

Self-Reported Adverse Events after Groin Hernia Repair, A Study Based on a National Register

Ulf Fränneby, MD, PhD,¹ Gabriel Sandblom, MD, PhD,² Olof Nyrén, MD, PhD,³ Pär Nordin, MD, PhD,⁴ Ulf Gunnarsson, MD, PhD⁵

¹Department of Surgery, Södersjukhuset, Stockholm, Sweden; ²Lund University Hospital, Lund, Sweden; ³Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden; ⁴Department of Surgery, Östersund, Sweden; ⁵Akademiska Sjukhuset, Uppsala, Sweden

ABSTRACT

Objectives: In most clinics, follow-up after inguinal hernia surgery is not a routine procedure and complications may pass unnoticed, thus impairing quality assessment. The aim of this study was to investigate the frequency, spectrum, and risk factors of short-term adverse events after groin hernia repair.

Methods: All patients aged 15 years or older with a primary unilateral inguinal or femoral hernia repair recorded in the Swedish Hernia Register (SHR) between November 1 and December 31, 2002 were sent a questionnaire asking about complications within the first 30 postoperative days.

Results: Of the 1643 recorded patients, 1448 (88.1%) responded: 1341 (92.6%) were men and 107 (7.4%) women, mean age 59 years. There were 195 (11.9%) nonresponders. Postoperative complications reported in the questionnaire

were hematoma in 203 (14.0%) patients, severe pain in 168 (11.6%), testicular pain in 120 (8.3%), and infection in 105 (7.3%). Adverse events were reported in the questionnaire by 391 (23.8%) patients, whereas only 85 (5.2%) were affected according to the SHR. Risk factors for postoperative complications were age below the median (59 years) among the studied hernia patients (OR 1.36; 95% CI 1.06–1.74) and laparoscopic repair (OR 2.66; 95% CI 1.17–6.05).

Conclusion: Questionnaires provide valuable additional information concerning postoperative complications. We recommend that they become an integrated part of routine postoperative assessment.

Keywords: groin hernia, postoperative complications, questionnaire study, risk factors.

Introduction

Although being one of the most common procedures in general surgery [1], complications after inguinal hernia repair have rarely been subject to large-scale audits. Contributing to the sparsity of systematic evaluations are logistical difficulties; as an increasing proportion of all operations are performed on an outpatient basis [2], and as routine follow-up visits are generally not considered to be necessary, complications may pass unnoticed from the caregivers' perspective [3]. Previous studies of the accuracy of complication recordings after, for example, colorectal cancer surgery have disclosed a substantial deficit in the completeness of quality registers [4]. Auditing of complications in hernia surgery is also complicated by the fact that patients and surgeons may define adverse events differently [5]. Whereas the patient is the only one who can give a full account of the postoperative course, the surgeon has a better knowledge of what to expect and what to characterize as deviations from normality. A

complete quality assessment can therefore only be achieved if the views of both the surgeon and the patient are taken into account.

The aim of this study was to estimate the frequency, spectrum, and risk factors of self-reported adverse events after groin hernia repair. An evaluation has also been made of how much additional clinically relevant information is yielded by a postal questionnaire 4 to 6 months after the operation over and above that obtained through a review of patient records. For this purpose, the information recorded in the Swedish Hernia Register (SHR) was supplemented by a questionnaire on postoperative complications that was distributed to all patients registered as having undergone a primary unilateral groin hernia repair during a defined period of time.

Patients and Methods

The SHR

The SHR started in 1992 and currently covers approximately 95% of all operating units in Sweden. Detailed information on more than 120,000 inguinal and femoral hernia operations on patients aged 15 years or older has been compiled since the start [6,7]. Every

Address correspondence to: Ulf Fränneby, Department of Surgery, Södersjukhuset, SE-118 83 Stockholm, Sweden. E-mail: ulf.franneby@sodersjukhuset.se
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operation at the participating hospitals is recorded according to a standardized protocol. Variables recorded include hospital, National Registration Number (NRN—a unique personal identifier assigned to all Swedish residents), gender, age, type of hernia (including left/right side) as noted during the operation, and type of repair. Postoperative complications occurring within the first 30 days and coming to the attention of the operating units are also recorded. Such complications typically include hematoma, infection, urinary retention necessitating a catheter, and severe pain. Nevertheless, active follow-up is not mandatory. The NRNs enabled us to follow up the patients regarding subsequent hernia surgery through annual cross-linkages to the SHR, and to obtain correct censoring information through record linkages with the continuously updated and essentially complete registers of Migration and Causes of Death, held by Statistics Sweden [8]. Each year, an external reviewer visits almost 10% of the participating units and compares a sample of register data with operative records and patient files to check the validity of register data. The register has been found to include some 98% of eligible operations [9].

Patients

All male and female patients of ages 15 years or older who were registered in the SHR between November 1 and December 31, 2002 for a primary unilateral inguinal or femoral hernia operation were included. The operating technique was at the surgeon's discretion and included open suture techniques, tension free procedures, and laparoscopic operations.

Questionnaire

Questions were asked about events which the patient perceived as adverse beyond normality, occurring within the first 30 postoperative days. The patient was further asked whether he or she had sought health care for such events. Events that lead to a health-care visit were expected to be known to the treating physician and thus to be recorded in the SHR. The patients were also asked to report their weight, height, and smoking habits.

Procedures

The patients received the questionnaire by regular mail in May 2003. Reminding letters were sent after 5 and 10 weeks. We divided the reports into two categories: 1) complications proper, which were reported by the caregiver (as a complication recorded in the SHR) or by both patient and caregiver; and 2) deviations from the expected postoperative course, reported only by the patient (and not by the caregiver).

Analyses

Statistical analysis was performed by using SPSS13.0 (SPSS, Chicago, IL). Multivariate logistic regression

was used to estimate the association of risk indicators such as age (above/below median), body mass index (BMI; above/below median), smoking status (non-smoker, smoker of up to 10 cigarettes a day, smoker of more than 10 cigarettes per day), type of hernia (medial, lateral, combined medial/lateral, femoral, and other), and type of hernia repair (Lichtenstein, plug, Shouldice, laparoscopic, other mesh repairs through groin incision, and other procedures) with any type of patient-defined complication. We used stepwise selection with entry testing based on the significance of score statistics, and removal testing based on the probability of a likelihood-ratio statistic based on the maximum partial likelihood estimates. Results are presented with odds ratios (OR) and/or 95% confidence intervals (CI) where appropriate. The number of responders may vary for each item in the questionnaire because only complete sets of data were analyzed.

Results

The number of unilateral primary inguinal or femoral hernia repairs registered in the SHR between November 1 and December 31, 2002 was 1643. Of these, 1524 (92.8%) were in men and 119 (7.2%) were in women. The mean age was 59 years (SD 16). The response rate to the questionnaire was 88.1%. Of the 1448 responders, 1341 (92.6%) were men and 107 (7.4%) were women, with a mean age of 59 years (SD 16). Of the 195 nonresponders, 11 (6%) had died and 17 (9%) had an unknown address or an erroneous NRN.

The distribution of adverse events as calculated from the questionnaire is presented in Table 1. Some 155 (10.8%; 95% CI 9.3–12.5%) patients reported an adverse event during or immediately after the operation and 323 (22.5%; 95% CI 20.4–24.7%) reported an adverse event within the following month. Altogether 391 patients experienced a complication during or within a month of the operation. The most common postoperative complications reported were: hematoma in 203 patients (14.4%; 95% CI 12.6–16.3%), severe pain in 168 (11.8%; 95% CI 10.2–13.5%), and testicular pain in 120 (8.3%; 95% CI 7.2–10.1%). Postoperative infection was reported by 105 (7.4%; 95% CI 6.2–8.9%) patients. Figures are based on the 1448 responders.

The number of patients reporting adverse events occurring during the operation and/or in the first postoperative month (N = 391, 23.8%) exceeded the frequency of complications recorded in the SHR (N = 85, 5.2%). This was true also for health-care visits for adverse events; according to the questionnaire reports, 198 (12.1%) made such visits, although only 85 (5.2%) were recorded in the SHR. The SHR thus contained records of 21.7% of all adverse events reported in the questionnaire and 42.9% of events leading to

Table I (a) Distribution of adverse events and (b) type of adverse events according to the questionnaire

Questions	No n (%)	Yes n (%)	Total	
(a)				
Did any complications arise at your hernia operation?	1285 (89.2)	155 (10.8)	1440	
Did you experience any problems within a month of your operation?	1114 (77.5)	323 (22.5)	1437	
Questions	No n (%)	Yes, but I have not sought help from the health care n (%)	Yes, I have sought help from the health care for it n (%)	Total
(b)				
Hematoma	1211 (85.6)	135 (9.5)	68 (4.8)	1414
Infection	1309 (92.6)	42 (3.0)	63 (4.5)	1414
Wound rupture	1372 (95.9)	22 (1.5)	37 (2.6)	1431
Severe pain	1259 (88.2)	116 (8.1)	52 (3.6)	1427
Thrombosis	1410 (99.1)	7 (0.5)	6 (0.4)	1423
Testicular pain	1285 (91.5)	104 (7.4)	16 (1.1)	1405
Anesthetic complications	1390 (97.3)	27 (1.9)	12 (0.8)	1429
Urinary infection/urinary retention	1369 (95.7)	43 (3.0)	18 (1.3)	1430
Constipation	1375 (96.4)	48 (3.4)	3 (0.2)	1426
Other complications	1131 (83.5)	158 (11.7)	65 (4.8)	1354

health-care consultations. The figures are based on all 1643 patients.

The incidence of patient-reported complications was highest in the age group 30 to 50 years, where almost 30% of the patients perceived themselves as being affected, in contrast to 5% recorded in the SHR. In the SHR, the incidence of complications increased slightly above the age of 60 years to 8% (Fig. 1). The most common type of complication according to the questionnaire in patients 40 to 60 years of age was severe pain, which was experienced by about 17% of patients, with a marked drop to below 10% in patients over the age of 60 years. Postoperative bleeding had its highest incidence in patients of ages 40 to 80 years (Fig. 2).

In the analysis of risk factors, young age (≤ 59 years, OR 1.36; 95% CI 1.06–1.74) and laparoscopic hernia repair (OR 2.66; 95% CI 1.17–6.05) were associated with an increased risk of complica-

tions. Type of hernia, smoking, and BMI did not significantly affect the risk of postoperative complications (Table 2 and Fig. 3).

Discussion

By actively obtaining data on the postoperative period directly from the patient, audits of health care can be accomplished in a way that would not be possible solely by recording complications that have come to the attention of the health-care providers. Although such data may include complaints of a kind that the surgeon would have interpreted as expressions of the normal healing process, they do reflect patient dissatisfaction, and patient satisfaction is one of the ultimate goals of health care.

There is an obvious divergence between complications registered in the SHR and adverse events recorded in a structured questionnaire. Many complications go unnoticed after surgery when patients are advised to seek medical attention only in the event of

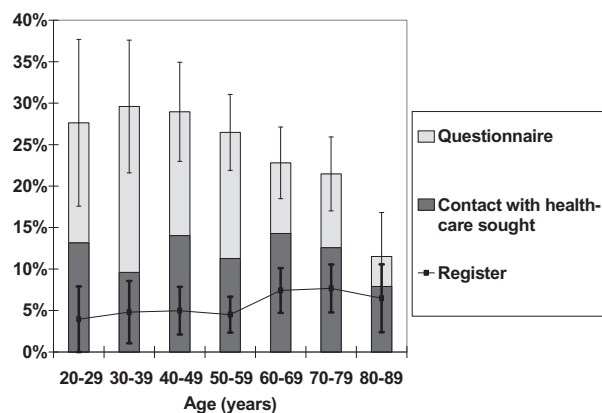


Figure 1 Adverse events notified in the questionnaire, with special regard to events the patients stated as cause for contact with health care, and complications recorded in the Swedish Hernia Register by age.

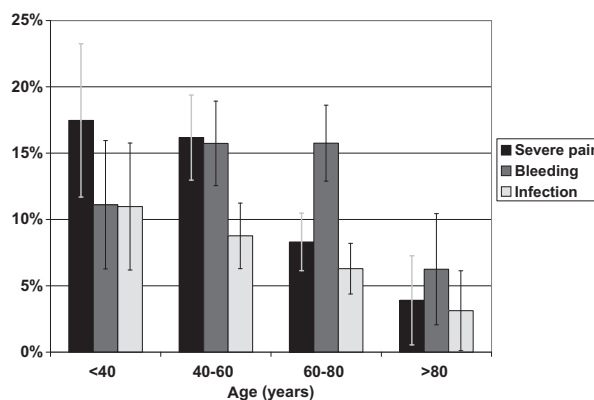


Figure 2 Type of adverse event according to the questionnaire by age.

Table 2 Multivariate logistic analysis

Factor	Adverse events* (%)	Univariate model		Final multivariate model [†]	
		OR	95% CI	OR	95% CI
Age (years)					
>median (59)	152/587 (25.9)	1	Reference	1	Reference
≤median (59)	216/658 (32.8)	1.55	1.22–1.96	1.36	1.06–1.74
Gender					
Male	338/1166 (29.0)	1	Reference		
Female	30/79 (38.0)	1.16	0.75–1.78		
Reducible vs. nonreducible hernia					
Nonreducible	21/88 (23.9)	1	Reference		
Reducible	347/1157 (30.0)	1.43	0.90–2.28		
Hernia repair					
Lichtenstein	225/789 (28.5)	1	Reference	1	Reference
Plug techniques	39/161 (24.2)	0.78	0.53–1.15	0.79	0.53–1.17
Other repairs with mesh through groin incision	32/90 (35.6)	1.19	0.77–1.84	1.36	0.86–2.15
Shouldice	32/111 (28.8)	1.02	0.67–1.56	1.00	0.64–1.55
Laparoscopy	13/24 (54.2)	2.78	1.31–5.92	2.66	1.17–6.05
Other repairs	27/70 (38.6)	1.46	0.92–2.32	1.56	0.94–2.59
Type of hernia					
Medial	124/399 (31.1)	1	Reference		
Lateral	200/716 (27.9)	0.85	0.66–1.10		
Combined medial and lateral	32/102 (31.4)	0.99	0.63–1.55		
Femoral	8/21 (38.1)	1.18	0.52–2.66		
Other	4/7 (57.1)	1.98	0.52–7.51		
Diameter of hernia defect					
<3 cm	261/837 (31.2)	1	Reference		
≥3 cm	107/408 (26.2)	0.75	0.58–0.98		
Number of surgeons performing the operation					
1	260/893 (29.1)	1	Reference		
>1	108/352 (30.7)	1.09	0.84–1.41		
Management of hernia sac					
Complete dissection	340/1127 (30.2)	1	Reference		
Distal part left in situ	28/118 (23.7)	0.71	0.46–1.10		
BMI					
<median (24.7)	171/621 (27.5)	1	Reference		
>median (24.7)	197/624 (31.6)	1.25	0.98–1.58		
Smoking habit					
Nonsmoker	318/1074 (29.6)	1	Reference		
Smoker	50/171 (29.2)	0.96	0.68–1.35		

*Number of patients stating adverse event/total number of responders.

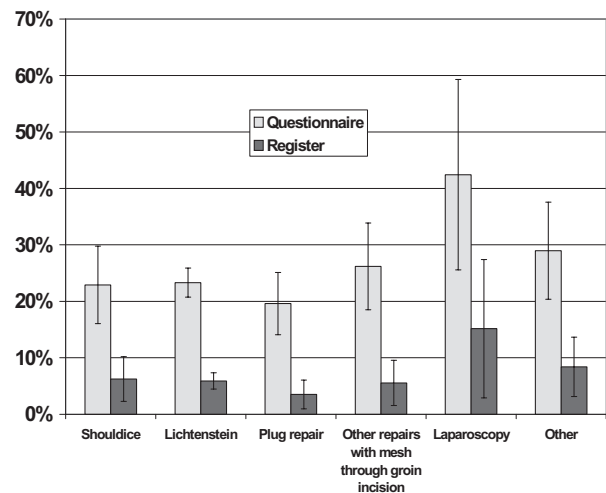
[†]Final model contains the variables with values in the OR column.

Complication is defined as a positive answer in the questionnaire. The analysis is based on patients with data on all variables.

BMI, body mass index; OR, odds ratio; 95% CI, 95% confidence interval.

an adverse reaction, as compared to a structured follow-up [10]. The discordance between the patient and surgeon should not, however, lead to a rejection of complications as an outcome measure. Instead of considering them as two contradicting entities, they can be treated as two separate measures of quality, with equal weighting [5].

Only 22% of all the adverse events reported in the questionnaire were recorded in the SHR. It is possible that patients are sufficiently well-informed to seek health care only for complications that need to be treated. In that case, adverse events not known to the health-care services might be mostly self-limiting adverse reactions that heal without any further treatment. Nevertheless, no more than 43% of the patient-reported consultations that were made because of alleged complications were recorded in the SHR. One reason for this might be that many patients seek help from other health-care facilities that are not connected to the SHR, such as the general practitioner's office.

**Figure 3** Complications by type of repair.

Another reason might be the disagreement between what the patient and the doctor perceive as a complication. As the concept of surgical complications is not well defined, and patients and surgeons differ in their appraisal, the latter category might well include real complications, but they are on average likely to be less serious than those that come to the surgeon's attention [5]. It may also include normal degrees of pain, swelling, and disability that are perceived by the patient as deviations, mainly because of insufficient information about what to expect. Patient satisfaction and complaints are strongly associated with the perioperative information [11], and it is well possible that patients who are not properly informed about the expected postoperative course will report more adverse events.

The incidence of self-reported adverse events was highest in patients 30 to 50 years of age and then dropped considerably in the older age groups. One explanation for this might be that severe pain was the predominant self-reported complication among younger patients. Younger patients seem to be more prone to report complications, notably pain, but only about 15% of these complications were recorded in the register. This might be because a large proportion of these patients understood that the pain would fade away eventually, that active surgical intervention was not indicated, and that a new consultation was unnecessary. Given the covert nature of postoperative pain without any objective signs of any other complication, it is likely that doctors who were consulted may have drawn a similar conclusion. Patients in the older age group reported fewer complications, but a higher proportion had sought health care for them and was thus recorded in the register. A corresponding peak was observed in recent studies of long-term pain after groin hernia surgery [12,13], indicating that the younger age group will either be more aware of symptoms after groin hernia surgery or more likely to have adverse events. One reason may be that patients in this age group return to physically harder work and are thus exposed to more triggering events. Bleeding was commonly reported in the age groups 40 to 80 years. This may be due to the fact that older patients, on average, have larger hernias necessitating extensive dissection, compared to younger patients, as well as to more frequent use of antithrombosis medication in the older age group. The markedly low incidence of complications in the oldest group can be related to selection of the fittest patients, in combination with a particularly gentle technique. Nevertheless, a generally greater tolerance among older patients, and thus a lower inclination to report complaints, could have contributed. Regardless of reason for the higher incidence of adverse events among certain age groups, this emphasizes the importance of proper information and easy access to contact with the surgical unit.

Complications were reported by 14 of the 28 (50%) patients who had undergone laparoscopic operations. This surgical technique was thus an independent risk factor for self-reported complications. This result is consistent with previous data indicating that laparoscopic surgery is associated with more complications [14–16], but because the number of laparoscopic treated patients is small in this study, the result should be interpreted cautiously. In this study, no increased risk of complications was found for smokers or patients with BMI above the median. Smoking has been linked to postoperative complications in previous studies [17], but these results were not reproduced here.

This study was performed among patients included in November and December 2002. Because most clinics do not deliver their annual data to the SHR until after the turn of the year, the study period is the most appropriate. The delay between surgery and receipt of the questionnaire was then minimized and fairly uniform (range 4–6 months). Most complications are likely to occur within the first month after the operation, reflecting the intention of the questionnaire [10]. Clearly, some nondifferential misclassification of the outcome because of imperfect recollection is probable, but there might also be some recall bias in the comparison between younger and older patients. Nevertheless, the investigated time-span was relatively short. Furthermore, the study might have given a slightly different result had it been carried out during the summer period, when most of the gainfully employed patients would have been on vacation and their occupational activity less demanding.

Adding a questionnaire to the follow-up routines provides valuable complementary information on the incidence and spectrum of adverse events as experienced by the patient. Without a strategy for systematic follow-up, the frequency of adverse reactions may become greatly underestimated. For the purpose of quality assurance, every operating unit should aim for essentially complete registration of complications. Although definitely of value, retrospective self-reporting by the patients may, however, suffer from the patients' lack of clear references as to what is a normal postoperative course. It is therefore reasonable to assume that better perioperative information to the patients, notably a realistic account of what to expect in terms of pain and discomfort, will result in more correct estimates of true complication rates. To improve the quality of hernia surgery, we believe that routine follow-up either with a questionnaire, with an outpatient visit or by telephone 1 month after the operation are helpful. An accurate quality assurance system requires at least intermittent audits to be regarded as having useful and reliable data for the purpose of improving the quality of care and controlling costs for treatment. The results of this study clearly show that relying on passive assembling of complication data is

not sufficient and may lead the operating unit into false beliefs of high quality and a high patient satisfaction. The only reasonable way to find out more on postoperative complications, patient discomfort, and dissatisfaction is by actively asking every patient in a structured way and thereby in the audit find ways to improve the outcome. The question as to whether early postoperative complications will predict long-term sequelae requires studies with continuous follow-up for longer periods than 4 to 6 months.

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Supplementary materials for this article can be found at: <http://www.ispor.org/publications/value/ViHsupplementary.asp>

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