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Prospective multicentre cohort study of patient-reported outcomes after cholecystectomy for uncomplicated symptomatic cholecystolithiasis

M. P. Lamberts^{1,2,3}, B. L. Den Oudsten⁴, J. J. G. M. Gerritsen⁶, J. A. Roukema⁵, G. P. Westert¹, J. P. H. Drenth² and C. J. H. M. van Laarhoven³

¹Scientific Institute for Quality of Healthcare, ²Department of Gastroenterology and Hepatology, and ³Department of Surgery, Radboud University Medical Centre, Nijmegen, ⁴Department of Medical and Clinical Psychology, Centre of Research on Psychology in Somatic diseases (CoRPS), Tilburg University, and ⁵Department of Surgery, St Elisabeth Hospital, Tilburg and ⁶Department of Surgery, Medisch Spectrum Twente Hospital, Enschede, The Netherlands

Correspondence to: Dr M. P. Lamberts, Radboud University Medical Centre, PO Box 9101, 6500 HB Nijmegen, The Netherlands (e-mail: marklamberts@hotmail.com)

Background: Up to 33 per cent of patients with uncomplicated symptomatic cholecystolithiasis report persistent pain after cholecystectomy. The aim of this study was to determine characteristics associated with patient-reported absence of abdominal pain after cholecystectomy, improved abdominal symptoms, and patient-reported positive cholecystectomy results in a prospective cohort multicentre study.

Methods: Patients aged 18 years or more with symptomatic cholecystolithiasis who had a cholecystectomy between June 2012 and June 2014 in one of three hospitals were included. Before surgery all patients were sent the Gastrointestinal Quality of Life Index (GIQLI) questionnaire and the McGill Pain Questionnaire (MPQ). At 12 weeks after surgery, patients were invited to complete the GIQLI and Patients' Experience of Surgery Questionnaire (PESQ). Logistic regression analyses were performed to determine associations.

Results: Questionnaires were sent to 552 patients and returned by 342 before and after surgery. Postoperative absence of abdominal pain was reported by 60.5 per cent of patients. A high preoperative GIQLI score, episodic pain, and duration of pain of 1 year or less were associated with postoperative absence of pain. These factors showed no association with improved abdominal symptoms (reported by 91.5 per cent of patients) or a positive surgery result (reported by 92.4 per cent).

Conclusion: Preoperative characteristics determine the odds for relief of abdominal pain after cholecystectomy. However, these factors were not associated with patient-reported improvement of abdominal symptoms or patient-reported positive cholecystectomy results, highlighting the variation of internal standards and expectations of patients before cholecystectomy.

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Introduction

Cholecystectomy is the treatment of choice for patients with symptomatic cholecystolithiasis. Cholecystectomy is performed about 60 000 times a year in the UK alone, with significant costs¹. Other Western countries have fairly similar patterns of care^{2–4}. Patients with a history of complicated symptomatic cholecystolithiasis are offered cholecystectomy to prevent recurrent complications⁵. The main purpose of cholecystectomy for uncomplicated symptomatic cholecystolithiasis is to relieve abdominal pain, as the diagnosis is based on abdominal pain combined

with ultrasound-confirmed gallstones^{6–9}. Despite the high number of cholecystectomies in the Western world, up to 33 per cent of patients still report abdominal pain after cholecystectomy¹⁰.

The large proportion of patients with persistent postoperative pain is caused by a variation in the indication for, and timing of, cholecystectomy resulting from the lack of evidence and differing opinions among surgeons^{11–13}. This variation may lead to unnecessary cholecystectomies, risk of complications and healthcare costs. Several characteristics have been shown to be associated with a good

outcome following cholecystectomy, including sex^{14–16}, age at surgery^{14,16}, preoperative absence of pain in the previous 2 weeks^{14,16}, centre where treated¹⁶, American Society of Anesthesiologists (ASA) classification^{17,18}, baseline Gastrointestinal Quality of Life Index (GIQLI) score^{15,19}, duration of pain of 1 year or less¹⁶, pain occurring during episodes¹⁶ and pain-induced awakening at night¹⁶. However, study results are often inconsistent and the generalizability of these associations may be limited because of the heterogeneity of patient characteristics, settings and patient-reported outcome questionnaires used¹⁶.

The present study aimed to assess the association between preoperative characteristics with absence of pain after cholecystectomy in a Dutch prospective multicentre cohort study. The association of these characteristics with patient-reported improved abdominal symptoms and with patient-reported positive cholecystectomy results was also determined.

Methods

All patients aged 18 years or more with symptomatic cholelithiasis, who visited the surgical outpatient clinic at a tertiary referral centre (Radboud University Medical Centre, Nijmegen) or one of two non-academic teaching

hospitals (St Elisabeth Hospital, Tilburg, and Medisch Spectrum Twente Hospital, Enschede) between June 2012 and June 2014, and were scheduled for elective cholecystectomy were eligible for participation in the study. Cholelithiasis was defined as abdominal pain associated with gallstones, confirmed by ultrasound imaging.

Patients with a history of complicated symptomatic cholelithiasis (acute cholecystitis, cholangitis, biliary pancreatitis, choledocholithiasis requiring endoscopic retrograde cholangiopancreatography)^{20,21} were excluded. Other exclusion criteria were ASA fitness grade III or IV, insufficient knowledge of the Dutch language, non-Dutch residency, blindness, pregnancy, cirrhosis, cancer treatment, schizophrenia, or any other disorder that might predispose the patient to unreliable responses. Eligible patients were asked to complete a questionnaire before and 12 weeks after cholecystectomy. Patients who did not return the questionnaire before and after surgery were excluded from the analyses.

The preoperative questionnaires included the GIQLI and the McGill Pain Questionnaire (MPQ), as generic and disease-specific patient-reported outcome questionnaires respectively, in line with the taxonomy²². In addition, the GIQLI and Patients' Experiences of Surgery Questionnaire (PESQ) were completed after surgery.

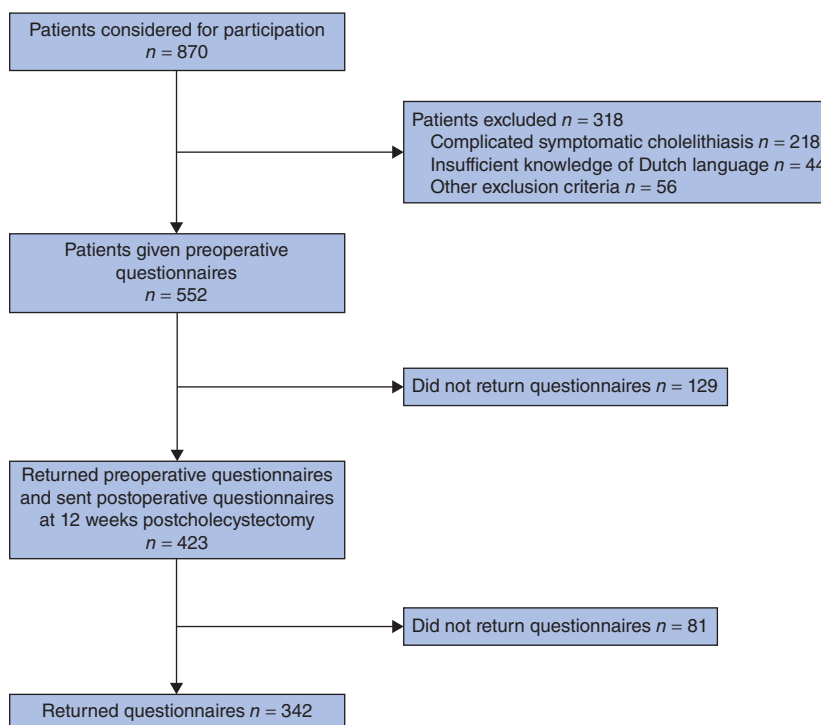


Fig. 1 Flow chart showing inclusion of patients in the study

Table 1 Characteristics of responders and non-responders to the questionnaires

	Responders (n = 342)	Non-responders (n = 210)	P†
Age (years)*	49.7(14.3)	43.5(15.1)	< 0.001‡
Sex ratio (M:F)	74:268	50:160	0.553
ASA fitness grade			0.042
I	160 (46.8)	117 (55.7)	
II	182 (53.2)	93 (44.3)	
Centre			
Radboud UMC	67 (19.6)	46 (21.9)	n.a.
MST	155 (45.3)	99 (47.1)	n.a.
St Elisabeth Hospital	120 (35.1)	65 (31.0)	n.a.

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). ASA, American Society of Anesthesiologists; UMC, University Medical Centre; n.a., not applicable; MST, Medisch Spectrum Twente Hospital. † χ^2 test, except ‡independent *t* test.

The GIQLI, which was developed in Germany²³, has been translated and validated in the Dutch language²⁴. It contains 36 questions on gastrointestinal symptoms for both the upper and lower digestive tracts, and on general, physical, emotional and social functioning in the previous 2 weeks. Each question consists of five response categories. Questions are scored using a response scale ranging from 0 (worst appraisal) to 4 (best appraisal) points for each question, giving an overall score of 0–144 points. The higher the score, the better the health status. The characteristics of abdominal pain were measured using the MPQ^{25,26}. This questionnaire consists of four sections: a section of general questions regarding pain; a section on the effect of pain on quality of life; a section on visual analogue scales for pain; and a section that includes a list of adjectives describing pain. In the present study, the first two sections were used to assess the duration of pain, its episodic nature, and pain-induced awakening at night. The PESQ includes questions on complications of surgery, abdominal symptoms in relation to cholecystectomy, and patient-reported results of surgery^{27,28}. The latter two questions consisted of five response categories.

The study was approved by the medical ethics committees of all three hospitals (Radboud University Medical Centre, Medisch Spectrum Twente Hospital and St Elisabeth Hospital) and conducted in accordance with the recommendations in the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines²⁹.

Outcomes and variables of interest

The primary outcome was defined as absence of abdominal pain, as reported on the GIQLI 12 weeks after

cholecystectomy. The results were dichotomized as absence *versus* presence of pain.

Secondary outcomes included improvement of abdominal symptoms, and outcome of the operation as reported by patients. Responses were dichotomized as positive (successful) *versus* negative (not successful) ratings. Positive rating of current abdominal symptoms consisted of the combined response categories 'slightly better' and 'much better'. Positive rating of surgery results included the combined response categories 'excellent', 'very good' and 'good'. Postoperative absence of abdominal pain was added to the selected independent variables to confirm the association with patient-reported success of the procedure.

Based on previous publications, the independent variables included sex^{14–16}, age at operation^{14,16}, preoperative absence of pain in the previous 2 weeks^{14,16}, centre¹⁶, ASA fitness grade^{17,18}, baseline GIQLI score^{15,19}, duration of symptoms of 1 year or less¹⁶, episodic pain¹⁶ and pain-induced awakening at night¹⁶.

Power analysis

An appropriate sample size was calculated for the proportion of patients with postoperative pain. Assumptions were based on the findings of a systematic review¹⁰. The proportion of patients with persistent pain was estimated as 33 per cent with an error rate of 5 per cent and a 95 per cent c.i., resulting in a sample size of 340 patients. In anticipation of an incomplete response rate of 40 per cent, at least 476 patients were invited to participate in the study. Given the sample size in the smaller of the two response groups (approximately 112 patients without relief of abdominal pain), there were sufficient observations to accommodate the development of a model with up to 11 variables.

Statistical analysis

Differences between responders and non-responders were examined using χ^2 or Fisher's exact tests for categorical data and the Student *t* test for continuous data. For responders, logistic regression analyses were applied to determine which variables were associated with absence of pain after cholecystectomy. Variables with $P < 0.100$ in univariable analyses were included in multivariable logistic regression analyses. Backward elimination was used as the variable selection method, retaining age, sex, centre and preoperative abdominal pain as reported on the GIQLI as co-variables. Postoperative absence of abdominal pain in relation to an increasing number of significantly associated preoperative pain characteristics was also assessed. The results of the analyses were reported as adjusted odds ratios

Table 2 Univariable and multivariable analysis of factors associated with patient-reported absence of pain after cholecystectomy

	Abdominal pain		Univariable analysis		Multivariable analysis	
	Absent (n = 207)	Present (n = 135)	Odds ratio†	P	Odds ratio†	P
Age (years)*	50.0(14.1)	49.3(14.6)	1.00 (0.99, 1.02)	0.670	1.00 (0.99, 1.02)	0.725
Sex						
F	154	114	0.54 (0.31, 0.94)	0.029	0.60 (0.32, 1.16)	0.129
M	53	21	1.00 (reference)		1.00 (reference)	
Hospital type						
Tertiary referral centre	36	31	0.71 (0.41, 1.21)	0.206	0.52 (0.28, 0.97)	0.041
Non-academic	171	104	1.00 (reference)		1.00 (reference)	
Preop. pain in last 2 weeks						
No	39	9	3.25 (1.52, 6.95)	0.002	1.46 (0.58, 3.66)	0.420
Yes	168	126	1.00 (reference)		1.00 (reference)	
ASA fitness grade						
II	103	79	0.70 (0.45, 1.09)	0.113		
I	104	56	1.00 (reference)			
Baseline GIQLI score*	106.6(20.2)	95.2(21.3)	1.03 (1.02, 1.04)	< 0.001	1.02 (1.01, 1.03)	0.004
Duration of pain (years)‡						
≤ 1	163	91	1.93 (1.16, 3.20)	0.011	2.22 (1.25, 3.94)	0.006
> 1	39	42	1.00 (reference)		1.00 (reference)	
Type of pain‡						
Episodic	132	58	2.31 (1.47, 3.61)	< 0.001	2.13 (1.29, 3.52)	0.003
Non-episodic	72	73	1.00 (reference)		1.00 (reference)	
Awakened because of pain‡						
Yes	105	74	0.85 (0.55, 1.32)	0.465		
No	97	58	1.00 (reference)			

Values are *mean(s.d.); †values in parentheses are 95 per cent c.i. ‡A few patients did not complete all questions for this factor. ASA, American Society of Anesthesiologists; GIQLI, Gastrointestinal Quality of Life Index.

Table 3 Multivariable logistic regression analysis of the association of increasing number of preoperative pain characteristics with postoperative absence of abdominal pain

No. of characteristics†	Absence of abdominal pain	Odds ratio*	P
2	100 of 138 (72.5)	6.23 (2.37, 16.38)	< 0.001
1	195 of 306 (63.7)	3.57 (1.49, 8.54)	0.004
0	9 of 31 (29)	1.00 (reference)	

Values in parentheses are percentages unless indicated otherwise; *values in parentheses are 95 per cent c.i. †Episodic pain, and duration of pain of 1 year or less.

(ORs) with 95 per cent c.i. $P < 0.050$ was considered statistically significant. Similar methods were used to determine which variables were associated with the patient-reported improvement of abdominal symptoms and with the results of surgery. All missing values were considered to be completely random and excluded from analyses. All statistical analyses were done with SPSS® statistical software version 20.0 (IBM, Armonk, New York, USA).

Results

A total of 870 patients were considered for participation. After exclusion of 318 patients, questionnaires were

sent to 552 patients. Some 423 patients (76.6 per cent) returned the questionnaires before surgery, and 342 (62.0 per cent) did so both before and after surgery (Fig. 1). Baseline characteristics both of these 342 study patients and the 210 non-responders are shown in Table 1. Statistically significant differences were found between responders and non-responders for mean(s.d.) age at surgery (49.7(14.3) versus 43.5(15.1) years; $P < 0.001$) and ASA fitness grade (53.2 per cent of responders were classified as ASA II compared with 44.3 per cent of non-responders; $P = 0.042$).

Associations with absence of pain after cholecystectomy

A total of 207 patients (60.5 per cent) reported absence of pain at 12 weeks after cholecystectomy. Univariable analysis showed preoperative GIQLI score, episodic pain, and duration of pain of 1 year or less to be associated with absence of pain (Table 2). Preoperative GIQLI score (OR 1.02, 95 per cent c.i. 1.01 to 1.03; $P = 0.004$), episodic pain (OR 2.13, 1.29 to 3.52; $P = 0.003$) and duration of pain of 1 year or less (OR 2.22, 1.25 to 3.94; $P = 0.006$) remained associated with postoperative absence of pain in multivariable analysis. Absence of abdominal pain was also assessed in relation to an increasing number of significantly associated pain characteristics (episodic pain, duration of pain

Table 4 Univariable and multivariable analysis of patient and clinical variables associated with patient-reported abdominal symptoms

	Abdominal symptoms		Univariable analysis		Multivariable analysis	
	Much or slightly better (<i>n</i> = 313)	About the same, slightly worse or much worse (<i>n</i> = 26)	Odds ratio†	<i>P</i>	Odds ratio†	<i>P</i>
Age (years)*	50.1(14.3)	46.2(14.0)	1.02 (0.99, 1.05)	0.192	1.02 (0.99, 1.05)	0.185
Sex						
F	244	21	0.84 (0.31, 2.32)	0.739	1.12 (0.38, 3.28)	0.837
M	69	5	1.00 (reference)		1.00 (reference)	
Hospital type						
Tertiary referral centre	61	6	0.81 (0.31, 2.10)	0.659	1.06 (0.39, 2.88)	0.907
Non-academic	252	20	1.00 (reference)		1.00 (reference)	
Preop. pain in last 2 weeks‡						
No	42	5	0.65 (0.23, 1.82)	0.413	0.41 (0.13, 1.23)	0.112
Yes	271	20	1.00 (reference)		1.00 (reference)	
ASA fitness grade						
II	164	17	0.58 (0.25, 1.35)	0.206		
I	149	9	1.00 (reference)			
Baseline GIQLI score*	102.2(21.5)	103.8(19.8)	1.00 (0.98, 1.02)	0.731		
Duration of pain (years)‡						
≤ 1	232	21	0.75 (0.27, 2.05)	0.570		
> 1	74	5	1.00 (reference)			
Type of pain‡						
Episodic	172	16	1.26 (0.55, 2.86)	0.587		
Non-episodic	135	10	1.00 (reference)			
Awakened because of pain‡						
Yes	168	9	1.96 (0.86, 4.46)	0.108		
No	137	16	1.00 (reference)			
Postop. pain in last 2 weeks						
No	198	8	3.87 (1.63, 9.19)	0.002	4.52 (1.81, 11.29)	0.001
Yes	115	18	1.00 (reference)		1.00 (reference)	

Values are *mean(s.d.); †values in parentheses are 95 per cent c.i. ‡A few patients did not complete all questions for this factor. ASA, American Society of Anesthesiologists; GIQLI, Gastrointestinal Quality of Life Index.

Table 5 Univariable and multivariable analysis of patient and clinical variables associated with patient-reported results of surgery

	Surgery results		Univariable analysis		Multivariable analysis	
	Good, very good or excellent (<i>n</i> = 316)	Moderate or bad (<i>n</i> = 22)	Odds ratio†	<i>P</i>	Odds ratio†	<i>P</i>
Age (years)*	49.9(14.3)	48.6(14.7)	1.01 (0.98, 1.04)	0.668	1.01 (0.97, 1.04)	0.773
Sex						
F	246	18	0.78 (0.26, 2.38)	0.664	1.20 (0.35, 4.09)	0.694
M	70	4	1.00 (reference)		1.00 (reference)	
Hospital type						
Tertiary referral centre	59	8	0.40 (0.16, 1.00)	0.050	0.46 (0.17, 1.25)	0.128
Non-academic	257	14	1.00 (reference)		1.00 (reference)	
Preop. pain in last 2 weeks						
No	45	2	1.66 (0.38, 7.35)	0.504	0.79 (0.16, 3.99)	0.774
Yes	271	20	1.00 (reference)		1.00 (reference)	
ASA fitness grade						
II	166	14	0.63 (0.26, 1.55)	0.316		
I	150	8	1.00 (reference)			
Baseline GIQLI score*	103.2(21.2)	91.9(19.1)	1.02 (1.00, 1.05)	0.020		
Duration of pain (years)‡						
≤ 1	238	14	1.92 (0.77, 4.75)	0.161		
> 1	71	8	1.00 (reference)			
Type of pain‡						
Episodic	174	13	1.13 (0.47, 2.72)	0.787		
Non-episodic	136	9	1.00 (reference)			
Awakened because of pain‡						
Yes	164	13	0.79 (0.33, 1.90)	0.596		
No	144	9	1.00 (reference)			
Postop. pain in last 2 weeks						
No	204	2	18.21 (4.18, 79.35)	< 0.001	19.01 (4.20, 85.93)	< 0.001
Yes	112	20	1.00 (reference)		1.00 (reference)	

Values are *mean(s.d.); †values in parentheses are 95 per cent c.i. ‡A few patients did not complete all questions for this factor. ASA, American Society of Anesthesiologists; GIQLI, Gastrointestinal Quality of Life Index.

of 1 year or less). The odds of pain relief increased progressively as the number of pain characteristics increased (Table 3).

Associations with improved abdominal symptoms and positive surgery results

A total of 313 patients (91.5 per cent) rated their abdominal symptoms after cholecystectomy to be 'much better' or 'slightly better' compared with their preoperative experience. Univariable analysis revealed postoperative absence of abdominal pain to be associated with patient-reported improved abdominal symptoms, and this remained associated in multivariable analysis (OR 4.52, 95 per cent c.i. 1.81 to 11.29; $P = 0.001$) (Table 4).

The postoperative result was rated as 'good', 'very good' or 'excellent' by 316 patients (92.4 per cent). In univariable analysis, baseline GIQLI score and postoperative absence of pain were associated with a patient-reported positive rating of the cholecystectomy result. Postoperative absence of pain remained associated in multivariable analysis (OR 19.01, 4.20 to 85.93; $P < 0.001$) (Table 5).

Discussion

In this prospective multicentre cohort study, only 60.5 per cent of patients reported complete relief of pain at 12 weeks after cholecystectomy. However, most of the patients reported improved abdominal symptoms and a successful outcome after surgery. A higher preoperative GIQLI score, duration of pain of 1 year or less, and episodic pain were significantly associated with postoperative absence of pain, but not with improved abdominal symptoms or positive surgery results.

The proportion of patients with complete pain relief after cholecystectomy, improved abdominal symptoms and a positive cholecystectomy result in the present study is consistent with other published literature. A systematic review¹⁰ showed that 59–100 per cent of patients experienced complete pain relief. In addition, 90–97 per cent of patients reported improved abdominal symptoms and 88–97 per cent rated the cholecystectomy result as positive^{30–32}. A large cohort study¹⁶ reported a 2 per cent difference between the proportion of patients with postoperative pain at 12 weeks and 1 year after cholecystectomy. In addition, a long-term follow-up study¹⁷ showed no significant difference in the proportion of patients reporting pain at 12 weeks and 10 years after cholecystectomy. These results suggest that pain relief at 12 weeks of follow-up persists for 10 years after cholecystectomy. This study also reported similar proportions of patient-reported improved

symptoms and positive surgery results, indicating consistency of these outcomes as well¹⁷.

The association of episodic pain and duration of pain of 1 year or less with postoperative absence of pain was confirmed by the present study, increasing the generalizability of these predictors¹⁶. Pain associated with gallstones is most typically characterized by its episodic nature and relief following cholecystectomy^{6,7,9}. Non-episodic abdominal pain is often caused by functional gastrointestinal disorders^{33,34}, which are chronic conditions and may have a significant impact on patients' health status³⁵. Patients with functional disorders are likely to continue to report abdominal pain after surgery. This was confirmed by the finding that patients with a duration of pain of 1 year or less and a higher preoperative health status score were more likely to report complete pain relief after cholecystectomy compared with patients with a longer duration of pain and a lower health status.

Remarkably, factors that were associated with absence of abdominal pain after cholecystectomy did not show an association with improved abdominal symptoms or a positive surgery result, despite the association of postoperative absence of pain with the latter two outcomes. The placebo effect of surgery or natural decline of symptoms may account for this discrepancy^{36–38}. In addition, these findings suggest a difference in internal standards and variable expectations from cholecystectomy^{39,40}. Many patients may not expect all types of abdominal pain to be relieved completely following cholecystectomy. It is therefore important to explore and set realistic expectations before the operation. This discrepancy also raises doubt regarding which patient-reported outcome to use for effective patient selection for cholecystectomy. Cholecystectomy appears to be far less successful when absence of abdominal pain is used as the benchmark compared with improved abdominal symptoms or positive surgery results as standard.

There are limitations of this study. First, selection bias may have occurred as a result of the limited response rate. The response rate of younger patients and those with ASA grade I might have been improved if both paper-based and web-based questionnaires had been used⁴¹. Second, the study was performed in a national setting with strict inclusion and exclusion criteria to limit recall bias. This may limit the generalizability of the results, although widely available patient-reported outcome questionnaires were employed. Third, multiple measurements might have added additional information, but could also have introduced additional bias as co-morbidities unrelated to gallstone disease or surgery may manifest themselves and cause abdominal pain. Finally, ORs in this study may

overestimate risk ratios, and thus should not be interpreted as risk ratios.

Strengths of the study include its prospective multicentre design, limiting potential information bias and increasing external validity. Additional strengths are use of the MPQ, GIQLI and PESQ. Abdominal pain is the characteristic feature of uncomplicated symptomatic cholecystolithiasis and the main predictor of an unsuccessful outcome^{6–9,18}. Other abdominal symptoms may co-exist⁴². Finally, transient episodes of abdominal symptoms could easily be undetected if measured at short intervals. This emphasizes the importance of the MPQ as pain-specific, the GIQLI as generic for abdominal symptoms and the PESQ as sequential follow-up questionnaires. Consequently, the authors believe that use of this combination of questionnaires will address all aspects of uncomplicated symptomatic cholelithiasis.

Future research should explore further not only which patients will respond favourably to cholecystectomy, but also which will benefit the most. Patients with uncomplicated symptomatic cholelithiasis may wonder whether a cholecystectomy is really necessary after one or a few episodes of pain, or whether surgery can be delayed. A watchful waiting strategy⁴³ was shown to be a feasible option in 31 per cent of patients with uncomplicated symptomatic cholelithiasis during 14 years of follow-up. At the same time, patients with uncomplicated symptomatic gallstone disease at risk of complicated symptomatic cholelithiasis should be considered for earlier surgery⁴⁴. Selection for earlier cholecystectomy of those patients who are most likely to benefit from it will further increase the cost-effectiveness of this common surgical procedure.

This study highlights the variation in internal standards and patient expectations. Doctors should explore and help create realistic expectations before admitting patients for cholecystectomy. Strict selection by the treating surgeon based on preoperative pain characteristics, whilst advocating the merits of a watchful waiting approach, is, for the present, the best way to avoid unnecessary surgery in patients with uncomplicated cholecystolithiasis.

Disclosure

The authors declare no conflict of interest.

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