Original article

Validation of an Inguinal Pain Questionnaire for assessment of chronic pain after groin hernia repair

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Background: **Long-term pain is an important outcome after inguinal hernia repair. The aim of this study was to test the validity and reliability of a specific Inguinal Pain Questionnaire (IPQ).**

Methods: **The study recruited patients aged between 15 and 85 years who had undergone primary inguinal or femoral hernia repair. To test the validity of the questionnaire, 100 patients received the IPQ and the Brief Pain Inventory (BPI) 1 and 4 weeks after surgery (group 1). To test reliability and internal consistency, 100 patients received the IPQ on two occasions 1 month apart, 3 years after surgery (group 2). Non-surgery-related pain was analysed in group 3 (2853 patients).**

Results: **A significant decrease in IPQ-rated pain intensity was observed in the first 4 weeks after surgery ($P < 0{\cdot}001$). Significant correlations with corresponding BPI pain intensity items corroborated the criterion validity ($P < 0{\cdot}050$). Logical incoherence did not exceed 5·5 per cent for any item. Values for κ in the test–retest in group 2 were higher than 0·5 for all but three items. Cronbach's α was 0·83 for questions on pain intensity and 0·74 for interference with daily activities.**

Conclusion: **This study found good validity and reliability for the IPQ, making it a useful instrument for assessing pain following groin hernia repair.**

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Introduction

Quality assurance of groin hernia repair has previously focused mainly on recurrence. Improvements of quality in hernia repair and the introduction of mesh repair techniques have markedly reduced the recurrence rate[1]. As a result, other important adverse outcomes have become evident. Recent studies have pointed to long-term pain as one of the major adverse outcomes after hernia repair[2,3]. The lack of a uniform definition of long-term postoperative pain, however, has led to diverging figures of its prevalence, ranging from 1 to 32 per cent[4–7]. A standardized and valid instrument for assessing the occurrence and severity of postoperative inguinal pain is therefore urgently needed, not only for obtaining comparable measures of results across centres, but also as a tool in the quality assurance efforts of each surgical department. With this in mind, the Inguinal Pain Questionnaire (IPQ) was developed. The full questionnaire can be found in *Appendix 1* (available as supplementary material online at http://www.bjs.co.uk). The aim of the present study was to evaluate its reliability and validity.

Methods

Inguinal Pain Questionnaire

The IPQ was developed as a modification of the questionnaire proposed by Kehlet and colleagues[8]. The earlier questionnaire treated pain intensity as a dichotomous variable; however, the IPQ uses a seven-step fixed-point rating scale to assess pain, with steps linked to pain behaviour rather than to numbers or verbal pain descriptions, with additional monitoring of

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pain duration. An identical Duration Intensity Behaviour Scale (DIBS) has been evaluated previously regarding compliance, authenticity, reliability and sensitivity among patients with functional abdominal pain[9]. By defining pain intensity operationally in terms of behaviour resulting from pain, the DIBS instrument avoids, at least to some extent, the unsolvable dilemma of pain level definitions and measurement calibration; furthermore the impact on daily life activities is easily inferred. In the IPQ, patients are asked in separate questions to report their current inguinal pain as well as the worst pain experienced during the preceding week. A second part of the questionnaire focuses on interference with daily activities, in line with a proposal by Kehlet and co-workers[8]. Altogether there are 18 items, and the total questionnaire takes about 10 min to fill in.

Patients

Validity and reliability testing was carried out in three separate samples. All had the same inclusion criteria: age between 15 and 85 years, and a primary inguinal or femoral hernia repair (ambulatory or on an inpatient basis). Patients with previous or bilateral operations were excluded. Group 1, to assess validity, consisted of 100 consecutive consenting patients who had surgery at Mora General Hospital between November 2003 and June 2004. Their mean(s.d.) age was 63(14) years, and 97 per cent were men. Group 2, to assess reliability, consisted of 100 patients treated at the same hospital between January and September 2001. Their mean(s.d.) age was 63(14) years, and 93 per cent were men. All patients in groups 1 and 2 had open groin hernia repair, as laparoscopic surgery was not performed in Mora at that time. An additional analysis of internal consistency was performed in group 2. In group 3, pain that was not surgery related was analysed with a large-scale evaluation of residual pain after inguinal hernia repair using the IPQ[10]. Patients for this group were selected from the population-based Swedish National Hernia Register, which covered 59 hospitals (60 per cent of all operating units in Sweden)[1]. Of 7536 patients with new primary hernia repairs in 2000 who had survived to May 2002, 2853 were randomly selected. The mean(s.d.) age of the 2456 responders in this sample was 58·5(15·4) years, and 2299 (93·6 per cent) were men.

Procedures

Before discharge, each member of group 1 received the IPQ questionnaire and was asked to fill it in on day 7 after surgery. To evaluate validity, the patients were asked to fill in the validated Brief Pain Inventory (BPI) at the same time[11]. The short form of the BPI was used, which assessed pain severity in the past week. A second set of IPQ and BPI questionnaires were sent out to be completed on day 28 after surgery. The questionnaires were completed mostly in the patients' homes, without any special assistance.

Patients in group 2 received a mailed IPQ on two occasions, 1 month apart, 3 years after their operation. On each occasion, they completed the questionnaire by themselves and immediately returned it to the investigators by regular mail.

Before the IPQ questionnaires were sent to the patients in group 3 in the first 3 months of 2003, a final check with the Swedish Cause of Death Register revealed 147 recent deaths, leaving 2853 still alive and available for contact. The patients filled in the questionnaire in their homes after receiving standard written instructions, and the answers were returned to the investigators by post.

Reminders were sent out after 5 and 10 weeks if answers were missing from patients in any of the three groups.

Statistical analysis

Postoperative inguinal pain was thought to subside typically between days 7 and 28 after the operation. A decline in recorded aspects of pain intensity in group 1 was therefore taken as proof of construct validity. For variables with a dichotomous response, the decline was tested with the χ^2 test, and a Wilcoxon signed rank test was used for ordinal scale responses. With 100 patients in group 1, the probability of detecting a reduction in the prevalence of pain from 40 to 20 per cent was higher than 80 per cent with a significance level of $P < 0{\cdot}050$.

Internal consistency can also be seen as an indication of construct validity. In group 2, the items concerning pain intensity (2–6) and also items concerning interference with daily activities (7–12) were compared using Cronbach's α coefficient[12]. In addition, logical coherence was examined using the responses from patients in group 2.

Criterion (concurrent) validity was assessed by comparing the results from the IPQ items 'pain right now' on each of days 7 and 28 in group 1 with the corresponding BPI measures of pain intensity. Correlations were tested with Spearman's rank correlation test.

Test–retest repeatability (reliability) was estimated among members of group 2 in whom the inguinal pain status 3 years after surgery was assumed to be reasonably stable over time. The concordance between two ratings by the same patient 1 month apart was estimated with κ statistics.

The specificity of the self-reports regarding pain related to hernia repair was tested by asking patients in group

Table 1 Patient selection and response rates in validity and reliability testing

	Group 1 ($n = 100$)	Group 2 ($n = 100$)	Group 3 ($n = 2853$)
	Validity	Reliability	Internal consistency and comparisons between treated and untreated groin
No. of responders, first occasion	94	90	2456
No. of responders, second occasion	85	80	
Age (years) of responders, first occasion*	63(14)	63(14)	58·5(15·4)
Sex ratio (M : F), first occasion	91 : 3	84 : 6	2299 : 157

*Values are mean(s.d.).

Table 2 Comparison of pain ratings for treated groin 1 week and 1 month after surgery in group 1

	Week 1	Week 4	*P**
Pain right now			
1	22 (23)	48 (56)	
2	28 (30)	25 (29)	
3	14 (15)	8 (9)	
4	18 (19)	4 (5)	
5	12 (13)	0 (0)	
6	0 (0)	0 (0)	
7	0 (0)	0 (0)	
Median	2	1	< 0·001
Worst pain in the past week			
1	15 (16)	40 (47)	
2	15 (16)	25 (29)	
3	18 (19)	8 (9)	
4	20 (21)	9 (11)	
5	21 (22)	3 (4)	
6	5 (5)	0 (0)	
7	0 (0)	0 (0)	
Median	3	2	< 0·001
How often have you felt pain?			
1	3 (4)	7 (18)	
2	14 (19)	9 (23)	
3	47 (64)	19 (49)	
4	7 (10)	4 (10)	
5	2 (3)	0 (0)	
6	0 (0)	0 (0)	
Median	3	3	0·001
How long have pain episodes lasted?			
1	45 (63)	26 (72)	
2	7 (10)	3 (8)	
3	14 (20)	5 (14)	
4	4 (6)	2 (6)	
5	1 (1)	0 (0)	
Median	1	1	0·007

Values in parentheses are percentages. For definitions of scale steps, refer to *Appendix 1* (available at http://www.bjs.co.uk). *Wilcoxon signed rank test.

Table 3 Comparison of pain ratings 1 week and 1 month after surgery in group 1

	Week 1	Week 4	*P**
Difficulties getting up from a chair	37/89 (39)	5/81 (5)	< 0·001
Difficulties sitting down	15/84 (16)	3/78 (3)	0·003
Difficulties standing up	19/89 (20)	4/81 (4)	< 0·001
Difficulties climbing stairs	20/89 (21)	3/81 (3)	< 0·001
Difficulties driving a car	12/89 (13)	3/81 (3)	0·025
Difficulties with exercise	39/88 (42)	14/81 (15)	< 0·001
Use of painkillers	50/94 (53)	2/94 (2)	< 0·001
Testicular pain	23/94 (25)	25/94 (27)	0·740

Values are number of patients, with percentages in parentheses. *χ^2 test.

3 about pain in the non-operated groin. Undiagnosed hernias and musculoskeletal conditions could cause pain in some patients, regardless of whether the groin had been operated on or not. However, it was postulated that if the self-reports were sufficiently specific the occurrence and mean pain severity would be greater on the operated side. The hypothesis of greater pain severity in the operated groin was tested with a Wilcoxon signed rank test.

Results

Some data on response rates and demographic characteristics of responding patients appear in *Table 1*. In group 1 (validity assessment), 85 of 100 patients reported pain on both days 7 and 28 after surgery. In the test–retest evaluation in group 2, 80 of 100 patients responded on both occasions. In group 3, 2456 (86·1 per cent) of 2853 responded.

Construct validity

The IPQ responses reflected the expected decline in pain following surgery (*Tables 2* and *3*). Participants'

Table 4 Presence of pain in the treated groin *versus* the untreated groin in group 3

	Pain right now		Worst pain in the past week	
	Treated groin ($n = 2390$)	Opposite groin ($n = 2335$)	Treated groin ($n = 2366$)	Opposite groin ($n = 2212$)
No pain	1731 (72·4)	2074 (88·8)	1608 (68·0)	1959 (88·6)
Pain present, easily ignored	387 (16·2)	162 (6·9)	424 (17·9)	160 (7·2)
Pain present, cannot be ignored but does not interfere with activities	175 (7·3)	55 (2·4)	190 (8·0)	54 (2·4)
Pain present, cannot be ignored and interferes with concentration and activities	74 (3·1)	29 (1·2)	94 (4·0)	23 (1·0)
Pain present, interferes with most activities	15 (0·6)	9 (0·4)	29 (1·2)	11 (0·5)
Pain present, necessitates bed rest	2 (0·1)	2 (0·1)	11 (0·5)	2 (0·1)
Pain present, prompt medical advice sought	6 (0·3)	4 (0·2)	10 (0·4)	3 (0·1)

Values in parentheses are percentages. The differences between the groins in pain score were significant both for 'pain right now' and 'worst pain' ($P < 0·001$) by Wilcoxon signed rank test.

retrospective evaluation of preoperative inguinal pain was similar (median score of 4 on both occasions; $P = 0·283$). Their assessments of current or worst contralateral groin pain during the preceding week were also similar (median score of 1 on both occasions). However, significant reductions were evident for all variables concerned with current or worst pain during the preceding week in the treated groin (*Tables 2* and *3*). The use of analgesics decreased over time. Questions on the patient's ability to perform potentially pain-provoking activities likewise mirrored the subsiding pain intensity. However, testicular pain did not show a clear decline over the first 4 weeks, possibly reflecting a slightly abnormal course from the onset. It appeared that the frequency and duration of inguinal pain episodes decreased less rapidly than the pain intensity, in line with the clinical impression.

Cronbach's α, calculated from responses of patients in group 2, indicated high internal consistency. The correlation between items on pain intensity (2–6) was 0·94. The corresponding value for items on interference with daily activities (7–12) was 0·51.

Criterion validity

Ratings with the IPQ and BPI were highly correlated, signifying satisfactory criterion validity. The Spearman rank correlation coefficient between ratings of 'pain right now' with the two instruments was 0·224 ($P = 0·030$) and 0·396 ($P < 0·001$) 1 and 4 weeks after surgery respectively. For the item 'worst pain in the past week', the Spearman rank correlation coefficients were 0·315 ($P = 0·002$) and 0·462 ($P < 0·001$) 1 and 4 weeks after surgery respectively.

Logical inconsistencies were analysed from group 2 answers. Illogical combinations of answers pertaining to pain intensity in the operated groin were detected in 3 per cent of the questionnaires (when 'pain right now' was described as worse than the 'worst pain in the past week'). The corresponding proportion for pain intensity questions regarding the non-operated groin was 6 per cent. There was perfect correspondence between pain intensity reports and responses to questions about behaviour affected by pain: none of the patients without pain reported analgesic use or pain-related limitations in daily activities.

Comparison with opposite groin

Pain that interfered with concentration and activities occurred in 6·1 per cent of patients in group 3 on the treated side and 1·9 per cent on the untreated side, with significant differences in score distributions ($P < 0·001$) (*Table 4*).

Test–retest repeatability

There was moderate to substantial test–retest repeatability in group 2 (*Table 5*). Contrary to expectation, self-reports of 'worst pain in the past week' were only marginally more stable than the corresponding self-reports of 'pain right now'. This was true for both the treated and the contralateral groin. Values for κ were higher than 0·4 for all items except 'getting up from a chair' and 'other operations'.

Table 5 Test–retest stability in group 2 according to κ estimation

	κ
Pain before operation, treated groin	0·61 (0·49, 0·74)
Pain in treated groin right now	0·58 (0·37, 0·79)
Worst pain, treated groin	0·60 (0·42, 0·79)
Time to disappearance of pain	0·67 (0·48, 0·86)
Frequency of pain, treated groin	0·64 (0·45, 0·82)
Duration of pain episodes	0·62 (0·44, 0·79)
Difficulties getting up from a chair	0·39 (0·00, 0·93)
Difficulties sitting down	0·53 (0·18, 0·89)
Difficulties standing up	0·66 (0·39, 0·93)
Difficulties climbing stairs	0·66 (0·04, 1·00)
Difficulties driving a car	0·49 (0·08, 0·89)
Difficulties exercising	0·78 (0·56, 0·99)
Working capability	0·65 (0·42, 0·88)
Pain right now in untreated groin	0·69 (0·48, 0·89)
Worst pain in treated groin	0·71 (0·51, 0·90)
Use of painkillers	0·63 (0·46, 0·80)
Testicular pain	0·50 (0·32, 0·67)

Value in parentheses are 95 per cent confidence intervals.

Discussion

The results of this study indicate that self-reports using the IPQ produce reasonably valid and reliable data on the occurrence and severity of inguinal pain[13]. The high compliance and relatively small number of logical contradictions in the answers demonstrated that the instrument is simple enough for most patients to complete. Although the IPQ provides more information about post-repair pain, the response rate and the clinical applicability of this questionnaire were not impaired in comparison with other, less detailed questionnaires that served as a model for its construction[2,8].

Although the aim of hernia surgery is to eliminate the discomfort and potential hazard associated with the hernia, its goal is also to minimize short-term and long-term pain. Accordingly, pain has evolved as an important quality parameter after hernia surgery. For a comprehensive evaluation of the results, follow-up after hernia surgery should include, besides a determination of recurrence or reoperation rate, an assessment of postrepair pain measured with a validated instrument. However, pain is a personal phenomenon, which defies measurement in a narrow sense and makes validation problematical.

The scale steps of the DIBS pain intensity dimension are defined in terms of pain behaviour, and do not measure the unobservable, subjective pain perception. The scale in this way circumvents the dilemma of anchoring the steps in abstract quantitative terms. Because of individual variation in the central processing of pain signals (pain threshold and sensitivity), as well as differences in coping ability, a scale may not perfectly reflect intensity. Therefore, the measured pain intensity may not correspond to the severity of the peripheral pain. On the other hand, the subjective sense of how pain interferes with daily living is usually what concerns the patient, so this measure seems clinically relevant. The items on interference with daily activity include events that are important for patients with chronic groin pain[2].

Reliability was high, indicated by test–retest κ values, despite the possibility that the factual pain might have varied between the two measurements 1 month apart.

Several questionnaires have been developed to evaluate pain syndromes and postoperative pain, including a questionnaire designed to assess chronic pain after groin hernia surgery[8,14–16]. The questionnaire developed by Kehlet and colleagues[8] is easy and quick to fill in. In this scale, the assessment of pain 1 year after surgery is divided into a part that asks about the degree of interference with daily life, a second part devoted to descriptions of the pain experience (both sensory and affective qualities) and a third part that aims to quantify the intensity (a three-step Likert scale) and frequency of pain (seldom, occasionally and always or nearly always). The IPQ is a modification of the questionnaire of Kehlet and colleagues, which has not been formally validated. Although direct comparisons of the psychometric performance of the IPQ and the Kehlet instrument have not been made, it is conceivable that the greater resolution of pain intensity in the IPQ (seven *versus* three steps) might make this scale more sensitive to change.

The questions about the extent to which pain interferes with daily life are constructed according to the proposal by Kehlet and co-workers[8]. The items involve body movements that put strain on the treated groin. For reasons of simplicity, the questions require 'yes' or 'no' answers.

Although the IPQ is unable to distinguish postrepair pain from inguinal pain of other aetiology, it is still sensitive enough to detect pain caused by the hernia surgery in a large population without confusion from all the other causes of groin pain.

The presence of pain in the contralateral groin indicates that there is a baseline level of pain in the population, even in the absence of previous groin hernia surgery. The reason for this pain cannot be determined. It may be due to an untreated hernia, adductor tendonitis, osteoarthritis of the hip joint, or some other cause including idiopathic pain, which may also have been present in the treated groin before surgery. However, even if the origin of the pain is unknown, it can be quantified and does not seem to be intense enough to compete with the chronic postoperative pain.

The frequency of pain is evaluated in two separate items, where the patient is asked to categorize the pain in terms of

number of events per week and duration of episodes, with five possible answers for each. A simpler way might be to categorize the pain frequency as proposed by Kehlet and co-workers in terms of 'seldom', 'occasionally' or 'always'[8]. The κ values of the test–retest procedure indicate that the responses to the more complicated questions of the present study are reproducible. With their greater resolution, they might be more sensitive to change than the frequency questions proposed by Kehlet and colleagues[8].

The questions included in the IPQ are those that a surgeon would usually ask a patient in the follow-up after a groin hernia repair. The self-administered questionnaire with uniformly designed items has sufficient reliability to enable comparisons over time and between different patients and surgical units. The evidence of construct and criterion validity also shows that the IPQ measures what it is intended to measure. It can therefore be used in clinical studies as well as clinical routine to assess long-term pain after groin hernia repair.

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