. Of these, 325 patients were aged over 85 years, did not have a registered telephone number or did not respond. At interview, only three of 119 patients reported having pain according to the study definition.

The proportion of non-responders with pain was lower than that among responders; otherwise there were no differences (*Table 1*). This suggests that patients who did not respond to the questionnaire had less pain than those who did.

Reliability

The test–retest of dichotomized answers (pain or no pain, based on pain defined as a score of at least 4), from 640

Table 3 Multivariable logistic regression analysis: odds ratio for pain (score 4 or more) and reoperation for recurrence

	Pain		Reoperation for recurrence	
	Odds ratio	*P*	Odds ratio	*P*
Open anterior mesh repair (*n* = 18 034)	1·00 (reference)		1·00 (reference)	
Endoscopic total extraperitoneal repair (*n* = 2688)	0·84 (0·74, 0·96)	0·013	2·14 (1·52, 2·98)	< 0·001
Laparoscopic transabdominal preperitoneal repair (*n* = 380)	1·05 (0·79, 1·38)	0·711	0·64 (0·16, 1·74)	0·453
Combined anterior and posterior techniques (*n* = 1022)	1·01 (0·84, 1·20)	0·946	0·55 (0·26, 1·13)	0·156
Open preperitoneal mesh techniques (*n* = 793)	1·01 (0·82, 1·24)	0·091	2·34 (1·42, 3·71)	< 0·001

Values in parentheses are 95 per cent confidence intervals. The analyses were adjusted for age (above and below median), sex, primary or recurrent hernia, and annual surgeon's volume (above and below median of 26 repairs in the year that index operation was performed).

of 680 patients who were asked to complete a second questionnaire 1 month after the first, showed moderate reliability ($\kappa = 0{\cdot}58$).

Sensitivity test

When the definition of pain was changed from a pain score of 4 and above to 5 and above, the results from the logistic regression analyses remained similar, whereas the absolute risk decreased (*Table 2*).

Similarly, further analysis excluding recurrent hernia repairs did not change the results (*Table S1*, supporting information). It was also noted that sliding hernias and irreducible hernias were quite common in the OAM group, but not in the other repair groups. These variables did not affect the risk of pain relative to that associated with OAM repair.

Finally, a pain score of 7, the highest level of pain, was analysed specifically; 5·0 per cent of patients reported this level of pain, with no significant differences between methods of surgical repair.

Discussion

In the present study, 15·2 per cent of patients experienced pain affecting everyday activities 1 year after groin hernia surgery in routine surgical practice. There were only small differences in chronic pain between the surgical methods of repair. In multivariable analysis, TEP repair was associated with less pain, but higher rates of reoperation for recurrence, than OAM repair.

The absolute risk of chronic pain that could not be ignored, and interfered with concentration on chores and everyday activities, was 15·2 per cent, which is unexpectedly high in comparison with that reported in other studies. Direct comparison with other studies is difficult, as the definition of pain is not standard globally. However, even studies using the same definitions showed vastly differing results. For example, in a randomized single-centre study[7], the rate of pain scored 4 or more was hardly detectable at 1-year follow-up. The reason for this difference is not clear, but the fact that the latter study employed strict inclusion criteria is a possible explanation. It raises the question of whether randomized studies of hernia surgery reflect the outcomes achieved in routine surgical practice. In another study[4], the same question was put to patients 24–36 months after hernia surgery, revealing pain rates of 7 per cent according to the definition in the present study. This suggests that chronic pain may decrease over time[12,15].

The TEP endoscopic technique for elective primary inguinal hernia repair is considered the best procedure for minimizing the risk of persistent chronic pain[1], and this was supported by the present results. However, the positive effect of TEP repair was less pronounced in this study than in most randomized studies to date[1,5,6]. Even though an odds ratio will overestimate the relative risk, a reduction in the odds of pain with TEP repair of 16 per cent would correspond to a maximum absolute decrease in pain rates of 2·5 per cent[16]. This difference in effect size might be explained by the fact that most studies included patients with a median age well below that in the present study, and that RCTs[6,17] included primary hernias only, and women were excluded.

A meta-analysis[18] from 2012 showed that reoperation rates for hernia recurrence are higher with TEP than with OAM repair. Furthermore, Kald and colleagues[19] showed that not all recurrences require surgery and so true recurrence rates are substantially higher than reoperation rates. Reoperation rates also seem to continue rising with prolonged follow-up[6]. In the present study, both TEP and OPPM techniques were associated with a higher reoperation rate for recurrence.

In a previous smaller SHR-based study[20] comparing different methods of fixation in endoscopic repair, the rate of pain (according to the present definition) was half that of the present study after a median follow-up of approximately 3 years. The rate of reoperation for recurrence was 1·5 per cent after 7 years of follow-up. Registry data revealed that the total number of surgeons performing TEP repair as well as the total numbers of such procedures

in that study were substantially lower than in the present series. The total rate of TEP repair (including bilateral and emergency repairs) almost tripled between the two study intervals (9 *versus* 25 per cent), indicating that surgeon experience and interest could be an explanatory factor[21].

The present study has also shown that it is possible to use health registries as platforms for PROMs. By including a questionnaire module in a high-coverage register with unselected consecutive enrolment, the advantages include adequate power to control for confounding, as well as a powerful tool facilitating follow-up and efficient and cost-effective studies.

This study has strengths and weaknesses. The almost complete coverage of the SHR minimizes the risk of selection bias. Registry data are collected prospectively, thereby minimizing recall bias. Annual validation of randomly selected variables ensures data quality. The use of a previously used, validated questionnaire is a further strength, allowing comparison with other studies. Reliability, sensitivity and non-responder analyses limit misinterpretation.

The main weakness of this study is the lack of information on preoperative pain. It has been shown that preoperative pain increases the risk of postoperative pain[6], and could be a possible unmeasured confounder. However, high preoperative pain scores would not have excluded patients from surgery, as these patients have the most to gain[22,23]. Other weaknesses are the non-controlled observational design of the study and the lack of specific details of the surgical techniques used. It must be stressed that some procedures such as TAPP repair were rarely performed in Sweden, and this study lacked the power to detect any clinically meaningful difference between TEP and TAPP repairs.

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Supporting information

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