



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



Daniel Rydbeck^a, Bengt Anesten^b, Therese Barje^c, Peter Hajnal^d, Johanna Österberg^e, Gabriel Sandblom^{f,*}

^a Department of Surgery, Hallands Sjukhus Halmstad, Sweden

^b Department of Surgery, Skene, Sweden

^c GallRiks, Sweden

^d Department of Surgery, Arvika, Sweden

^e Department of Surgery, Mora, Sweden

^f Karolinska Institutet, CLINTEC, Department of Surgery, Stockholm, Sweden

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

* Corresponding author. Gastrocentrum, Karolinska University Hospital Huddinge, 141 86 Stockholm, Sweden.

E-mail address: gabriel.sandblom@ki.se (G. Sandblom).

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)

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