



## Health-Related Quality-of-Life in a cohort undergoing cholecystectomy



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### HIGHLIGHTS

- The SF-36 questionnaire was distributed pre- and postoperatively to patients undergoing planned cholecystectomy.
- Preoperatively, patients rated lower on all subscales than the background population.
- The low ratings did not persist postoperatively.
- Patients of high age perceived less benefit from the procedure.
- Patients who had undergone open surgery also perceived less benefit from the procedure.

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### ABSTRACT

**Introduction:** Patient-related outcome measures are crucial when assessing outcome from surgical intervention registers. The aim of this study was to analyse what factors affect Health-Related Quality of Life (HRQoL) in patients undergoing cholecystectomy, and to assess the feasibility of SF-36 as a HRQoL instrument in a patient register.

**Methods:** The SF-36 questionnaire was distributed to patients preoperatively and 6–9 months after surgery. The outcome of patients who had undergone planned surgery between January 1, 2010 and June 30, 2011 at six units, with response rates of at least 100 per year, formed the basis for the present study. Expected outcome from a background population was determined from a Swedish cohort assembled previously.

**Results:** Altogether 919 patients (646 women, 273 men) at the six units answered the questionnaire. Mean age was 52 years, standard deviation 15 years. Preoperatively, the surgery cohort rated lower on all subscales of the SF-36 than the age- and gender-matched background population. Postoperatively, they did not rate lower in any of the subscales. High age was associated with a significantly lower increase in bodily pain and Physical Component Summary (both  $p < 0.05$ ). Open surgery was associated with a significantly lower increase in the Physical Component Summary ( $p < 0.05$ ).

**Discussion:** Regardless of indication for surgery, high age is associated with less benefit from surgery according to this questionnaire study. SF-36 is appropriate for measuring the impact of gallstone surgery on HRQoL.

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## 1. Introduction

Despite the widespread use of laparoscopic cholecystectomy for gallstone disease, little is known about the long-term impact of gallstone surgery on Health-Related Quality of Life (HR-QoL). There

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are many factors that may affect outcome besides the technical success of the procedure itself. Expectations from new innovative technology as well as the placebo effect may have influenced long-term outcome results [1]. Furthermore, the increasing use of minimally invasive procedures over the past two decades may have resulted in a change in the threshold to perform surgery, which could affect the overall outcome of gallstone surgery. The shift in indication for surgery may have affected the risk for symptoms, not related to the gallstones, persisting postoperatively. The widening indication for surgery may also have resulted in an increasing number of patients undergoing surgery without adequate assessment of their preoperative symptoms.

Auditing the outcome of an intervention requires complete and valid registration of the immediate outcomes, positive and negative, as well as registration of the long-term outcome in terms of HR-QoL and late complications. The ultimate goal in gallstone surgery is to reduce gallstone-related morbidity and mortality and improve Health-Related Quality of Life. The Swedish Register for Gallstone Surgery and ERCP (GallRiks) was launched in 2005 as a database for quality assurance of gallstone surgery [2]. GallRiks includes data on indications, complications, results, and quality of life (QoL) outcome of gallstone surgery. GallRiks has nationwide coverage, with about 70 hospitals participating, constituting more than 90% of all units performing gallstone surgery in Sweden.

The indication for elective cholecystectomy is biliary colic in about 75% of cases [3]. Consequently, the main outcome measure of elective cholecystectomy is ideally the patient's symptoms and Health-Related QoL after surgery. The SF-36 instrument is used for pre- and postoperative assessment of QoL in GallRiks [4]. At present QoL outcome is only measured and registered at a limited number of units.

The aim of this study was to analyse which factors have the greatest impact on QoL in patients undergoing cholecystectomy, and to assess the feasibility of SF-36 as a QoL instrument for routine use in a healthcare register.

## 2. Method

Self-reported HR-QoL, measured by SF-36 pre- and postoperatively, in patients undergoing cholecystectomy, was analysed between January 1st, 2010 and June 30th 2011. In order to avoid selection bias complete data for a minimum of one hundred patients per unit was required to be eligible for inclusion. In units with lower response rates, the non-responders could represent selected groups, not representative of the whole group of patients undergoing cholecystectomy. The SF-36 questionnaire was distributed by mail to patients preoperatively, either upon referral to the outpatient clinic for assessment of suspected gallstone disease, when scheduled for elective cholecystectomy, or given directly to the patient in the outpatient clinic at the time of consultation. The means of distributing the form was left to the coordinator in each unit to decide, as local circumstances vary. A second SF-36 questionnaire was completed 6–9 months after surgery. For patients admitted for ongoing complications to gallstone disease, and for whom no previous SF-36 was available, the questionnaire was completed prior to surgery. All patients registered in GallRiks are free to decline registration in GallRiks. All patients responding to the questionnaire had given their consent to participation. The study was approved by ethics committee of Stockholm (EPN 2008/43-31/4).

### 2.1. Statistical analysis

The Physical Component Summary (PCS) and Bodily Pain were taken as the main outcome measures. BP was selected as outcome

measure as it has been shown to have the highest responsiveness in this patient group [4]. The difference between the preoperative and postoperative ratings were used in univariate and multivariate regression analyses to determine which factors had the greatest impact on treatment outcome. The multivariate model was based on stepwise inclusion of statistically significant covariates. Expected outcome in the age- and gender-based general population was determined in a previous study [5] constituting of 8930 Swedish residents who responded to the questionnaire 1991–1992.

## 3. Results

Six units provided complete SF-36 data for at least 100 patients per year, and these were included in the analysis. Altogether 919 patients (646 women, 273 men) at the units included had filled in the questionnaire. Mean age was 52 years, standard deviation 15 years. Indications for surgery were: ongoing acute cholecystitis (N = 10); previous history of cholecystitis (N = 150); ongoing acute biliary pancreatitis (N = 3); previous history of acute biliary pancreatitis (N = 76), ongoing obstructive jaundice (N = 16), previous history of obstructive jaundice (N = 115); and biliary colic (N = 647). Some patients underwent surgery on more than one indication; the total number thus exceeds 919. Patients undergoing open cholecystectomy were significantly older than those undergoing laparoscopic surgery ( $p < 0.05$ ). Median age of patients in the laparoscopic cholecystectomy group was 53 years and in the open cholecystectomy group 69.5 years. In the open cholecystectomy group, there were also a significantly higher proportion of patients undergoing surgery for complicated gallstone disease, i.e. cholecystitis, pancreatitis or common bile duct stones ( $p < 0.05$ ). Mean outcome in the age- and gender-matched population and ratings pre- and postoperatively are presented in Table 1.

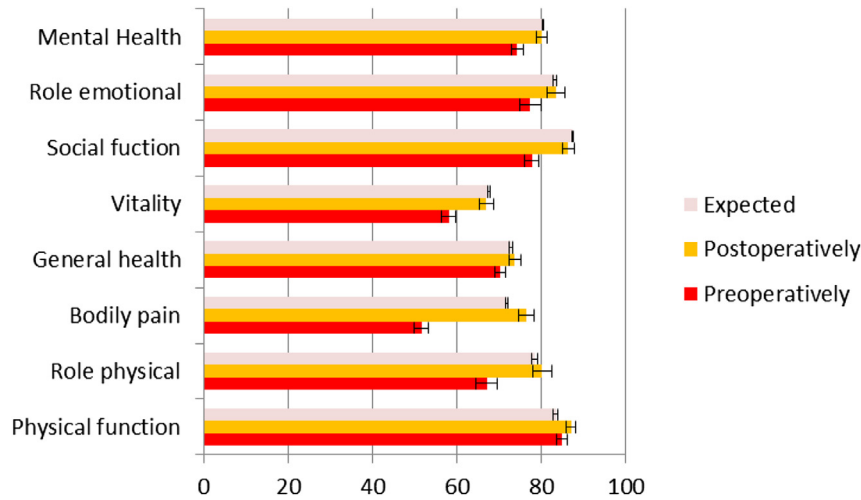
Preoperatively, the surgery cohort gave lower ratings on all the SF-36 subscales than the age- and gender-matched background population (Fig. 1). Postoperatively, they did not rate lower on any of the subscales. For the physical functioning, role physical, bodily pain and role emotional subscales, the postoperative estimates exceeded the background population significantly (all  $p < 0.05$ ). High age was associated with a significantly lower increase in bodily pain and Physical Component Summary (Tables 2 and 3). Open surgery was associated with a significantly lower increase in Physical Component Summary (Table 3).

## 4. Discussion

For patient registers based on benign conditions, patient-related outcome is crucial. Quality of care for diseases with low mortality

**Table 1**  
Expected outcome in the age- and gender matched population and pre- and postoperative ratings.

	Mean (95% confidence interval) ratings in the age- and gender-matched general population	Mean (95% confidence interval) ratings preoperatively	Mean (95% confidence interval) ratings postoperatively
Physical functioning	83.4 (83.1–84.0)	84.9 (84.3–86.0)	87.1 (86.5–88.2)
Role physical	78.4 (78.0–79.1)	67.0 (65.7–69.7)	80.2 (79.0–82.4)
Bodily pain	71.8 (71.7–72.1)	51.6 (50.8–53.3)	76.5 (75.6–78.2)
General health	72.8 (72.6–73.2)	70.2 (69.6–71.5)	73.7 (73.0–75.1)
Vitality	67.6 (67.5–67.8)	58.0 (57.2–59.6)	67.0 (66.2–68.6)
Social functioning	87.5 (87.4–87.7)	77.7 (76.9–79.3)	86.4 (85.6–87.8)
Role emotional	83.2 (83.0–83.6)	77.4 (76.2–79.8)	83.4 (82.3–85.6)
Mental health	80.3 (80.2–80.4)	74.3 (73.6–75.6)	80.1 (79.4–81.3)



**Fig. 1.** Health-Related Quality-of-Life measured with SF-36 pre- and postoperatively based on 919 responders. Expected outcome was determined from the age- and gender-based background population [5]. Error bars indicate 95% confidence intervals.

implies identification of patients where HRQoL is impaired by the disease and where there is a significant improvement in HRQoL following the intervention. Safety is not a sufficient measure of quality. If an intervention targeted at a disease with low mortality is to be considered effective, an unequivocal benefit in terms of HRQoL must be shown. The present study confirms that the SF-36 instrument is appropriate for this purpose.

Patients undergoing cholecystectomy show improvement in self-reported QoL to levels equivalent to, or exceeding the background population. Improvement in self-reported QoL in elderly patients, however, was significantly less, probably attributable to several factors including more prevalent co-morbidity. A younger otherwise healthy individual experiences the symptoms of gallstone disease without being influenced by other concurrent disease, resulting in a relatively greater impact on QoL. Conversely, factors such as chronic pain, heart and pulmonary disorders and a less active lifestyle, may decrease the impact of gallstone-related symptoms on the total burden of concurrent disease. It may also

be more difficult to diagnose symptoms as originating from gallstone disease, when other causes of pain exist concurrently.

Primary open cholecystectomy was significantly associated with poorer improvement in QoL. The same was not true for laparoscopic procedures converted to open surgery, as these patients reported a significant improvement in QoL. The number of patients who had a primary open procedure, however, was very low. These patients represent an older and more physically affected cohort, more often treated for gallstone complications than biliary colic. Even if the multivariate model adjusted for age, there may have been residual confounding related to high age and co-morbidity explaining the poorer improvement in QoL in the open cholecystectomy group. Improvement in QoL did not differ significantly between subjects treated for biliary colic and those treated for complications to gallstone disease, nor were complications to surgery associated with a worse improvement at follow-up.

The limited number of units participating in this study is a weakness since the results may not be representative of all patients

**Table 2**

Multivariate logistic analysis of variables predicting the outcome of the bodily pain (BP) subscale of SF-36. The outcome was defined as the difference between BP prior to surgery and 6 months postoperatively. The multivariate model was based on stepwise inclusion of statistically significant covariates.

	N (%)	Univariate Standardised		Multivariate Standardised	
		Beta	p	Beta	P
Gender					
Female (ref)	646 (70.3%)				
Male	273 (29.7%)	0.012	0.716		
Age					
≤median (50years) (ref)	424 (46.1%)				
>Median (50 years)	491 (53.4%)	-0.157	<0.001	-0.157	<0.001
Data missing	4 (0.4%)				
Indication for surgery					
Biliary colic only (ref)	647 (70.4%)				
Secondary complications	272 (29.6%)	-0.039	0.240		
Method of approach					
Laparoscopic/conversion to open (ref)	907 (98.7%)				
Primary open	10 (1.1%)	-0.072	0.030		
Data missing	2 (0.2%)				
Postoperative complications					
Not registered (ref)	846 (92.1%)				
Registered	73 (7.9%)	-0.012	0.727		

**Table 3**

Multivariate logistic analysis of variables predicting the outcome of the Physical Component Summary of SF-36. The outcome was defined as the difference between PCS prior to surgery and 6 months postoperatively. The multivariate model was based on stepwise inclusion of statistically significant covariates.

	N (%)	Univariate Standardised		Multivariate Standardised	
		beta	p	beta	p
Gender					
Female (ref)	646 (70.3%)				
Male	273 (29.7%)	-0.013	0.706		
Age					
≤median (50years) (ref)	424 (46.1%)				
>median (50 years)	491 (53.4%)	-0.157	<0.001	-0.150	<0.001
Data missing	4 (0.4%)				
Indication for surgery					
Biliary colic only (ref)	647 (70.4%)				
Secondary complications	272 (29.6%)	-0.009	0.784		
Method of approach					
Laparoscopic/conversion to open (ref)	907 (98.7%)				
Primary open	10 (1.1%)	-0.089	0.009	-0.077	0.023
Data missing	2 (0.2%)				
Postoperative complications					
Not registered (ref)	846 (92.1%)				
Registered	73 (7.9%)	-0.045	0.183		

undergoing cholecystectomy in Sweden. The proportion of patients treated acutely at the participating units was lower than the national average. Thus selection bias cannot be ruled out. Another possible weakness is the risk for overestimation of the treatment effect, due to a regression to the mean phenomenon. In the present analysis this would give the impression of a large improvement in QoL following surgery because of a poor HRQoL in patients selected for surgery. Even without surgery these patients would have regressed to levels closer to the general population [6]. This may in part explain the finding that, following surgery, patients scored significantly higher than the background population for the SF-36 subscales bodily pain, role physical, physical functioning and role emotional. As improvement in the main outcome measure bodily pain was so marked, it is unlikely this effect would alter the results significantly.

In conclusion, following cholecystectomy for gallstone disease, patients report a significantly improved QoL. Primary open cholecystectomy is associated with less improvement in QoL than laparoscopic cholecystectomy. Whereas the risk of developing secondary manifestations from the gallstone disease, e.g. biliary pancreatitis and cholecystitis, increases with age, high age was associated with less improvement in QoL. The decision to perform cholecystectomy in elderly should thus be considered carefully, weighing the risks against the potential benefits. The SF-36 is an appropriate instrument for assessing QoL in patients undergoing gallstone surgery.

### Conflicts of interest

None of the authors has any conflict of interest that influence the work.

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### Ethical approval

The study was approved by ethics committee of Stockholm (EPN 2008/43-31/4).

### Consent

All patients registered in GallRiks are free to decline registration in GallRiks. All patients responding to the questionnaire had given their consent to participation.

### Author contribution

Daniel Rydbeck: prepared the manuscript, data collection.  
Bengt Anesten, Therese Barje, Peter Hajnal, Johanna Österberg: data collection, participated in drafting the manuscript.

Gabriel Sandblom: Designed the study, analysed data, responsible for study design.

### Guarantor

Gabriel Sandblom is the guarantor of the work.

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