



Dr. Marco Scarpa, PhD, Series Editor

Health-related quality of life outcomes after cholecystectomy

Amedeo Carraro, Dania El Mazloum, Florian Bihl

Amedeo Carraro, Department of Surgery, Veneto Oncological Institute, IRCCS, 35128 Padova, Italy

Dania El Mazloum, School of Medicine, University of Padova, 35128 Padova, Italy

Florian Bihl, Gastroenterology and Hepatology Unit, San Giovanni Hospital, 6500 Bellinzona, Switzerland

Florian Bihl, Gastroenterology and Hepatology Service, University Hospital of Geneva, 1201 Geneva, Switzerland

Author contributions: Bihl F, Carraro A and El Mazloum D designed the study; Carraro A and El Mazloum D performed the research; Bihl F and Carraro A contributed analytic tools; Bihl F, Carraro A and El Mazloum D analyzed the data and wrote the paper; all authors revised and approved the final version of the manuscript.

Correspondence to: Florian Bihl, MD, Gastroenterology and Hepatology Unit, San Giovanni Hospital, Via Ospedale 32, 6500 Bellinzona, Switzerland. florian.bihl@eoc.ch

Telephone: +41-91-8118708 Fax: +41-91-8118708

Received: December 23, 2010 Revised: June 15, 2011

Accepted: June 22, 2011

Published online: December 7, 2011

Abstract

Gallbladder diseases are very common in developed countries. Complicated gallstone disease represents the most frequent of biliary disorders for which surgery is regularly advocated. As regards, cholecystectomy represents a common abdominal surgical intervention; it can be performed as either an elective intervention or emergency surgery, in the case of gangrene, perforation, peritonitis or sepsis. Nowadays, the laparoscopic approach is preferred over open laparotomy. Globally, numerous cholecystectomies are performed daily; however, little evidence exists regarding assessment of post-surgical quality of life (QOL) following these interventions. To assess post-cholecystectomy QOL, in fact, documentation of high quality care has been subject to extended discussions, and the use of patient-reported outcome satisfaction for quality improvement has been advocated for several years. However, there has been little research published regarding QOL out-

comes following cholecystectomy; in addition, much of the current literature lacks systematic data on patient-centered outcomes. Then, although several tools have been used to measure QOL after cholecystectomy, difficulty remains in selecting meaningful parameters in order to obtain reproducible data to reflect postoperative QOL. The aim of this study was to review the impact of surgery for gallbladder diseases on QOL. This review includes Medline searches of current literature on QOL following cholecystectomy. Most studies demonstrated that symptomatic patients profited more from surgery than patients receiving an elective intervention. Thus, the gain in QOL depends on the general conditions before surgery, and patients without symptoms profit less or may even have a reduction in QOL.

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Key words: Gallbladder disease; Gallstones; Quality of life; Laparoscopy

Peer reviewers: Bernabe Matias Quesada, MD, Department of Surgery, Hospital Cosme Argerich, Talcahuano 944 9 A, Buenos Aires 1013, Argentina; Hayrullah Derici, MD, Associate Professor, Department of General Surgery, Balikesir University Medical Faculty, Balikesir 10145, Turkey

Carraro A, El Mazloum D, Bihl F. Health-related quality of life outcomes after cholecystectomy. *World J Gastroenterol* 2011; 17(45): 4945-4951 Available from: URL: <http://www.wjgnet.com/1007-9327/full/v17/i45/4945.htm> DOI: <http://dx.doi.org/10.3748/wjg.v17.i45.4945>

INTRODUCTION

Gallbladder diseases are very common in developed countries. They comprise a large spectrum of disorders caused by alterations in bile composition and biliary function, placing a substantial burden on inpatient and outpatient resources. Clinical manifestation of gall-

stone disease varies from attacks of intense biliary colic, prompting surgical intervention, to an absence of symptoms. Biliary colic is usually secondary to temporary obstruction of the cystic duct by a gallstone. When obstruction holds over, the gallbladder becomes inflamed and the patient may develop cholecystitis or other, potentially serious complications, such as cholangitis, gangrene, perforation, peritonitis, sepsis or pancreatitis. Complicated gallstone disease (e.g., symptomatic cholelithiasis) represents the most frequent of biliary disorders for which surgery is regularly advocated. In fact, patients with cholelithiasis account for about 10% to 15% of the total adult western population^[1-4]; among them around 30% have surgery, and only 2% develop symptoms^[4,5]. Today, cholecystectomy is a standard practice for cholelithiasis, and surgery for complicated gallstone diseases has a significant impact on quality of life (QOL) in developed countries^[4]. QOL assessments are increasingly being recognized as an integral factor in surgical decision-making. However, considering the enormous number of cholecystectomies performed daily worldwide, surprisingly little data has been collected about QOL after biliary surgery. Laparoscopic cholecystectomy (LC) has become a very frequent surgical procedure, with over 500 000 operations annually in Western countries^[5]. The laparoscopic technique, introduced in the 1990s, resulted in a significant reduction in the number of open cholecystectomies. As a consequence of this movement towards minimally invasive procedures, over the past 15 years the number of cholecystectomies increased, which may reflect a change in the threshold to perform surgery. This shift has also significantly impacted postoperative QOL. Today, estimates are that 86% of cholecystectomies are performed laparoscopically. This number continues to increase, especially in the treatment of acute cholecystitis and biliary colic; therefore, in recent years, the accumulating surgical experience and advances in technology have extended the indications for LC to include patients with complicated gallbladder disease^[6,7]. On this basis, there is suggestive evidence that immediate postoperative health-related QOL (HRQOL) may be better after laparoscopic procedures. That being said, the introduction of LC has also increased the incidence of injuries to the biliary tree, along with an increasing number of serious vascular lesions^[8-10]. In fact, 15%-20% of patients require conversion to open cholecystectomy for the safe completion of the procedure, countering the potential benefit of the laparoscopic approach^[11].

To assess QOL, documentation of high quality care in cholecystectomy has been subject to extended discussions, and the use of patient-reported outcome satisfaction for quality improvement has been advocated for several years^[12]. It would be ideal to consider the entire spectrum of gallbladder diseases that indicate surgery. Among them, for example, acalculous cholecystitis represents a controversial clinical indication for surgery, yet it accounts for 5%-20% of all cholecystectomies^[13]. Fur-

thermore, debate continues regarding the decision for elective surgery in patients following an acute episode of gallstone disease. Although several tools have been used to measure QOL after cholecystectomy, difficulty remains in selecting meaningful parameters in order to obtain reproducible data to reflect postoperative QOL. Classically, evaluations of surgical procedure outcomes have focused on perioperative complications, morbidity, recurrence rate, and long-term survival. However, much of the current literature lacks systematic data on patient-centered outcomes. Endpoints such as symptom resolution or duration of convalescence represent QOL measures that are at least as important as the classical outcomes. There has been little research done regarding QOL outcomes following cholecystectomy. Furthermore, laparoscopic surgery is usually perceived by patients as a routine procedure. Thus, the impact of LC on QOL, as well as the identification of predictors of subjective patients outcomes, remains undetermined in these patients^[14].

Usually, the principal criterion guiding patients' acceptance of a treatment modality is their subjective condition prior to surgery. Additionally, those subjective reports become important criteria in a surgeon's decision-making process^[15]. Thus, the aim of this review is to evaluate and summarize the published data on QOL after cholecystectomy in adults. A text word literature search was performed using the Medline databases. Although this was not a systematic review, the search terms used were as follows: gallstones, cholecystitis, surgery, gallbladder disease, and quality of life. The reference lists of identified articles were searched for further relevant publications. The databases were consulted from January 1993 to July 2010. The authors independently selected the studies, particularly those comparing different surgical approaches. Whenever there was discordance regarding study inclusion the authors negotiated an agreement.

GLOBAL QOL MEASURES FOR CHOLECYSTECTOMY: A LACK OF STANDARDIZED AND UNIVERSALLY VALIDATED INSTRUMENTS

HRQOL measures have been shown to be useful in predicting health care expenditure; different QOL indices exist and have been validated to determine the general subjective perceptions and expectations of individuals; in surgery in general, and in particular in the case of cholecystectomy, there is no clear, validated and standardized instrument for assessing QOL postoperatively. The development of well-validated and sensitive non-disease-specific questionnaires is useful for comparing different surgical approaches and techniques. Although specific, HRQOL instruments have been proposed for cholelithiasis and cholecystectomy, they have appeared

with only limited reproducibility, restricted psychometric aspects and with linguistic gaps when translated into different languages^[16-18].

The most frequently used tool to assess QOL is the short form (SF)-36 questionnaire and the Gastrointestinal Quality-of-Life Index (GIQLI), each instrument having its own advantages and limitations. The generic SF-36 is a widely used instrument that allows comparison between different studies. However, it has a low discriminative ability and low specificity for identifying determinant changes related to a specific clinical factor. The GIQLI is an established tool for assessing QOL outcomes for patients with various gastrointestinal symptoms including domains of general health, but it is not specific for gallbladder disease.

Some studies used both SF-36 and GIQLI, combining a questionnaire for general well-being and another for more specific postoperative QOL. Quintana *et al*^[19] used, for example, the SF-36 to validate the explicit appropriateness criteria in subjects after cholecystectomy. Their results indicated similar improvements in SF-36 QOL measures compared with GIQLI, indicating that both tools were adequate QOL measures and thus confirmed their validity. Recently Fledman *et al*^[20] proposed a physical activity questionnaire (Community Health Activities Model Program for Seniors) as an indicator of postoperative recovery. Their aim was to specifically correlate physical activity caloric expenditure as an estimation of postoperative recovery after LC in older patients; evidence has been provided for the validity of this questionnaire as a measure of surgical recovery.

However, the most appropriate measures for identifying relevant changes in QOL after biliary surgery remain to be determined.

An important proposed concept of a questionnaire's appropriateness is the accuracy of a measure over time in the same patient, assessing prospective changes in the patient's health status. In fact, a highly responsive QOL instrument has been considered able to detect significant treatment effects in a small sample size: an outstanding proposed tool is the "minimal clinically important difference" (MCID) that potentially can examine all significant differences at the individual patient level^[21,22]. The MCID is one of the most effective and widely used methods of HRQOL assessment, and can be used to provide an indication of the minimal change that is of clinical relevance. An interesting work by Shi *et al*^[23] aimed to estimate MCIDs for the GIQLI score of patients after cholecystectomy; they showed that this instrument can play a role in interpretation of scores and useful application in clinical practice. Thereafter, the same group clinically compared the responsiveness derived by the SF-36 and the GIQLI before and after cholecystectomy; correlation analyses revealed significant correlation between the SF-36 and GIQLI in the preoperative and 3-mo postoperative period^[24].

In conclusion, there is an overall propensity to use

both generic instruments, SF-36 and GIQLI, to assess the QOL after cholecystectomy; however in the case of limited time and resources, the GIQLI index may be used alone since it incorporates all domains of a QOL. The main issue is the choice of disease-specific outcome measures, adjusted for potential variables, that may act as confounders to identify the effective relevant changes after cholecystectomy.

IMPACT ON QOL OF LAPAROSCOPIC VS OPEN CHOLECYSTECTOMY

The literature offers positive and encouraging results in several reports comparing laparoscopic *vs* open surgery in the clinical setting. The development of the laparoscopic technique has drastically changed the protocols for treatment of gallstone disease and cholecystitis, and has been accompanied by evident clinical benefit for patients. Over the years since its introduction, reduced morbidity and mortality rates have confirmed LC as a safe and standard procedure in the treatment of some gallbladder diseases^[25]. These results reinforce the feasibility of laparoscopy as a treatment modality for the biliary tract itself, and have provided reliable scientific material in support of an expanded role for laparoscopy in hepatobiliary surgery. Collected data seems to confirm a positive post-laparoscopic subjective satisfaction and perceived QOL^[20,26]. Indeed, Harju *et al*^[27] compared minilaparotomy with LC, demonstrating that the minilaparotomy procedure represents a good alternative to the LC procedure, when QOL is measured.

Although the rate of increase of QOL following LC is greater than that after open surgery, long-term overall QOL has proven to be only slightly better or show no difference when compared with open surgery. Therefore, the only significant long-term advantage of laparoscopic surgery, as compared with open surgery, seems to be the higher satisfaction rate regarding the cosmesis of the surgical scar. There remains no clear explanation regarding the similarity of this comparative data between the two surgical techniques; feasible hypotheses are that indications for LC might be more easily proposed than those for open surgery. This could impact patient selection as well as patient expectation regarding laparoscopy^[28]. Furthermore, patients selected for open surgery more frequently have a lower perception of QOL and more co-morbidities than matched laparoscopic patients prior to surgical intervention. These factors likely influenced outcomes and potentially introduced bias in the above-mentioned studies.

ADULT PATIENTS WITH CHOLELITHIASIS: IMPACT OF QOL FOLLOWING LC

The use of objective outcome measures after surgical procedures, even though non-disease specific, is helpful

for laparoscopic surgery such as cholecystectomy. Quintana *et al.*^[29] aimed to determine clinical variables that predicted changes in HRQOL using both instruments, GIQLI and SF-36. Patients were grouped according to diagnosis (complicated symptomatic cholelithiasis, including acute cholecystitis, choledocholithiasis, pancreatitis or cholangitis; uncomplicated symptomatic cholelithiasis; asymptomatic cholelithiasis) and surgical risk categories; patients were asked to complete a questionnaire before and 3 mo after cholecystectomy. The study concluded that cholecystectomy is the suitable treatment especially for patients with symptomatic cholelithiasis and low surgical risk since they experienced the highest QOL gains; whereas patients with asymptomatic cholelithiasis or high surgical risk experienced least improvement. Conversely, Montes *et al.*^[30] observed significant GIQLI score improvements in both symptomatic and asymptomatic gallstone groups. However, the gallstone-related QOL improvements were particularly marked in symptomatic patients, indicating that gallstone patients with lower baseline GIQLI scores are more likely to benefit from LC. Thus, LC seems to be the appropriate intervention for patients with symptomatic gallstone and low surgical risk.

Alternatively, Vetrhus *et al.*^[31] evaluated gallstone-related acute cholecystitis *vs* symptomatic but non-complicated disease. They used QOL and pain surveys to compare chronic gallbladder disease outcomes between conservative observational treatment and cholecystectomy. The patients in this study answered standardized questions at baseline (before surgery), and at 6, 12 and 60 mo post-cholecystectomy. The observation group (no intervention) had a higher rate (36% *vs* 19%) of gallstone-related events, but the difference was not significant. When patients were grouped according to randomization or actual operative outcome (+/- cholecystectomy), the authors did not find any significant differences in pain or QOL measurements. The authors concluded that conservative treatment in acute cholecystitis did not significantly increase the risk of subsequent gallstone events, and importantly this did not influence the QOL outcome and pain measurements. Thus, conservative (non-operative) treatment and observation of acute cholecystitis would be an acceptable option and should at least be considered in high risk patients^[27].

Another longitudinal QOL study from Taiwan provided data using the SF-36 questionnaire and GIQLI scores^[32]. The preoperative SF-36 scores from gallstone patients were significantly inferior to an age- and sex-matched control population; LC effectively reduced gastrointestinal symptoms, confirmed by the improvement in GIQLI total, physical well-being, mental well-being, gastrointestinal digestion, and defecation subscale scores. Yet, certain authors' evidence indicates that some patients did not regain full GIQLI scores after surgery, deducing that some residual gastrointestinal discomfort remained. Indeed, some investigators described a persis-

tent decrement in many of the SF-36 health dimensions at 12 mo following surgery; thus they identified different markers to evaluate QOL outcomes after surgery; they found that QOL improvements can be partially predicted by the preoperative direct bilirubin level and by the placement of a drainage tube intra-operatively. This aspect confirms data indicating that patients with worse preoperative health conditions may have greater gains in QOL improvement following LC surgery; moreover, QOL measures should consider potential variables that may act as confounding events. In fact, although there is no doubt that cholelithiasis may decrease the QOL during its acute symptomatic phase, the postoperative course after cholecystectomy, independent of the operative technique, might be potentially altered by other factors (bloating, slow digestion, *etc.*) that were not sufficiently controlled or distinguished by researchers, and could determine cholecystectomy as an overused procedure.

Finan *et al.*^[33] designed a study to determine gastrointestinal symptoms and QOL after cholecystectomy for better measurement of the change in QOL after surgery. In this study, SF-36 was employed along with a symptom survey that was designed to include both classic symptoms of biliary disease as well as other benign gastrointestinal (GI) diseases. Their results showed that LC significantly improved GI symptoms as well as QOL in subjects with symptomatic gallstone disease; the quantitative evaluation of GI symptoms allowed for analysis of symptom improvement by including patient perceived severity and distress. These results permitted the development of clear indications for operative management, supporting the effectiveness of cholecystectomy for elective biliary disease. In conclusion, in adult patients operated for cholelithiasis, QOL improved most in patients with symptomatic disease and average surgical risk; particular attention must be paid in regard to appropriate selection of patients, especially in terms of discrimination between biliary disease-related symptoms and other GI disorders.

IMPACT ON QOL OF LC FOR ACALCULOUS CHOLECYSTITIS

One of the most controversial and frequent dilemmas for surgeons in clinical practice is recurrent acalculous biliary pain. Surgical treatment of this disease represents a controversial issue, especially considering the similarities between its clinical presentation and that of other GI conditions. Therefore, clinical resolution cannot be guaranteed with surgical interventions and there is significant risk for decreased QOL following this procedure. Planells Roig *et al.*^[13] evaluated the QOL in patients with chronic acalculous cholecystitis in comparison to a control group of patients who underwent cholecystectomy for chronic calculous cholecystitis. They concluded that the prevalence of associated gastrointestinal symptoms

was similar for both groups, and QOL was similarly affected by both chronic diseases. The limitation of this work was primarily a disparity between the numbers of subjects (34 patients with chronic acalculous cholecystitis *vs* 297 with chronic calculous cholecystitis); moreover, the study population was a highly selected, though heterogeneous group of patients. A comprehensive and reproducible preoperative investigation for proper diagnosis of biliary disease has constituted an essential prerequisite for the appropriate selection of patients for surgery, and the appropriate exclusion for other GI disorders. Thus, the frustration due to the lack of understanding this disease consequently implies an impact in terms of post-surgical QOL for these patients. An accurate clinical selection seems to remain the most important criterion for surgical and healthcare expenditures in primary hepatobiliary centers.

CHANGES IN QOL FOLLOWING IATROGENIC INJURIES AFTER CHOLECYSTECTOMY

Unfortunately, with the introduction of LC, an increase in potentially dangerous injuries to the biliary tree has been observed, along with an increasing number of serious vascular lesions. Nowadays iatrogenic bile duct-related injuries (BDI) occur in less than 0.3% of all cholecystectomy procedures^[34]. BDI are not always identified immediately during the surgical procedure and sometimes appear only in the postoperative course, mostly between days 1 and 5^[35]. The clinical manifestations start with early biliary obstruction, biliary abdominal collection or biliary peritonitis, whereas late presentations include obstructive jaundice and ascending cholangitis. On this basis the optimal management of complications often advocates interventional procedures such as percutaneous drain placement or, sometimes, second-look surgery. The literature includes numerous studies confirming satisfactory technical and clinical approaches, demonstrating acceptable clinical outcomes, even in tertiary hepatobiliary centers. However, data is lacking regarding QOL. Only poor documentation of high quality care after bile-duct injuries exists. Results vary significantly between studies, and most recorded true BDI rather than simple cystic duct leaks.

Hogan *et al*^[36] has recently published an interesting study, which compared an iatrogenic BDI study group with an age- and sex-matched control group, which underwent uncomplicated cholecystectomy. The SF-36 form was administered to the patients at a median postoperative time of 12 years (range, 2 mo to 20 years). The authors finally concluded that QOL of the surviving patients following BDI seems to be favorable to that after uncomplicated LC. Other studies showed different results; in particular, Sarmiento *et al*^[37] and Melton *et al*^[40] showed favorable comparisons between BDI and a control group whereas Boerma *et al*^[39] and Moore *et al*^[38] found that the

BDI group had lower QOL scores. However, Boerma's work has been criticized, although they had the largest series^[37,39]: for example, patient enrollment included those with cystic duct as well as peripheral hepatic injuries (e.g., leakage, 30%), which technically do not represent BDI. Furthermore, different QOL instruments were used for measuring health-related impact, invalidating any potential comparison between groups. Sarmiento *et al*^[37] assessed QOL with the SF-36 questionnaire with a minimum follow-up of 5 years; the QOL after surgical biliary reconstruction compared favorably with that of patients undergoing uneventful LC. Melton *et al*^[40] assessed QOL of patients after surgical reconstruction of major bile duct injury from LC with a median follow-up of 59 mo. Although using different survey instruments, the conclusions of the studies are quite similar, and all found that major BDI should be managed surgically, which constitutes a definitive therapy (although more invasive), and is not punctuated by repetitive interventions; in fact, patients with BDI managed endoscopically often require repeat intervention resulting in a worse QOL. In any case, an equivalence of QOL in BDI and uncomplicated LC is quite surprising and points to a possible bias. Patients with the most severe BDI may die, thus QOL cannot be assessed. Moreover, the numbers of patients included were small and in general, the instruments employed were nonspecific.

CONCLUSION

Many studies in the literature lack systematic data regarding QOL outcomes after cholecystectomy. Reported works have conflicting data and sometimes several limitations (i.e., small sample size, single-institution experience), and thus may not be generalizable. A general agreement is that postoperative QOL depends on preoperative clinical status; moreover the first essential criterion for an improvement in subjective change in QOL is accurate preoperative diagnosis. In fact, appropriate patient selection for surgery represents the most important criteria guiding the patients' subjective feeling after cholecystectomy, independent of the selected surgical technique. On the other hand, an effective way to investigate the factors that may influence subjective QOL outcomes would be to measure the satisfaction rate pre- and post-surgery, and repeatedly after surgical treatment; a QOL assessment is generally suggested at 1 and 6 mo postoperatively. On this basis, symptomatic patients usually gain more QOL from a surgical intervention (open or laparoscopic) in terms of long-term well-being. Even though LC improves QOL faster than open surgery, long-term results are only slightly better or show no difference compared with those of open surgery; at the same time, these data should be considered as a mean, and might be limited by study design (e.g., small sample size, biased and confounding variables). The only certain and significant long-term advantage of laparoscopic surgery might be the higher satisfaction rate in regard to

scar cosmesis, in the absence of complications.

In conclusion, although sensitive and responsive instruments for the measurement of post-cholecystectomy QOL exist, more research is needed to identify modifications that could lead to significant improvements.

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