

Quality of Life in Bile Duct Injury: 1-, 5-, and 10-year Outcomes After Surgical Repair

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Abstract

Background Quality of life after bile duct injury is a relevant health issue besides physician-oriented outcomes. A prospective study was performed to explore short- and long-term outcomes after surgical repair.

Method We studied a cohort of patients with Strasberg E injuries who underwent Roux-en-Y jejunal anastomosis from 1990 to 2008. The Short Form Health Survey (SF-36) was selected as the appropriate quality of life assessment instrument. Two groups were comprised: Group I included patients with 10-year follow-up after surgery. Group II included patients operated during 2008 with preoperative 1- and 5-year questionnaires.

Results Group I patients ($N=41$) were operated from 1990 to 2003 and Group II ($N=44$) during 2008. There is a significant improvement in quality of life after the first year of repair in all domains. Readmissions (48 vs 25 %; $p<0.01$), colangitis (46 vs 14 %; $p<0.001$), and hepatojejunal redo (26 vs. 4 %; $p<0.0001$) were less frequent in Group II. No differences in quality of life summary scores were found between Group I and II.

Conclusions Quality of life improves significantly after the first year of surgical repair, reaching a plateau at 5 years. No correlation exists with physician-centered outcomes.

Keywords Biliary tract diseases · Quality of life · Laparoscopic cholecystectomy · Bile duct injury · Hepatojejunostomy

Introduction

Laparoscopic cholecystectomy is one of the most frequent surgeries performed in the world; more than 750,000 per year are done in the USA.¹ Despite a culture of safety in cholecystectomy is highly promoted among surgeons,² bile duct injury persists as an uncommon but serious complication occurring in 1 of every 200 cholecystectomies.³ A wide spectrum of scenarios can be found depending on the anatomic site of lesion as explained in the Strasberg classification, needing endoscopic and/or radiologic procedures for most of Strasberg

A to D and in severe cases, where a complete section of the main biliary duct is damaged (Strasberg E), a Roux-en-Y hepatojejunostomy.⁴

Quality of life (QOL) refers to the patient's self perception of well being. It considers not only functionality or relief of a particular symptom, but includes concepts of emotional status, social role, and mental health.⁵ Most surgical outcomes are physician-centered as morbidity, mortality, and length of stay; QOL constitutes a unique instrument to measure the impact of a specific intervention in the health-disease process suffered by the patient.

Currently, there are important advances in surgical outcomes after bile duct repair.^{6–8} Centralization of cases in high volume centers with surgeons committed and interested in the management of this complication shows improvement in early and long-term results.^{6–8}

Previous studies on QOL outcomes after bile duct injury are contradictory, probably as a result of underpowered designs and the inclusion of heterogeneous population.⁹ We focus on a homogeneous type of injury (Strasberg E) expecting to have less noise in the QOL results including patients with similar characteristics, particularly regarding

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the treatment required. Most of the previous studies have not addressed this and may be the reason of discordant results in the literature.

The aim of this work is to evaluate the impact in short and long-term QOL after surgical repair of post-cholecystectomy bile duct injuries with complete transection of the duct.

Material and Methods

After obtaining Institutional Review Board approval, 178 patients with Strasberg E bile duct injury were enrolled from a cohort of 312 patients treated at the Instituto Nacional de Ciencias Médicas y Nutrición “Salvador Zubirán” in México City from January 1990 to December 2008. All of them underwent a Roux-en-Y hepatojejunostomy performed by a single surgeon (M.A.M.). Two sample groups were considered to accrue patients within a range of 5 to 10 years of postoperative follow-up; Group I comprise cases operated from January 1990 to December 2003 and Group II cases treated from January to December 2008. In addition, the two different sample groups within the cohort represent different periods of bile duct injury repair in our center, where differences in technical issues and clinical outcomes have been found and published elsewhere.⁶

Group I was conformed of 41 out of 134 patients with 10 years of postoperative follow-up. Group II was conformed of 44 patients operated during 2008 with 5 years of follow-up.

Clinical and demographic data, as well as morbidity and postoperative outcomes, were recorded. Follow-up was done directly at clinic visits.

Other bile duct injuries (Strasberg A–D) resolved through endoscopy and/or interventional radiology were not included in the study.

Quality of Life Assessment

The Short Form Health Survey (SF-36) (QualityMetric, Lincoln RI) was selected as the appropriate QOL assessment instrument considering its general scope, validity, and the existence of SF-36 QOL norms in randomly selected not institutionalized Mexican adults.¹⁰ Eight health domains were assessed: physical function (PF), social function (SF), physical role (PR), physical pain (PP), mental health (MH), emotional role (ER), vitality (VT), and perception of general health (GH). Scores are standardized to a range of 0 (worst result) to 100 (best result). The eight domains are grouped into two summary scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS).

In Group I, a physician not directly related to the patient's care, administered questionnaires at clinic 10 years after surgical repair according to SF-36 (QualityMetric, Lincoln RI) Health Survey Manual & Interpretation Guide recommendations.¹¹

The same procedure was done in Group II at preoperative setting, 1 and 5 years of follow-up.

Since 2008, preoperative SF-36 questionnaires have been administered to bile duct injury (BDI) cases surgically treated. As a consequence, Group II has preoperative questionnaires available to make comparisons from each case, in order to assess the direct impact of surgical repair in QOL. On this regard, each patient represents his own control, as paired comparisons over time can be performed between preoperative and postoperative QOL scores from every single case.

Sample size needed to detect a minimum of 10 points difference between Group I and a fixed norm (SF-36 Mexican norms) is 27 patients. In Group II, at least 21 patients were required to detect a 10 points difference over time within one group. Estimates assume $\alpha=0.05$, two-tailed *t* test, and power 80 %.

Patient-centered outcomes are measurements of any aspect of patient's health status that come directly from the patient, also known as patient-reported outcomes.¹²

Physician-centered outcomes are clinician assessments on the evolution of a disease-related variable as specific symptoms, interventions, or complications (pain, surgery, cholangitis) that cannot capture the patient's self perception of health.¹³

Data Analysis

T-student or U-Mann Whitney statistics was used to describe continuous clinical and QOL variables, depending on their parametric or nonparametric distribution. A Levene test was done to assess equality of variances. χ^2 test was performed to describe differences between Group I and II regarding clinical and postoperative categorical variables.

T-student test to compare means of two independent groups (Group I vs. SF-36 (QualityMetric, Lincoln RI) Mexican Norms) was performed considering a significance level of 5 %.

A paired T-student test was performed to assess QOL change over time after surgical repair within the same sample of patients (Group II). We compared QOL preoperative scores vs. QOL postoperative scores 1 and 5 years after surgery.

Statistical analysis was done with IBM SPSS 20 package.

Results

Of the 178 patient cohort, 134 cases with 10 years of follow-up after surgical repair were initially eligible to survey. Group I was conformed of 41 out of 134 patients available to answer the QOL questionnaire; 82 (61 %) were lost at follow-up, 10 (8 %) died of non-biliary disease, and 1 (1 %) patient rejected to answer the questionnaire.

Table 1 Demographic and operative outcomes after bile duct injury repair

Variable	1990–2003 Group I	2008 Group II	<i>P</i>
Female (%)	34 (83)	33 (75)	0.3
Male	7 (17)	11 (25)	
Age (M, SD)	51 (14)	40 (14.9)	0.0001
Repaired before M.A.M. (%)	24 (58.5)	12 (28)	0.005
Interval time from injury to M.A.M. repair (months)	18 (27.6)	16 (25.6)	0.7
Comorbidity	11 (26.8)	18 (42)	0.14
Segment IV resection	24 (60)	38 (90)	0.001
Biliary-related reoperation	11 (26.8)	3 (7)	0.015
Readmission	20 (48.8)	11 (25)	0.023
Colangitis	19 (46.3)	6 (14)	0.001
Hepatojeuno reoperation	11 (26.8)	2 (4.5)	0.0001
Status			
Alive	41 (100)	25 (56.8)	0.0001
Dead	0	5 (11.4)	
Lost at follow-up	0	14 (31.8)	
QOL (M, SD)			
PCS	73 (16.7)	70.4 (17)	0.4
MCS	71 (15.5)	66.7 (18.7)	
Total	41	44	

M mean, *SD* standard deviation, *PCS* Physical Summary Score, *MCS* Mental Summary Score, *QOL* quality of life, *M.A.M.* Miguel Angel Mercado

Group II was conformed of 44 consecutive cases operated during 2008. At follow-up, four patients (9 %) missed clinic appointments at first year postoperative and no questionnaire was answered. The same happened with 14 (31 %) patients on fifth year of follow-up. Five patients (11 %) died before the 5-year time point. On average, Group II patients answered two

questionnaires, with a minimum of one and maximum of three.

Clinic and demographic characteristics are shown in Table 1. Operative outcomes improve in Group II with a significant decrease of reoperations, postoperative cholangitis, and hepatojeuno redo.

Clinical and operative variables were compared with cases lost at 5 years of follow-up; no differences were found.

Quality of Life

In Group II, we found a significant QOL improvement in every single domain of SF-36 (QualityMetric, Lincoln RI) at 1 and 5 years after surgical repair, comparing with preoperative scores. The smallest difference was 12 points in the mental health domain at 1 year, the largest being 60 points at 5 years in the physical role. Table 2

Quality of life at 10 years of follow-up showed a significant difference compared to SF-36 norms. Every domain score is below the expected normal value. The smallest difference is 16 points in physical function and the largest is 35 points in general health. Table 3

Figure 1 shows a comparison of QOL data between Group I and II. A significant improvement of QOL occurs after the first year of repair, with no changes among the 1-, 5-, and 10-year time points. Group I cases after 10 years of follow-up remain below the expected normal value of QOL.

We expected to find improvements in QOL scores between Group I and II, concordant with the better operative outcomes in the latter. However, when mental (71 vs. 66.7, *p*=0.4) and physical (73 vs. 70.4, *p*=0.4) summary scores were assessed, no significant differences were found.

Table 2 Positive differences in QOL score after surgery comparing to preoperative score

Quality of life domain	Preoperative vs. 1 year Mean difference (CI 95 %)	<i>p</i>	Preoperative vs. 5 year Mean difference (CI 95 %)	<i>p</i>
Physical function	32.4 (21–43)	0.0001	38 (24–52)	0.0001
Physical role	60 (45–75)	0.0001	60 (40–77)	0.0001
Body pain	50 (35–54)	0.0001	40 (24–55)	0.0001
General health	15.2 (7.3–23)	0.0001	23 (10–35)	0.001
Vitality	19 (10–27)	0.0001	22 (10–35)	0.001
Social function	35 (23–47)	0.0001	38 (4–53)	0.0001
Emotional role	44 (27–61)	0.0001	51 (30–74)	0.0001
Mental health	12 (4–20)	0.002	14 (5–24)	0.004
Total	40		25	

CI 95 % 95 % confidence interval

Table 3 Negative differences below expected S-36 Mexican norm score

Quality of life domain	10 years postoperative vs. Mexican norms Mean difference (CI 95 %)	<i>p</i>
Physical function	16 (10–22)	0.0001
Physical role	22 (10–32)	0.0001
Body pain	21 (13–30)	0.0001
General health	35 (30–40)	0.0001
Vitality	33 (28–39)	0.0001
Social function	25 (18–32)	0.0001
Emotional role	26 (14–38)	0.0001
Mental health	27 (21–33)	0.002
Total	41	

CI 95 % 95 % confidence interval

Discussion

Contradictory results in clinical studies may result from important differences in design, and sample selection. On this regard, QOL in bile duct injury is still a controversial topic. Gouma and collaborators reported a decrease in physical and mental scores after BDI. They included a heterogeneous population treated with surgery, endoscopy, or interventional radiology.^{14,15} No independent variables were found associated with a clinically relevant QOL decrease; this may be

explained because of an unstable binary logistic regression model. There is no report of the event/variable ratio neither an analysis of the internal calibration of it.¹⁵

A subgroup analysis with a longitudinal assessment was performed in 50 patients showing no differences in QOL comparing 5.5- and 11-year time points.¹⁵ This is concordant with our findings in Group II; we performed a longitudinal analysis with the same QOL instrument as Gouma did, comparing three time points: before surgical repair, 1 and 5 years after surgery. After a paired analysis, no differences in QOL were found comparing 1 and 5 years.

Our study is probably the first to perform a direct assessment of surgical repair in QOL considering different time points. No previous reports have compared preoperative vs. postoperative scores in the same set of patients using a paired analysis. As a result, each patient represents his own control after repair. Considering patients that underwent laparoscopic cholecystectomy (LC) as a control group, is equivalent to compare to normal population, as it is shown in Moore and Sarmiento studies.^{16,17} It is impossible and it would be unethical to have a control group of Strasberg E injured patients where no surgical treatment was offered.

In Group II, we found a significant improvement in every SF-36 (QualityMetric, Lincoln RI) domain after the first year of surgery. At 5-year time point, there is no difference in QOL scores, remaining significantly below the expected in normal population.

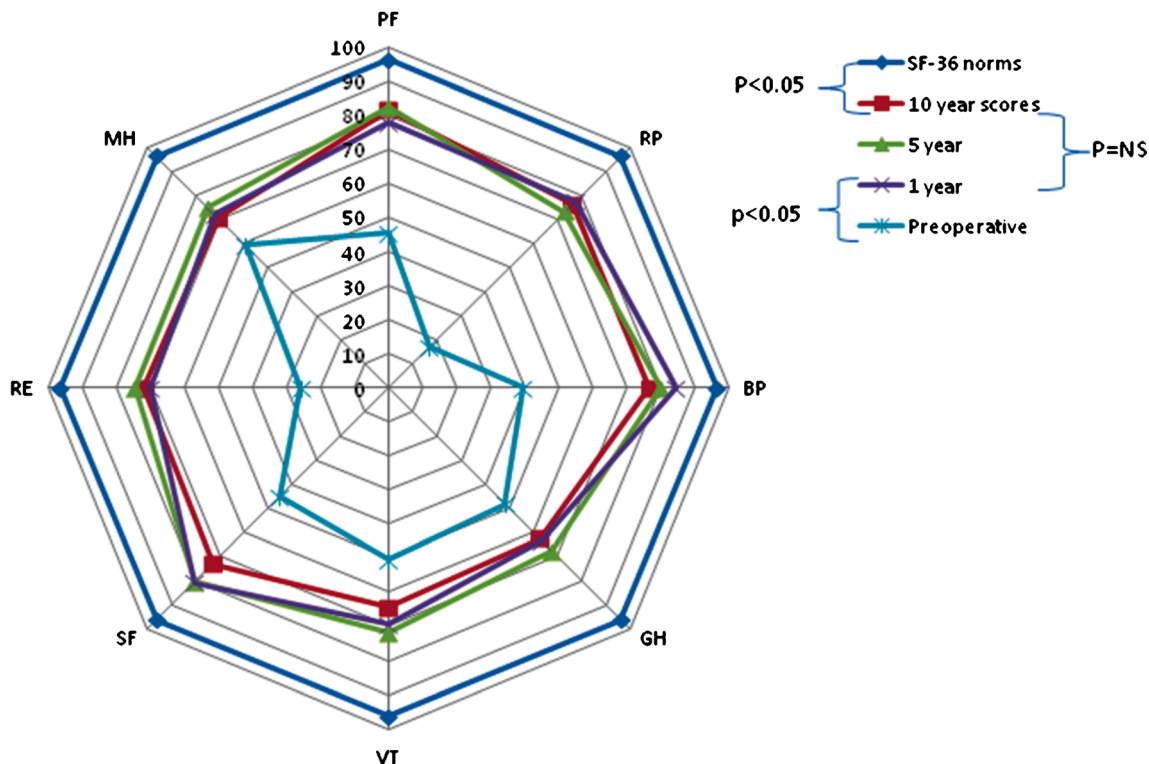


Fig. 1 Polar graph comparing SF-36 QOL score in different time points after surgical repair. PF physical function, SF social function, PR physical role, PP physical pain, MH mental health, ER emotional role, VT vitality, GH perception of general health, NS non-significant

In addition, we compared summary postoperative QOL scores between Group II and Group I and no differences in physical or mental scores were found between 5 and 10 years after surgery. Moore and colleagues as well did not find differences in SF-36 summary scores between less than 5 years of follow-up vs. more than 5 years after BDI.¹⁶

Gouma and colleagues' study is probably the largest series assessing QOL outcomes. However, when considering surgically treated injuries, only 103 (37 %) patients with a mean follow-up of 5.9 years were included. In the longitudinal subgroup analysis, only 16 patients were operated.¹⁵

Moore and colleagues studied 50 patients with BDI with a mean follow-up of 5 years; only 37 (74 %) were surgically treated.¹⁶ Their results are similar to Gouma and our study, with a decrease of SF-36 QOL scores in all domains when comparing to normal population.

Different results have been found by Sarmiento and Hogan. Both studies used SF-36 and compared to LC and normal population. No significant differences were found when comparing BDI. Despite they included a homogeneous population with an acceptable follow-up (8 and 12 years, respectively), QOL seems to be similar to non-BDI population.^{17,18} This may be explained by intrinsic differences of QOL expectations in every normal population studied as well as selection bias of the BDI cases surveyed.

Limitations in our study are noteworthy: selection bias is present as most of our cases represent those who continued care after surgery. It will not be adequate to generalize these results to the complete cohort, as 60 % of patients with expected 10 years of follow-up after surgery were not included in Group I because of drop out.

Some of the reasons for dropping out may respond to economic and geographic issues, as many patients come from far underserved areas of México. That been said, the group of patients that remained in follow-up represent the best scenario of care after bile duct injury repair. If we had included cases lost at follow-up, it is probable that we would have seen an even wider difference in QOL when comparing to normal population.

Despite imputation data analysis is an option to overcome this frequent flaw of QOL studies, we considered it unreliable as missing data is not a random event in this group of patients.

There is no correlation between improvement in operative outcomes and QOL scores. In our study, Group I and II represent different samples from the same cohort where improvement in technique and operative outcomes has taken place as a result of the transition to a high volume center of bile duct injury management.⁶ This supports the concept of discordance between physician-centered and patient-centered outcomes. Despite our efforts to improve surgical outcomes, patients' perception of well-being may differ from what we think as care providers, highlighting the importance of communication and fair expectations on surgical outcomes.

Conclusion

This study demonstrates the favorable impact on QOL after surgical repair of complex bile duct injuries.

In short and long-term follow-up, QOL achieves favorable scores but never reaches normal population expectations. Better surgical outcomes are no guarantee of QOL improvement.

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