Real Benefits of the Laparoscopic Approach

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9.1 Introduction

Classical outcome measures (mortality and complications) have to be considered to compare surgical treatments. As no significant differences between laparoscopic cholecystectomy (LC) and open cholecystectomy (OC) were found in classical outcome measures, it is justified to consider health-related quality of life (HRQoL) an important secondary outcome measure. Indeed quality of life (QoL), symptoms resolution, duration of convalescence, and patient satisfaction and well-being are at least as important as the classical outcomes from a patient's point of view.

Instruments for measuring HRQoL may be disease specific or generic:

(a) *Disease-specific instruments* are administrated in clinical trials to detect progressive changes after medical or surgical interventions and focus on improvements in symptoms and physical functioning.

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(b) *Generic health instruments* are designed for application to many diseases or interventions and are intended to obtain an overall evaluation of health outcomes.

The Gastrointestinal Quality of Life Index (GIQLI) is a self-reported, system-specific measure designed for use with people with different gastrointestinal disorders, and it has proved to be useful for outcome assessment after cholecystectomy. The 36 items (reflecting physical, emotional, and social function as well as typical gastrointestinal symptoms) are each scored on a 5-point scale (Likert) with higher scores denoting better QoL.

The Short-Form 36-Item Health Survey (SF-36) is a widely used generic quality-of-life measuring instrument that divides QoL into eight domains, including physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Each subscale score is from 0 to 100, with 100 as the most optimal health status.

The Nottingham Health Profile (NHP) is another validated generic instrument to measure QoL, but it is not frequently used. This questionnaire is divided in two sections: the first one consists of 38 questions in 6 subareas, with each question assigned a weighted value; the sum of all weighted values in a given subarea adds up to 100 (energy level, pain, emotional reaction, sleep, social isolation, physical abilities); the second part investigates about 7 dimensions of the social life that could be affected by disease or treatment (work, looking after home, social life, home life, sex life, interest and hobbies, vacation).

In addition to those mentioned above, some authors have used other instruments such as: Visual Analogue Scale (VAS), Hospital Anxiety and Depression Scale (HADS), Body Image Questionnaire (BIQ), EuroQol-5D, Karnofsky Performance Scale (KPSS), Psychosocial Adjustment to Illness Scale (PAIS), and City of Hope QoL.

9.2 Methods

A systematic review based on a comprehensive literature research via *PubMed* and *The Cochrane Library* was done to evaluate the HRQoL.

The search details were ("cholecystectomy, laparoscopic"[*MeSH Terms*] *OR* ("cholecystectomy"[*All Fields*] *AND* "laparoscopic"[*All Fields*]) *OR* "laparoscopic cholecystectomy"[*All Fields*] *OR* ("laparoscopic"[*All Fields*] *AND* "cholecystectomy"[*All Fields*])) *AND* ("quality of life"[*MeSH Terms*] *OR* ("quality"[*All Fields*] *AND* "life"[*All Fields*]) *OR* "quality of life"[*All Fields*]) *AND* (("1994/01/01"[*PDAT*]: "2012/12/31"[*PDAT*]) *AND English*[*lang*]).

A total of 147 citations were identified. The titles and abstracts of the retrieved citations were scanned to exclude all publications that were clearly not relevant to the guideline topic. Articles were considered relevant if they reported QoL outcomes using standardized or self-developed questionnaires. Full texts from selected abstracts were used based on specific criteria. Multiple publications of the same study were included only once. Pertinent studies from other references were also

Table 9.1 Selected studies and their level of evidence

N. 1	Evidence-based guidelines	
N. 1	Meta-analysis of retrospective case-control or case-series study	LoE 4
N. 7	Randomized controlled trial	N.2: LoE 3[a] N.5: LoE 2
N. 10	Nonrandomized prospective cohort/observational study	LoE 3
N. 8	Case-control study	LoE 4
N. 2	Case series	LE 4

[a]Evidence Level was downgraded from 2 to 3 because the study population is small

been selected. A total of 23 publications were examined for relevance; 6 further relevant publications were identified from citation of other references (Table 9.1).

Level of evidence of these selected papers was graded according to Oxford Centre for Evidence-Based Medicine 2011.

9.3 Considerations

An effective way to investigate the factors that may influence QoL outcomes after LC would be to measure the pre- and postsurgery satisfaction rate (QoL assessment is generally suggested at the 1st and 6th months after surgery) administrating SF-36 as generic instrument in conjunction with GIQLI as disease-specific instrument. If time and resources are limited, the GIQLI may be used alone because it incorporates all domains of a QoL assessment.

We pointed our attention to the QoL considering the following main topics:

(a) Effectiveness of LC
(b) Comparison to OC
(c) Comparison to small-incision laparotomic cholecystectomy (SC)
(d) Impact of iatrogenic bile duct injury (BDI)

9.3.1 QoL After LC: Is the Operation Effective?

From our systematic review of the literature, after exclusion of duplicates, we found only three prospective cohort studies concerning QoL after LC [1–3] [LE 3] (Table 9.2).

Finan et al. designed a study to determine gastrointestinal symptoms and QoL after cholecystectomy for better measurement of the change in QoL after surgery [1] [LoE 3]. This is a prospective cohort of consecutive patients with a small population (55 subjects) at a mean time to follow-up of 17.1 months; indeed only 64 % of patients involved in the study returned the filled questionnaire. In this study, SF-36 was employed along with a symptom survey that was designed to include both classic symptoms of biliary disease and other benign gastrointestinal (GI) diseases. Their results showed that LC significantly improved GI symptoms as well as QoL in subjects with symptomatic gallstone disease; nevertheless symptoms

Table 9.2 QoL after LC in 3 prospective nonrandomized study (410 patients)

Author	Test	Questionnaire delivered	Response rate (%)
Finan KR [LoE 3] [1]	SF-36 GISS (gastrointestinal symptom survey)	Median follow-up 17.1 months (range 2–32)	64
Lien HH [LoE 3] [2]	SF-36 GIQLI (Taiwan version)	12 months	100
Hon-Yi [LoE 3] [3]	SF-36 GIQLI (Chinese version)	3, 6, 12, and 24 months	72.5

associated with reflux (food or stomach contents in the throat, belching, feeling full after small meals, and pressure in the chest), irritable bowel syndrome (flatulence, constipation, and diarrhea), and chronic pain (pain all the time) did not show significant improvement. These results support the effectiveness of LC for elective biliary disease, with particular attention in regard to appropriate selection of patients, especially in terms of discrimination between biliary disease-related symptoms and other GI disorders.

Lien et al. reported the results of a prospective nonrandomized follow-up study on a cohort of 99 consecutive patients evaluated preoperatively and 12 months after surgery with SF-36 and GIQLI [2] [LoE 3]. 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; particularly patients with worse preoperative health condition are shown to benefit from greater QoL improvements following LC surgery. Yet some patients did not regain full GIQLI scores after surgery, deducing that some residual gastrointestinal discomfort remained 12 months after surgery.

Shy et al. reported the scores of SF-36 and GIQLI before surgery and then at 3, 6, 12, and 24 months after surgery in a prospective cohort study that includes 353 consecutive patients [3] [LoE 4]. Only 72.5 % of them returned the questionnaire after 24 months of follow-up, so the study consisted of 256 patients. All the LC patients had significantly improved GIQLI and SF-36 subscale scores at the 6-month follow-up survey. Interestingly most dimensions of the GIQLI and the SF-36 improved remarkably not only until the first year after surgery but also thereafter. In each GIQLI dimension, the fastest improvement occurred immediately after surgery and then reached a plateau after approximately 2 years. In particular, among eight SF-36 subscales, physical functioning, role physical, and role emotional showed the best improvement by the second year after surgery. HRQoL improvement after LC was inversely related to age, and according to Lien HH, the best predictors of postoperative HRQoL were preoperative functional status scores. The authors suggested that direct interventions to reduce role limitations due to physical and emotional problems may enhance physical functioning of patients after LC, increasing HRQoL in all dimensions.

We found only one paper in which the impact on QoL of a perioperative intervention after LC was investigated [4] [LoE 3]. The study was a randomized

single-blinded trial, in which a population of 60 patients was followed up and analyzed. Those in the intervention group attended a standardized 45 min relaxation session with a health psychologist and were given relaxation exercise compact disk to take home; the control group did not have the intervention. Both groups had similar fatigue at baseline measured using the identity-consequence fatigue scale. The results of the trial demonstrated a reduction of fatigue on postoperative day 30 in the intervention group, allowing faster return to normal functions and activities.

From the above it could be deduced that:

- LC significantly improved either GI symptoms or QoL in subjects with symptomatic gallstone disease.
- Best results may be achieved by an appropriate selection of patients, in terms of discrimination between biliary disease-related symptoms and other GI disorders.
- Patients with worse preoperative health condition are shown to benefit from greater QoL improvements following LC surgery.
- Preoperative functional status scores are the best predictors of postoperative HRQoL.

9.3.2 QoL After LC Versus OC

EAES evidence-based guidelines on the evaluation of QoL after laparoscopic surgery published in 2004 focused on comparison of QoL after LC and OC [5]. Two randomized and eight nonrandomized trials were analyzed [6–15] [LoE 2]. The authors reported that LC improves QoL faster than OC and that long-term results after LC are slightly better or not different compared to OC. However, the authors included in the study publications that compare LC with classical OC together with publications that compare LC with SC. In particular there were no randomized controlled trials (RCT) in which QoL after LC was compared with QoL after classical OC: four prospective nonrandomized longitudinal studies and four retrospective case–control or population studies were cited in EAES guidelines about this topic [8–15] [LoE 3].

Sanabria et al., using an ad hoc questionnaire over an 8-week period after laparoscopic or open cholecystectomy, studied all patients who underwent elective cholecystectomy during three consecutive periods; there were 121 patients in each period [8] [LoE 4]. In the first period all patients underwent OC, in the second period 58 % underwent LC, and in the last period almost all patients underwent LC. A significantly shorter hospital stay and shorter recovery period in favor of LC was found, but at the final evaluation, the patients' answer did not differ between groups regarding their postoperative QoL.

Eypash et al. evaluated a cohort of 179 patients (21 OC versus 158 LC) with GIQLI and VAS score 2 and 6 weeks after surgery; QoL score was then compared with 70 healthy persons [9] [LoE 4]. LC resulted in immediate postoperative improvement of QoL; at both time points, there was a trend toward better QoL in the laparoscopic group.

Ludwig et al. used GIQLI in a prospective nonrandomized comparative study including 103 patients (29 OC and 74 LC) with 35 days of follow-up. The authors reported a quicker convalescence after LC with an earlier return to work [10] [LoE 3].

Plaisier et al. prospectively studied the course of QoL and gastrointestinal symptoms after laparoscopic and open cholecystectomy, demonstrating that LC improved QoL and symptomatology at an earlier stage than OC, yet the population of the study was very small including 31 patients only (14 LC and 17 OC) [11] [LoE 3].

Similarly Chen et al. confirmed in their prospective nonrandomized trial, in which GIQLI was used preoperatively and then 2, 5,10, and 16 weeks after surgery, that LC can improve the QoL better and more rapidly than OC [12] [LoE 3]. Even for this paper the population of the study was small (51 patients).

Kane et al. retrospectively evaluated consecutive cases of elective cholecystectomy from 35 hospitals sending an ad hoc questionnaire about symptoms and functional status 6 months postoperatively [13] [LoE 4]. The questionnaire was returned in 76 % of cases; the population studied consisted of 2.481 patients: no difference in pain, symptoms, or general health was noted after LC or OC, but the mean time to return to work and to perform usual activities was significantly shorter for LC.

Topcu et al. performed a retrospective comparative study on 200 patients (100 LC and 100 OC) using the SF-36 questionnaire with a mean administration time of more than 40 months [14] [LE 4]. Both groups were comparable prior to surgery for demographic data, but no data about preoperative QoL were reported. The gastrointestinal clinical symptoms were similar in the two groups during the long-term follow-up evaluation, but LC was found to be significantly superior to OC with respect to the QoL over the long term. Authors reported a statistically significant difference in the scores of all eight domains of SF-36 in favor of LC; it would be understandable if the social aspect of QoL were impacted due to worse cosmesis after OC, but it is surprising that other aspects of QoL still showed significant differences as long as more than 3 years after the operation. Because preoperative QoL is not reported, these differences could simply reflect preexisting pretreatment differences; moreover, QoL data were not periodically collected, and the protracted period of more than 3 years that elapsed between the operation and the data collection casts more doubt on the reliability of the findings.

Quintana et al. conducted a prospective observational study of consecutive patients using GIQLI and SF-36 questionnaires [15] [LE 3]. 77.6 % patients (688 subjects) completed the questionnaires both before and 3 months after the intervention. HRQoL improvement at 3 months was relevant and similar for both surgical techniques, although the health transition perception was worse for those who underwent open surgery. Yet it must be noted that these results may depend by significant differences of the groups for sociodemographic and preoperative clinical variables. Patients who underwent OC had indeed symptomatic lithiasis with complications more frequently than those who underwent LC, mean age was older, and there were more patients with comorbidities and high surgical risk, measured by the ASA (American Society of Anesthesiologists) score, in the group treated with OC.

From our systematic review of the literature, we identified three papers comparing QoL after LC or OC: there are no randomized controlled trials [16–18] [LoE 3].

Velanovich et al. prospectively assessed the health status outcomes of 100 patients who underwent different types of laparoscopic and open procedures using SF-36 questionnaire before and 6 weeks after surgery [16] [LoE 3]. LC had better QoL outcomes than OC, but in the paper three other procedures are mixed with cholecystectomy, and the population who underwent cholecystectomy in the study is very small.

Hsueh et al. reported a large-scale prospective cohort study in which GQLI and SF-36 were used preoperatively and then 3 and 6 months after the procedure in 297 patients (38 OC and 259 LC) [17] [LoE 3]. They reported that HRQoL of patients who underwent cholecystectomy was significantly improved at 3rd and 6th months after surgery. At 3rd month postsurgery, HRQoL was significantly larger in LC than in OC patients. Additionally, after controlling for related variables, preoperative health status was significantly and positively associated with each subscale of the GQLI and SF-36 throughout the 6 months.

At last in the study of Matovic et al., 59 and 61 patients respectively treated with LC and OC were prospectively studied using GLQI before surgery and then at 2-, 5-, and 10-week intervals after surgery [18] [LE 3]. Patients' QoL at 2 and 5 weeks was significantly better in laparoscopic method group versus open method group in all four domains of GLQI, but after 10 weeks there were no differences in QoL total and domain score between two groups.

In conclusion, as a general agreement, postoperative QoL depends on preoperative clinical status: patients with worse preoperative health condition may benefit from better QoL improvements following LC surgery. There are no RCT or high-evidence-level studies that compare QoL after LC or OC. Based on the studies available, even though LC improves QoL faster than open surgery, long-term results are only slightly better or show no difference compared to OC (Table 9.3); at the

Table 9.3 QoL: LC versus OC data from E.A.E.S. Evidence-based guidelines 2004 (4,096 patients) and 3 prospective non-randomized studies (447 patients)

		QoL results		
Author	Test	Questionnaire delivered	Short term	Long term
EAES Evidence-based guidelines [5]	2 SF-36 4 GIQLI 3 ad hoc questionnaire 1 VAS		LC > OC	LC ≥ OC
Velanovich [EL 3] [16]	SF-36	6 and 9 weeks	LC > OC	–
Hsueh et al. [EL 3] [17]	SF-36 GIQLI	3 and 6 months	LC > OC	LC ≥ OC
Matovic et al. [EL 3] [18]	GIQLI	2, 5, and 10 weeks	LC > OC	LC = OC

same time, these data should be considered as a mean and might be limited to study design (e.g., small sample size, biased and confounding variables, low response rate to questionnaires).

9.3.3 QoL After Laparoscopic Versus SC

SC or minilaparotomic cholecystectomy is a surgical procedure performed through a subcostal incision shorter than 8 cm.

Barkun et al. studied 35 and 23 patients prospectively randomized in the LC and SC groups, respectively, and used GIQLI in addition to NHP and VAS to assess QoL [6] [LoE 3]. No blinding was used. Cumulative totals of both GIQLI and NHP data were used instead of using subscales. Changes in one dimension might be offset by changes in other dimensions. Both questionnaires have more than one dimension; subscales indeed provide the advantage of additional information on several dimensions. As a rather small number of patients were included (the trial was stopped preliminary), no subscales were assessed, and no considerations were given to the construct or divergent validity of both questionnaires. The authors reported that LC patients improved more quickly than did SC patients.

McMahon et al. compared health status in 151 and 148 LC and SC patients, respectively, using the SF-36 health survey questionnaire and the "Hospital Anxiety and Depression Scale" (HADS) [7] [LoE 2]. Generation of the allocation sequence in their trial was unclear and no blinding was used. They found that patients recovering from LC enjoyed significantly better health 1 and 4 weeks after the operation compared with those recovering from SC, but no significant difference was found at 12 weeks. Moreover, LC patients were more satisfied with the appearance of their scar. The absence of preoperatively baseline measurements makes conclusions about postoperative data uncertain; moreover, they used in SC group a subcostal incision up to 10 cm long.

Squirrell et al. used the NHP in 100 patients (50 in each group) preoperatively and 3 weeks and 6 months postoperatively [19] [LoE 2]. At no time there was a significant difference between the two groups. The study used a rather small sample size and unfortunately without a disease-specific questionnaire, but only one generic questionnaire.

Nilsson et al. randomized 726 patients in two groups: LC (364 patients) and SC (362 patients) [20] [LoE 2]. The total population of consecutive patients of this study was of 1,719 subjects: 993 patients were not randomized (227 patients not eligible, 472 patients were excluded by surgeon in charge, and 244 patients choose not to participate), representing an important bias of this large trial. EuroQol-5D and VAS questionnaires were used to assess QoL. EuroQoL-5D questionnaire consists of five questions with three response alternatives concerning patient mobility, self-care, activity, pain or discomfort, and mood. One week postoperatively, there were small but statistically significative differences favoring LC compared with SC in four EuroQol-5D dimensions (mobility, self-care, main activity, pain/discomfort) and in "self-reported health status today compared with the status the previous 12 months," whereas patients in two groups did not differ with respect to mood and

self-estimated well-being according to the EuroQol-5D VAS. After 1 month and 1 year, there were no differences between the two groups in any EuroQol-5D dimension. At the end, direct and indirect costs due to loss of production were calculated in this study: total costs between LC and SC did not differ with high-volume surgery (>100 procedures per year) and using disposable laparoscopic instruments, whereas LC was more expensive in low-volume surgery (<50 procedures per years) and using disposable instruments.

Harju et al. randomized 157 not consecutive patients between LC and SC treatment [21] [LoE 2]. Patients were reevaluated 4 weeks after surgery using the SF-36 QoL questionnaire. In the LC group role functioning/physical score was slightly but significantly better than in the SC group, but in the other SF-36 dimensions (physical functioning, role functioning/emotional, energy, emotional well-being, social functioning, bodily pain, general health), there were no statistically significant difference between the two groups.

Kues et al. used SF-36, GIQLI, and Body Image Questionnaire (BIQ) delivered preoperatively, the first day after surgery and at outpatient follow-up at 2-, 6-, and 12-week intervals, to a total of 257 patients randomized between LC and SC [22] [LoE 2]. No significant differences between both operative techniques concerning health status were reported with the exception of perceived health change in SF-36 that was significantly different in favor of laparoscopic procedure at 2 and 6 weeks postoperatively, but not at 3 months follow-up. This difference in perceived health change was not reflected in an earlier return to work. Interestingly subgroups analysis showed significant differences immediately after surgery and in long-term follow-up in pain perception; physical, social, and mental functioning; and body image comparing minimal invasive procedures (both laparoscopic and small incision) and procedure converted to the classical OC.

In conclusion when LC is compared with SC, the perception of health immediately after surgery is slightly better for patients treated with laparoscopic procedure, but the gain in HRQoL is small and of very limited duration; moreover, it does not reflect in an earlier return to work (Table 9.4). Conversion of minimally invasive cholecystectomy in classical open procedure affects short-term and long-term QoL.

9.3.4 Impact of Iatrogenic BDI on QoL

The occurrence of a BDI has a significant impact on QoL. From the systematic review of the literature, 7 publications were found about this topic (1 meta-analysis including 831 patients from 6 retrospective case-control or case-series study) [23–29] [LoE 4]. Long-term results are conflicting (Table 9.5). In the first three publications, a detrimental effect of BDI in long-term follow-up has been reported in both mental and physical aspects [23–25] [LoE 4]. Boerma et al. studied 241 patients affected by bile duct injury in the course of LC, 70 % of whom were treated endoscopically or radiographically [23] [LE 4]. The follow-up ranged from about 3 years to 9 years. Authors demonstrated that scores on the 8 domains of the SF-36 of patients with BDI were significantly different from those of patients with uncomplicated LC and Dutch population norms.

Table 9.4 QoL after laparoscopic versus SC in 6 randomized controlled trials (1,597 patients)

		QoL results		
Author	Test	Questionnaire delivered	Short term	Long term
[a]Barkun et al. [LE 3] [6]	NHP GIQLI VAS	10 days, 1 month, 3 months	LC ≥ SC	LC = SC
McMahon et al. [LE 2] [7]	SF-36 HADS	1, 4, and 12 weeks	LC > SC	LC = SC
Squirrell et al. [LE 2] [19]	SF-36	3 week, 6 month	LC = SC	LC = SC
Nilsson et al. [LE 2] [20]	EuroQol-5D	1 week, 1 month, 1 year	LC > SC	LC = SC
Harju et al. [LE 2] [21]	SF-36	4 weeks	LC = SC	–
Keus et al. [LoE 2] [22]	SF-36 GIQLI BIQ	1 day, 2, 6, and 12 weeks	LC = SC	LC = SC

[a]Evidence Level was downgraded from 2 to 3 because the study population is small

Table 9.5 Impact of BDI on QoL in 831 patients enrolled in 5 case-control study and 1 case series

			QoL results
Author	Test	Follow-up (median—months)	Complicated (C) versus uncomplicated (UnC)
Boerma et al. [LE 4] [23]	SF-36	70	C < UnC
Moore et al. [LE 4] [24]	SF-36 KPSS PAIS	62	C < UnC
de Reuver et al. [LE 4] [25]	SF-36 GIQLI	66/132	C < UnC
Melton et al. [LE 4] [26]	City of Hope QoL	59	C ≤ UnC
Sarmiento et al. [LE 4] [27]	SF-36	100	C = UnC
Hogan et al. [LE 4] [28]	SF-36	152	C = UnC

Similarly Moore et al. in a study including 86 patients with bile duct injury during LC reported at an average of 5 years of follow-up lower scores on the Karnofsky Performance Scale and all SF-36 measures of HRQoL, when compared with patients who underwent uncomplicated LC [24] [LoE 4]. When the authors categorized patients into those with less than 5 years of follow-up and those with 5 years or more of follow-up, their findings were similar. While physical functioning in both groups remained relatively constant despite the length of follow-up, their mental functioning worsened with duration of follow-up. Less than one fourth of these patients reported filing lawsuits. There were no significant demographic or clinical differences between those who reported filing a lawsuit and those who did not. However, patients who did file a lawsuit reported significantly greater impairment in HRQoL. Despite long-term physical and psychosocial impairment, the majority of the patients with BDI were able to return to work. However, they

returned to work almost 3 months later on average than patients who underwent uncomplicated LC.

de Reuvers et al. reported in a cohort of 278 patients with BDI a score significantly worse than the healthy population norms in seven of the eight QoL domains [25] [LE 4]. The longitudinal assessment after another 5.5 years of follow-up did not show improvement in QoL. Nineteen percent of the patients ($n = 53$) filed a malpractice claim after BDI. These patients reported better QoL when the claim was resolved in their favor than when the claim was rejected.

On the opposite three other publications documented a detrimental effect of BDI in long-term follow-up only in mental, but not in physical, aspect [26–28].

Melton et al. examined QoL in 89 patients with BDI, all of whom underwent surgical repair [26]. They used the City of Hope Medical Center Quality of Life Survey, which comprises three domains: physical, psychological, and social. Authors reported that patients with BDI had physical and social QoL similar to that of patients undergoing uncomplicated LC, but greater impairment in psychological QoL. In addition, they found that legal activity was associated with worse outcomes. However, the QoL instrument used in that study was developed for and validated in cancer patients only.

Sarmiento et al. studied 59 consecutive patients undergoing surgical reconstruction of the biliary tract after the injury induced by LC (mean follow-up of 8.4 years) using SF-36 questionnaires [27] [LE 4]. All eight dimensions evaluated in the SF-36 questionnaire were similar for patients undergoing biliary reconstruction, their matched controls, and national norms.

Even in the paper reported by Hogan et al., the QoL of surviving patients following BDI compares favorably to that after uncomplicated LC [28] [LoE 4]. Authors compared 78 patients treated for BDI with an age- and sex-matched control cohort of 62 patients undergoing to uneventful LC. SF-36 was used to assess the QoL, with a median follow-up of 12 years. Such comparison has revealed that seven of eight examined variables were statistically similar to those of the control group (physical functioning, role physical, bodily pain, general health perceptions, vitality and social functioning, and mental health index). Mean role emotional scores were slightly worse in the BDI group. Subgroup analysis by method of intervention for BDI did not demonstrate significant differences.

A recent meta-analysis included all the six publications cited above [29] [LoE 4]. Because the HRQoL surveys differed among reports, BDI and uncomplicated LC groups' HRQoL scores were expressed as effect sizes (ES) in relation to a common, general population, standard. A negative ES indicated a reduced HRQoL, with a substantive reduction defined as an $ES \leq -0.50$. Weighted logistic regression tested the effects of BDI (versus LC) and follow-up time on whether physical and mental HRQoL were substantively reduced. The analytic database has comprised 90 ES computations representing 831 patients and 11 unique study groups (6 BDI and 5 LC). After controlling for follow-up time ($P \leq 0.001$), BDI patients were more likely to have reduced long-term mental [odds ratio (OR) = 38.42, 95 % confidence

interval (CI) = 19.14–77.10; $P < 0.001$] but not physical ($P = 0.993$) HRQoL compared with LC patients.

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