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ARTICLE *in* INTERNATIONAL JOURNAL OF SURGERY (LONDON, ENGLAND) · MAY 2015

Impact Factor: 1.53 · DOI: 10.1016/j.ijss.2015.05.004 · Source: PubMed

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## Original research

# Long-term follow-up of 120 patients after hepaticojejunostomy for treatment of post-cholecystectomy bile duct injuries: A retrospective cohort study



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## HIGHLIGHTS

- Fourteen (11.6%) patients had anastomotic stricture manifested at median interval 63 months, range (2–204 months).
- Seventeen (14.2%) patients developed recurrent episodes of cholangitis at median interval 48 months.
- As regard quality of life assessment, the physical component was more affected than the mental component.
- Post-ERCP pancreatitis, number of anastomosis, operative time, post-operative early complications, and post-operative bile leak were independent risk factors for poor outcome.

## ARTICLE INFO

## Article history:

Received 15 March 2015  
 Received in revised form  
 17 March 2015  
 Accepted 4 May 2015  
 Available online 9 May 2015

## Keywords:

Bile duct injury  
 Hepaticojejunostomy  
 Anastomotic stricture

## ABSTRACT

**Background:** Long-term follow-up is essential for assessment of success of the surgical repair of post-cholecystectomy bile duct injuries (BDI). Factors affecting the long-term outcome and satisfactory length of follow-up have been little reported in the literature. The aim of this study is long-term evaluation of hepaticojejunostomy regarding clinical, radiological, laboratory and quality of life assessment. **Method:** Between January 1992 to December 2007, 120 patients with postcholecystectomy bile duct injury surgically treated by hepaticojejunostomy Roux-en-Y were followed up for 20 years in Mansoura Gastro-enterology Center. Long-term outcomes and quality of life (QOL) were evaluated for all patients. Univariate and multivariate analyses were done for detection of factors affecting long-term outcome. **Results:** The median follow up period was 149 months, range (70–246 months). Successful long-term outcome was detected in 106 (88.3%) patients. Long-term complications were detected in 35 (29%) patients. Fourteen (11.6%) patients developed anastomotic stricture within different follow up intervals up to 17 years, of which. Seventeen (14.2%) patients developed recurrent episodes of cholangitis at median interval 48 months, range (2–156 months). Post-ERCP pancreatitis, number of anastomosis, operative time, post-operative early complications, and post-operative bile leak were predictors for poor outcome. Physical component was much more affected than mental component in QOL. **Conclusion:** Management of BDI in specialized centers is highly recommended. Longer time for follow-up of the patients of surgical repair of bile duct injury up to 20 years should be adopted to ensure successful outcome. Quality of life assessment is essential component of long-term follow-up.

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## 1. Introduction

The incidence of bile duct injuries (BDI) following laparoscopic cholecystectomy is much higher than that of open cholecystectomy (0.4%–0.6% and 0.1%–0.2% respectively) [1,2]. BDI has been supposed to be the most serious complication during cholecystectomy with possible reduced quality of life with high rates of subsequent

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litigation [3]. Unfortunately, BDI affect younger population leading to marked decrease in their productivity and as well as considerable financial problem [4]. The goal of surgical repair of the BDI is to restore the continuity of the injured bile duct. Hepaticojejunostomy (HJ) Roux-en-Y is the preferred method of surgical treatment of most of major BDI [5]. Many studies have reported the short-term outcome following HJ with complications' rate reaching up to 20–40% [6]. There has been a considerable decline in the operative mortality with many large series reporting zero perioperative deaths [7]. HJ may result in long-term complications such as anastomotic stricture formation, recurrent cholangitis and secondary biliary cirrhosis (SBC) [8].

The main concern of long-term follow up is detection of anastomotic stricture which is the most important complication with reported incidences reaching 2%–25% [9] resulting in marked affection of quality of life [10,11] and considerable mortality rates in these groups of patients [12]. An absence of biliary anastomotic stricture is considered the target of successful surgical management [13]. Anastomotic stricture occurred at different intervals after the reconstructive procedure reaching up to 7 years in 90% of this category of patients [14]. Previous studies reported many factors affecting the long-term outcome after surgical repair of BDI [15,16]. Few studies have reported long-term follow up after 10 years and factors affecting it. The aim of this retrospective study is long-term evaluation of HJ regarding clinical, radiological, laboratory for detection of anastomotic stricture and quality of life assessment.

## 2. Material and methods

Between January 1992 to December 2007, 120 patients underwent HJ Roux-en-Y for treatment of postcholecystectomy bile duct stricture in Gastro-enterology surgical center (GEC), Mansoura University. Patients with cholecystectomy-related BDI and didn't require surgical repair and those who lost follow up were not included in the study. Patients with post-cholecystectomy BDI who underwent HJ Roux-en-Y after December 2007 till now were excluded. Data for this study was retrieved from medical records of the patients included in the medical archive of the GEC. This study was approved by local ethical committee of Mansoura Gastro-enterology surgical center (GEC) at March, 2013. All patients underwent written consent for surgery. The STROBE statement checklist of items of cohort observational studies were fulfilled in this article [17].

### 2.1. Data collected

The patients' demographics, mode of presentation, type of offending cholecystectomy, type of referred hospitals and time of recognition of injury and referral to our tertiary center were recorded. Preoperative haematological and biochemical parameters, diagnostic evaluation including radiological and endoscopic investigations, classification of bile duct injury and any pre-reconstruction interventions before and after referral were reviewed. Details of surgical management, early post-operative outcome including short-term complications were defined as those occurring within 30 days of the repair surgery or during the same hospitalization and their management were extracted. Long-term follow up was done for all patients on the grounds of medical review, physical examination, and additional laboratory investigations in the form of complete blood picture and liver function test and abdominal ultrasonography (US). When anastomotic stricture was suspected, magnetic resonance cholangiopancreatography (MRCP) was performed for confirmation of diagnosis.

### 2.2. Assessments

The primary outcome was anastomotic stricture. The outcome was classified into two groups as regard presence or absence of anastomotic stricture (G1: excellent, G2: poor outcome). The secondary outcomes were operative time needed for reconstruction, early and late postoperative morbidities, quality of life assessment using SF-8 health survey.

### 2.3. Statistical analysis

All statistical analyses were performed using IBM SPSS v.19 software. P value of less than 0.05 was considered statistically significant. Numerical data were presented as means and standard deviations. Student's *t* test, Chi square test, Fischer's exact test or Mann–Whitney tests were used as appropriate. Multivariate analysis was performed using stepwise logistic regression test.

## 3. Results

### 3.1. Patient demographics and presentation

Between January 1992 and December 2007, 120 referred patients with post-cholecystectomy major bile duct injuries underwent HJ Roux-en-Y. Of the 120 patients, 90 (75%) were females and 30 (25%) were males with median age 39.5 years, (range, 20–75 years). Presentation of the patients after injury were shown in Table 1. Three BDIs were recognized during cholecystectomy, 75 (62.5%) were early ( $\leq 2$  weeks), 19 (15.8%) were intermediate (2–6 weeks) and 23 (19.2%) were late ( $\geq 6$  weeks) after operation. The median time of recognition was 0.17 month, range (0–158.17 m) and that of referral was 1.5 months, range (0–158.17 m). Seven (4.2%) patients were referred within 10 days after offending cholecystectomy, 109 (66.3%) in the period between 10 days and 3 months and 49 (29.5%) late after 3 months. The median interval for repair was 2.13 months, range (0.03–121.9).

We classified this interval into early (less than 3 days) in 1 (0.8%) patient, intermediate (3 days–6 weeks) in 45 (37.5%) patients, and late (more than 6 weeks) in 74 (61.7%) patients. Preoperative laboratory and radiological investigations and pre-reconstruction interventions were shown in Table 2.

**Table 1**  
Patient demographics, presentation and type and place of cholecystectomy.

	Number	Percent (%)
1- Age (median, range)	39.5 years (20–75)	
2- Sex:	30	25%
a- Male	90	75%
b- Female		
3- Presentation:	88	73.3%
a- Jaundice	33	27.5%
b- Pain	29	24.2%
c- EBF	25	20.8%
d- Cholangitis		
4- Type of cholecystectomy	109	90.8%
a- Open	7	5.8%
b- Laparoscopic	4	3.3%
c- Converted to open		
5- Place of cholecystectomy	75	62.5%
a- Private practice	36	30%
b- 1ry general hospitals	9	7.5%
c- University hospitals		

**Table 2**  
Preoperative investigations and interventions.

	Number	Percent (%)
Preoperative investigations		
1- Preoperative lab <sup>a</sup>		
a- Bilirubin (mg/dl)	15.36 ± 12.48	
b Albumin (gm/dl)	3.85 ± 0.5	
c- ALP (KAU)	33.77 ± 28.57	
2- Abdominal US		
Collection	20	16.7%
3- Level of injury <sup>a</sup>		
a- E1	22	18.3%
b- E2	76	63.3%
c- E3	17	14.2%
d- E4	5	4.2%
Prereconstruction interventions		
1- Radiological		
a- PTD	7	5.8%
b- USTD	3	2.5%
c- Both	3	2.5%
2- ERCP		
a- Failed	59	49.2%
b- BD ± stent	11	9.2%
c- Post-ERCP pancreatitis	9	7.5%
3- Surgical		
a- Peritoneal toilet & drainage	10	8.3%
b- CBD exploration over T-tube	5	4.2%

<sup>a</sup> Preoperative laboratory investigations are expressed as mean ± SD, ALP: alkaline phosphatase. Level of injury according to Strasberg classification. PTD: percutaneous transhepatic drainage. USTD: US guided tube drainage. ERCP: endoscopic retrograde cholangiopancreatography. BD: balloon dilatation.

### 3.2. Operative data

Data of operative findings and technique were shown in details in Table 3. The median hospital stay was 5 days, range (4–22 days).

### 3.3. Long-term follow up

One hundred and twenty patients were followed up within the

median period of 149 months, range (70–246 months). As shown in Table 4, long-term complications were detected in 35 (29%) patients. Fourteen (11.6%) patients had anastomotic stricture manifested at median interval 63 months, range (2–204 months), of which, 2 (1.6%) patients were asymptomatic and had abnormal liver function tests with radiological evidence of anastomotic stricture in MRCP. 21.4% (3 patients) of strictures developed at 1 year, 43% (6 patients) within 5 years from surgical repair, 78.5% (11

**Table 3**  
Operative details.

	Number	Percent (%)
1- Operative findings:		
a- Cirrhotic liver	21	(17.5%)
b- Internal choledochoduodenal fistula	9	(7.5%)
c- Intra-abdominal biloma	20	(16.7%)
d- RHA injury	4	(3.3%)
2- Operative technique		
1- No. of anastomosis		
a- Single	113	94.2%
b- Ductoplasty	2	1.7%
c- 2 duct anastomosis	5	4.1%
2- Size of stoma (mm)		
Mean ± SD	4.4 ± 4.6	
3- Technique		
a- Hepp-Couinaud	37	30.8%
b- Hepaticojejunostomy		
1- Side-to-side	18	15%
2- End-to-side	65	54.2%
4- Suturing technique		
a- Interrupted	71	59.2%
b- Continuous	15	12.5%
c- Combined	34	28.3%
5- Stent		
a- Single	3	2.5%
b- Double	2	1.7%
c- No stent	115	95.8%
6- Hepatotomy		
7- Operative time (min)	180	1.7%
Median, range	(90–360)	
8- Operative complication (vascular)		
	3	2.5%

RHA: right hepatic artery injury.

**Table 4**  
Early and late complications, quality of life assessment and mortality.

	Number	Percent (%)
Early complications	43	35.8%
Intra-abdominal collection	31	25.8%
Bile leak	23	19.2%
Wound infection	7	5.8%
Internal haemorrhage	2	1.7%
Persistent hyperbilirubinemia	2	1.7%
Late complications	35	29%
1- Anastomotic stricture	14	11.6%
2- Recurrent cholangitis	17	14.2%
3- SBC	8	6.7%
4- Incisional hernia	4	3.3%
5- DU	3	2.5%
6- Intrahepatic stones	3	2.5%
Quality of life assessment (mean $\pm$ SD)		
1- Physical component summary (PCS)	40.98 $\pm$ 8.88	
2- Mental component summary (MCS)	48.36 $\pm$ 7.26	
Late mortality	10	0.083%
1- Causes related to surgery*	1	0.008%
2- Causes not related to surgery	9	0.075%

\*Prolonged hyperbilirubinemia which was defined as persistent or increase of serum bilirubin above its preoperative level for one week postoperatively then decrease to the normal level.

\*SBC: secondary biliary cirrhosis, DU: duodenal ulcer.

\*One patients died at 10 years after surgical reconstruction due to septicemia & septic shock as a result of anastomotic stricture.

patients) within 10 years. Three patients with recurrent stricture were diagnosed after 10 years up to 17 years from surgical repair. Seventeen (14.2%) patients developed recurrent episodes of cholangitis at median interval 48 months, range (2–156 months), and 5 (4.2%) patients of them had no any documented biliary stricture.

As regard treatment of anastomotic stricture, 4 (3.3%) patients underwent refashioning of the HJ after 4–72 months interval, 2 (1.7%) patients underwent percutaneous transhepatic drainage and one of them underwent PT dilatation, the remaining 8 (6.7%) patients underwent conservative treatment due to unfit patients for surgery, markedly cirrhotic liver and ascites. All patients (5–4.2%) with recurrent cholangitis without evidence of biliary stricture were treated conservatively.

As regard quality of life assessment, the total mean score of the physical component summary was higher (more affected) than the total mean score of the mental component summary as shown in Table 4. The physical component summary scale was more affected in complicated HJ group than the non-complicated HJ group (complicated vs non-complicated, 35.54 vs 42.15;  $P = 0.01$ ), and mental component summary scale was similar between 2 groups and there was no significant difference (complicated vs non-complicated, 46.65 vs 48.49;  $P = 0.29$ ) during long-term follow up. The long-term outcome according to Terblanche clinical grading system was excellent (grade I) in 75 (62.5%) patients, good (grade II) in 31 (25.8%) patients, fair (grade III) in 9 (7.5%) patients and poor (grade IV) in 5 (4.2%) patients.

On performing univariate analysis, the following factors were found to be significantly affecting and associated with anastomotic stricture: post-ERCP pancreatitis ( $P = 0.035$ ), preoperative serum alkaline phosphatase level ( $P = 0.045$ ), previous attempts of repair ( $P = 0.015$ ), level of injury according to Strasberg-Bismuth classification ( $P = 0.024$ ), number of anastomosis ( $P = 0.028$ ), operative time ( $P = 0.016$ ), post-operative early complications ( $P = 0.018$ ), post-operative bile leak ( $P = 0.023$ ), interval from injury to referral ( $P = 0.011$ ), and referral after 3 months ( $P = 0.025$ ). On multivariate analysis, we found that post-ERCP pancreatitis ( $P = 0.018$ ), number of anastomosis ( $P = 0.028$ ), operative time ( $P = 0.007$ ), post-operative early complications ( $P = 0.027$ ), and post-operative

bile leak ( $P = 0.003$ ) were independent risk factors for poor outcome.

#### 4. Discussion

Bile duct injuries (BDI) are the most catastrophic complications of cholecystectomy [18]. Despite advances in technology, BDI is still a considerable challenge for any surgeon [19]. The definitive management of BDI especially in loss of bile duct continuity or biliary stricture is bilio-enteric anastomosis [20]. The Hepaticojejunostomy for repairing post-cholecystectomy bile duct stricture is the most important determinant of post-operative complications and offers the best possible long-term results [21].

Laparoscopic cholecystectomy is the standard procedure for treatment of gallbladder disease [22]. Interestingly, the majority of BDIs treated in our center were following open cholecystectomies, reflecting the fact that open cholecystectomy was performed far more commonly in the general and private hospitals (86.6% after OC vs 6.4% BDIs after LC) which had low facilities for laparoscopic surgeries in our country in the period of the study. In review of literature, long-term complications were detected in 41% of patients [23], while in our study, the rate was 29%. Many authors in referral hepatobiliary centers reported the rate of biliary strictures following reconstructions was 10–50% of patients [24,25]. Two-thirds (65%) of recurrent biliary strictures develop within 2–3 years after the reconstruction, 80% within 5 years, and 90% within 7 years. Recurrent strictures 10 years after the surgical procedure are also described in the literature [26]. In the present study, 43% of strictures developed within 5 years from surgical repair, 78.5% within 10 years. Three patients with recurrent stricture were diagnosed after 10 years up to 17 years from surgical repair. In our series, the rate of recurrent cholangitis was 14.2% in 7 patients while in Lubikowski et al study [27], it was detected in one patient (5%) and in Goykhman et al study [28], it was 27.6% detected in 8 patients.

Many previous studies in the literature recommended satisfactory length of follow-up in order to assess long-term results of the repair procedure, is 2–5 years [14] and few authors recommend 10 or 20 years of observation [29]. In our study, we found that even within 20 years of follow-up from surgical procedures, there was still potential risk for development of biliary restructure. In our series, the long-term outcome according to Terblanche clinical grading system was excellent (grade I & II) in 106 (88.6%) patients, and poor (grade III & IV) in 14 (11.4%) patients. In review literature, Bansal et al study [15] showed that the outcome as following; excellent (87%), good (7.3%), fair (3.6%) and poor (2.1%) at median follow up of 54 months, range (6–83 months) and these results were comparable to that of Sikora et al study [30].

In the present series, the quality of life assessment of the patients during long-term follow up showed that the physical health was affected more than the mental health of the patients (40.98  $\pm$  8.88 vs 48.36  $\pm$  7.26). The physical component summary scale was more affected in complicated HJ group than the non-complicated HJ group (complicated vs non-complicated, 35.54 vs 42.15;  $P = 0.01$ ). In review of literature, many studies found that BDI patients had significantly lower physical and mental component scores compared with those BDI patients who did not pursue litigation [31,32], while in contrast to other studies which Sarmiento et al [33] and Hogan et al [34] reported no effect of BDI on either physical or mental component.

As regard the factors affecting the long-term outcome in the present series, longer delay of referral (>3 months) from index surgery was associated with poor outcome ( $P = 0.02$ ) as detected in 8 of 14 patients who developed anastomotic stricture. It is most

probably due to earlier control of sepsis and earlier drainage of intra-abdominal collection and better care at a tertiary care center. The results were consistent with that reported in Bansal et al study [15]. In our study, 2 of 5 patients with previous attempts of repair developed anastomotic stricture after definitive surgical repair in our center ( $P = 0.044$ ). We believe that the expertise of hepatobiliary surgeon is important to ensure optimal results following repair of BDI as reported by other several authors [35,36]. As regard the level of injury, we found that the majority of the patients (12 of 14) developed anastomotic stricture had lower level of injuries (E1/E2). Only 2 patients had higher level of injury (E4), while many studies in the literature [15,37] showed that poor outcome were associated higher-level injury (E3/E4). The number of anastomosis significantly affected the outcome ( $P = 0.028$ ) in our study while it had no effect in other studies [38].

The early post-operative complications ( $P = 0.018$ ) including bile leak ( $P = 0.017$ ) and intra-abdominal collections ( $P = 0.028$ ) had significant effect on long-term outcome. We observed that 5 of 14 patients (35.7%) with poor outcome had postoperative bile leakage and 6 of 14 patients (42.9%) had intra-abdominal collections. Our explanation that bile leakage and intra-abdominal collection induce peri-anastomotic inflammation resulting in fibrosis with stricture formation. Other studies showed that bile leakage wasn't statistically significant [39]. In the present series, post-ERCP pancreatitis was associated with poor outcome. Our explanation that ERCP trials may induce acute inflammatory changes leads to fibrosis in the bile duct which makes the surgical repair difficult and increases the incidence of biliary restriction.

The incidence of vascular injuries in our patients was 3.3% and we found that they didn't affect long-term outcome ( $P = 0.460$ ) as no patients with anastomotic stricture in long-term follow up had associated vascular injury as resulted in other studies [27]. Higher incidence of associated with vascular injuries was reported in Schmidt et al study [37]. We proposed that there was association between vascular injury and timing of repair and their effect on the long-term outcome as most of patients with RHA injury underwent late surgical repair. On the contrary, we believe that the incidence of vascular injury in our study was underestimated due to no routine preoperative angiography was done for patients for diagnosis.

Sources of bias in this study were selection of the date of surgical repair, type of biliary drainage whether by ERCP, radiological or surgical drainage, detection of associated vascular injury, technique of anastomosis, diameter of stoma, and management of anastomotic stricture and need further studies in the future. Being a retrospective study was the major limitation of this study. The study results can be generalized due to considerable large number of patients included in the study followed up for relatively longer time (more than 5 years up to 20 years), but with caution due to its limitations and bias.

## 5. Conclusions

Our results showed that any attempts of repair of BDI by inexperienced surgeons should be avoided and early referral of patients with BDI to tertiary referral centers for early better management of BDI is highly recommended. Avoidance of ERCP for biliary stricture before reconstruction for its potential complications. Standardized surgical technique of hepaticojejunostomy is essential for decrease of early postoperative complications and subsequently better long-term results. Longer time for follow of the patients of surgical repair of bile duct injury up to 20 years should be adopted to ensure successful outcome. Quality of life assessment is essential component of long-term follow-up.

## Conflicts of interest

None.

## Acknowledgment

Special thanks and appreciation to all professors and assistant professors in Mansoura Gastro-enterology Surgical Center for their general support and providing technical help.

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