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# Quality of Life Assessment Before and After Bile Duct Injury Repair Using the sf-36 Health Questionnaire

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### 1. Introduction

The advent of the laparoscopic approach in cholecystectomies has revolutionized the field of general surgery. The decrease in recovery time, shorter hospital stays, and the aesthetic benefits offered by this approach have made it the gold standard for the management of benign gallbladder pathologies [1-3]. Unfortunately, this has resulted in an increase of Bile Duct Injuries (BDI) [4]. Proportionally, the number of studies that aim to find a successful management of these patients, appropriate techniques and the right time to solve these events has also increased, as well taking into account their economic implications in the health system: they are often associated with high rates of litigation and civil lawsuits ranging from 250,000 dollars to 500,000 dollars [5]. However, few studies have investigated the effects of psychosocial and Health-Related Quality of Life (HRQL) as a result of BDI and their subsequent repair.

We ask ourselves: Are laboratory test results and the evaluation of symptoms by a MD more important than the HRQL evaluation?

In our study, we aim to analyzed HRQL in a consecutive series of patients with BDI before and after the definitive treatment performed by specialists in a high-volume center.

# 2. Objective

To analyze HRQL in a consecutive series of patients with BDI before and after the definitive treatment performed by specialists in a high-volume center.

#### 3. Materials and Methods

We performed a combined retrospective and prospective cohort study including patients diagnosed with BDI referred to our center between December 2015 and June 2019. Analyzed variables were sex, age, initial diagnosis, surgery performed, repair attempted prior to referral, number of procedures performed and time elapsed until final resolution.

Strasberg classification was used to stratify BDI [6]. Injuries involving the hepatic duct confluence, previous failures in repair attempts, association with vascular injuries and presence of portal hypertension or secondary biliary cirrhosis were classified as complex BDI [7].

The SF-36 (36-item Short Form health survey) health questionnaire was used as an instrument to assess HRQL [8], 9 items were evaluated with results ranging from 0 to 100 (Annex1). The survey was carried out either at hospital or by phone.

A first survey was completed retrospectively taking into account the patient's condition 2 weeks prior to definitive repair surgery. As from 2018, it was implemented prospectively. The second survey was carried out in our center not before at least 3 months after the definitive resolution of the injury.

Statistical analysis was performed using the IBM SPSS Statistics 25. Data were expressed as absolute values and percentages or as median values and ranges. The Chi2 test was used to compare categorical variables. For the evaluation of form SF-36 the Student t test was used. A univariate analysis was performed to associate variables by using the Mann-Whitney U test and Kruskal-Wallis with 95% confidence intervals were calculated. A p value < 0.05 was considered significant.

#### 4. Results

During the evaluated period, 48 patients with bile duct injuries were referred to our center. 72.9% (n = 35) of patients were female; the average age was 40.5 years (r 14-68).

The diagnoses that led to surgeries where BDI occurred can be

seen in Table 1. 81.3% of the injuries were incurred during a scheduled surgery. In most of them, it is unknown if intraoperative cholangiography was performed (56.3%), while it was performed in 27.1% of the cases. 35% of patients had undergone at least one previous attempt at repair at the center where the BDI occurred. The average number of procedures performed prior to referral was 2.29 (r 0-26). According to the Strasberg classification, more than 50% of patients had type E1 or E2 injuries (Table 2). 66.7% (32 patients) of the injuries were classified as complex - within these,

9 patients had a combination of biliary and vascular injuries; 4 patients, arterial injury; 2 patients, hepatic artery and portal vein injuries; 3 patients, portal vein injury. 87.5% of the cases (42 patients) were resolved in our hospital; 2 patients are awaiting definitive resolution (1 patient is under endoscopic treatment and 1 patient is on liver transplant waiting list), 1 patient was lost to follow-up and 3 died awaiting definitive treatment (2 patients, on transplant waiting list and 1 patient, due to complications of percutaneous treatment).

Table 1: Diagnoses that led to surgeries where BDI occurred

INITIAL DIAGNOSTIC	Frequency (%)
Asymptomatic Gallstones	21 (43,8)
Symptomatic Gallstones	8 (16,7)
Choledosian Syndrome	6 (12,5)
Cholescystitis	5 (10,4)
Acute Pancreatitis	2 (4,2)
Hepatic Tumor	2 (4,2)
Stab/gunshot Wound	2 (4,2)
Cholangitis	1 (2,1)
Mirizzi Syndrome	1 (2,1)

Table 2: Type BDI According to the Strasberg classification

Injury based on Strasberg Classification	Frequency (%)
C	2 (4,2)
D	2 (4,2)
E1	13 (27,1)
E2	12 (25)
E3	7 (14,6)
E4	8 (16,7)
E5	1 (2,1)
Not know	3 (6,3)

The definitive treatment consisted in biliodigestive anastomosis 78.5% (33 patients): Hepatic-jejuno, bi-hepatic, tri-hepatic or cholangio-jejuno anastomosis; liver transplant 7.1% (3 patients); endoscopic treatment 7.1% (3 patients); percutaneous treatment 2.4% (1 patients); combined percutaneous-endoscopic treatment 2.4% (1patient) and 2.4% (1 patient) only required laparoscopy and drainage.

Median time between the bile duct injury and its definitive resolution was 264 days with a range between 0 (intraoperative resolution) and 8055 days (secondary biliary cirrhosis). Overall mortality was 14.6% (7), not showing correlation with the complexity of

the BDI (p = 0.5) but associated with vascular injury (p = 0.02) and with the type of implemented treatment (p = 0.017).

The first quality of life assessment survey was completed by 24 patients; 22 of them also answered the second questionnaire while 2 patients were less than three months away from their postoperative period (1 patient underwent a complex biliodigestive bypass surgery and 1 patient, a liver transplant from a cadaveric donor), which excludes them from the second survey.

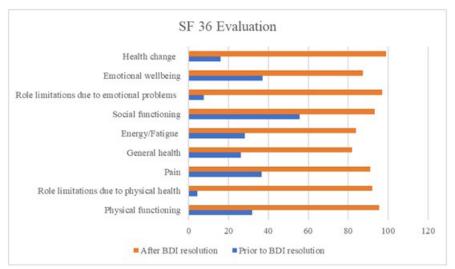
The 24 excluded patients correspond mostly to loss of follow-up (15 patients), death (7 patients) and pending resolution (2 patients). The results of the first and second surveys can be seen in table 3.

Table 3: Results of the first and second surveys

SF-36				
	Prior to BDI resolution	After BDI resolution		
	Average % (IC 95%)		р	
Physical functioning	31,8 (19-44)	95,5 (93,4-97,5)	<0,001	
Role limitations due to physical health	4,5 (-4,9-14)	92 (83,4-100)	<0,001	
Pain	36,6 (20,6-52,6)	91,1 (83,7-98,5)	<0,001	
General health	26,1 (16,7-35,6)	81,8 (73,7-90)	<0,001	
Energy/Fatigue	28,2 (18,7-37,7)	83,9 (74,1-93,6)	<0,001	
Social functioning	55,7 (39,8-71,6)	93,2 (85,4-101)	<0,001	
Role limitations due to emotional problems	7,6 (-3,5-18,7)	97 (90,7-103,2)	<0,001	
Emotional wellbeing	37 (26,2-47,8)	87,3 (79,7-94,9)	<0,001	
Health change	15,9 (5,3-26,5)	98,9 (96,5-101,2)	<0,001	

In all cases physical functioning (self-care, walking, climbing stairs, bowing, lifting weights and making moderate and strenuous efforts), role limitations due to physical health (degree to which health interferes with work and daily activities), pain and general health (current and future prospects), energy/fatigue (energy versus fatigue), social functioning (degree to which physical or emo-

tional health problems interfere with social life), role limitations due to emotional problems (degree to which emotional problems interfere with work or daily life), emotional wellbeing (depression, anxiety, behavior and emotional self-control) and health change (assessment of current health condition compared to that of one year before) showed statistically significant differences (p <0.001) (Graph 1).



Graph 1: Graphic show differences between prior and after BDI resolution

It was observed that the presence of a complex injury affected emotional wellbeing in the univariate analysis (p = 0.019). Physical functioning and social functioning prior to repair were related to the type of injury according to Strasberg (p = 0.001 and p = 0.032). BDI associated with vascular injuries were poorly rated as regards physical functioning (p = 0.019), energy/fatigue (p = 0.033), emotional wellbeing (p = 0.005) and pain (p = 0.026) prior to repair.

It is important to note that after having examined separately all questions included in the univariate analysis of the questionnaire, we observed that in the first survey 58% of patients referred to their HRQL as "bad", that is to say, their own perception of their health condition was in correlation with the lowest score in the questionnaire; 23% of patients referred to it as "poor" and the remaining 19% as "good", having the questionnaire been completed by all patients included in the survey. Therefore, at this point of his/her course of illness, no patient referred to his health as "very good" or "excellent" (the two highest scores in the questionnaire). In the second survey, however, when we evaluated the same group of patients no patient referred to his/her quality of life as "bad" after definitive resolution. Only 9% (n = 2) of them referred to it as "poor" (one of them as a result of postoperative depression and the other one due to a groin hernia not resolved in our center, which is a high complexity hospital); 9% of patients referred to their health as "good", and the remaining 82%, referred to it as "very Good" or "excellent."

#### 5. Discussion

The SF-36 questionnaire is a widely recognized and validated instrument to assess the quality of life after BDI [9-12]. At present, it is the most used questionnaire worldwide; it has been translated into more than 20 languages and is considered as the standard tool of assessment [13]. Augustovski et al. [14] demonstrated that the Argentine-Spanish version of the SF-36 is a valid and reliable tool for the investigation of results in our country.

Currently, numerous studies that focus on the quality of life of patients who suffered a BDI are not available in the literature, let alone those that compare stages before and after injury repair.

Landman et al. [15] published a meta-analysis concluding that patients who experience bile duct injuries report they are detrimentally affected in their emotional, but not physical, quality of life when compared to the population at large, and illustrated the importance of addressing both the results reported by patients and the technical results as well as patients HRQL in the immediate postoperative period and beyond.

Pawlik et al. [16] report their experience on 259 patients with BDI, showing a 24% effectiveness in their survey. HRQL was evaluated before and after BDI repair. At the time of BDI, mental health seemed to be the most affected, with almost half of all patients reporting a depressed mood (49.2%) or lack of energy (40.0%) "most of the time" or "at all times" before final repair. These symptoms improved significantly after repair, since only 18.3% reported having a depressed mood and 18% lack of energy "most of

the time" or "at all times". Interestingly, limitations in physical activity and overall health condition remained unchanged before and after surgical repair.

In our experience, after having evaluated the differences between the two surveys, we observed that the most important changes took place in the field of emotional wellbeing and physical functioning, that is, there was a marked improvement in the degree to which physical and emotional health affected daily activities and work; this difference was also very clear when assessing the present health condition compared to that of the previous year. The aspect that showed less, though significant change had to do with the social performance of patients. 81.8% of patients answered they had felt sad or discouraged "many times" or "always" prior to the resolution of the injuries, while 86.4% reported a lack of energy. These parameters varied dramatically after the definitive treatment: only 4.5% of patients reported feeling depressed while all patients answered their energy had improved and none reported low energy levels.

Rystedt et al. [17] in a study on a cohort of 168 patients with iatrogenic bile duct injury, with a 64% effectiveness in their survey, conclude that the quality of life after bile duct injury is comparable to uneventful cholecystectomies, this being so despite an unusually high 92% of intraoperative diagnoses of the injuries and the fact that intraoperative repair attempts were made in 90% of patients. The subgroup with postoperative and late diagnoses reported a deterioration in their HRQL regarding their physical performance.

In our study on a cohort of 48 patients and a response rate of 46%, equivalent to or greater than in other published studies, we have observed that prior to definitive repair, patients' health condition appeared to be dramatically affected in all the fields included in the SF 36 questionnaire (table 3). This may well be due to the fact that most of the patients underwent late repairs either because of a late referral to our center or because of the time required for an adequate sepsis control, the improvement of patients' clinical health condition, and the achievement of optimal control of local infection to perform the definitive repair.

Martinez-Lopez et al. [18] in a study on a cohort of 63 patients with BDI, showed that a delayed referral was associated with a higher incidence of postoperative complications, requiring more invasive procedures and a longer recovery.

It has also been observed that 30% of patients referred to our center had already undergone unsuccessfully some attempt at repair through different procedures (percutaneous drainage, ERCP, laparotomy and drainage) performed by the initial surgeon prior to referral. Stewart and Way [19] reported that only 13% of repairs made by the initial surgeon with no experience in HPB surgery were successful. Other studies have shown similar results. Therefore, definitive treatment by an HPB surgeon is advisable [20-22]. Dageforde et al [23] report significantly higher costs associated

with repair by non-specialist surgeons as a result of little success and high complication rates (approximately 80% as informed in current reports).

#### 6. Conclusion

The definitive resolution of patients in a high-volume center specialized in hepatobiliopancreatic surgery showed an important improvement in the quality of life of patients. Although our initial experience has been carried out on a small population, this is the first publication that includes a study on HRQL in patients with BDI in our country.

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