

Predictors of satisfactory outcome following repair of postcholecystectomy bile duct injury

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Background

We aim to report the short-term and long-term outcome of surgical repair following Roux-en-Y hepaticojejunostomy for postcholecystectomy bile duct injury (BDI) in a tertiary hepatobiliary center in Upper Egypt (Assiut University).

Patients and methods

A retrospective study was conducted on all patients diagnosed with postcholecystectomy BDI during the period 2014–2018 at Al-Rajhi Liver Institute, Assiut University, who had undergone surgical repair of BDI. Patients were grouped according to the time interval between previous surgery and surgical repair into two groups: group 1: time interval less than or equal to 6 weeks and group 2: time interval more than 6 weeks.

Results

Of 43 patients enrolled, 18 were in group 1 and 25 in group 2. The overall incidence of stricture was 14% (27.9% in group 1 and 4% in group 2), which is statistically significant ($P=0.026$). Other factors that have a significant association with incidence of stricture included bilirubin level. On multivariate analysis, none of these factors had a significant effect on the development of biliary stricture.

Conclusion

We believe that timing of repair of BDI following cholecystectomy has a significant effect on the outcome of repair. Moreover, best results in biliary reconstruction can be achieved in a specialized hepatobiliary center.

Keywords:

bile duct injury, biliary stricture, Roux-en-Y hepaticojejunostomy

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Introduction

Bile duct injury (BDI) is a relatively uncommon but catastrophic complication of cholecystectomy. It can lead to devastating consequences in terms of morbidity, mortality health care costs, and malpractice litigation [1].

BDI can be attributed to many risk factors, including bile duct anomalies, lack of surgeon's experience, significant inflammation, dense adhesions, and bleeding obscuring the field of vision [2].

BDI is best managed by a multidisciplinary team in a specialized tertiary hepatobiliary center. Despite the advances in endoscopic and percutaneous techniques in recent years, these procedures are limited to a subset of patients with BDI, where biliary-enteric continuity is maintained or restored by a previous repair [3,4]. Surgery remains the cornerstone for the management of major BDI. Different techniques are described in the literature for major duct injury, including duct-to-duct anastomosis, choledochoduodenostomy, hepaticoduodenostomy, and Roux-en-Y hepaticojejunostomy (RYHJ);

however RYHJ is associated with more favorable long-term outcomes [5–9]. Predictors of satisfactory outcome following RYHJ are still a matter of debate.

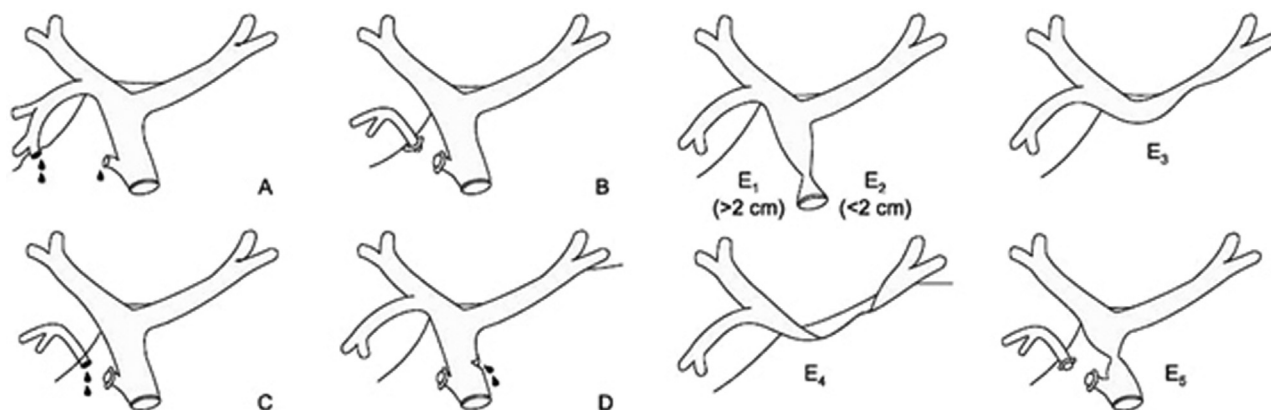
The aim of this study was to report the short-term and long-term outcome of surgical repair following RYHJ for postcholecystectomy BDI in a tertiary hepatobiliary center in Upper Egypt (Assiut University).

Patients and methods

This is a retrospective cohort study that includes patients diagnosed with postcholecystectomy BDI referred to Al-Rajhi Liver Institute, Assiut University, between October 2014 and November 2018. This study was approved by the local institutional review board (IRB). An informed consent has been obtained.

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Figure 1



Strasberg classification [10]. (a) Leak from cystic duct stump or minor radical in gallbladder fossa. (b) Occluded right posterior sectoral duct. (c) Leak from divided right posterior sectoral duct. (d) Leak from main duct without major tissue loss. (E1) Transected main duct with a stricture more than 2 cm from the hilus. (E2) Transected main bile duct with a stricture less than 2. (E3) Stricture of the hilus with right and left ducts in communication. (E4) Stricture, with separation of right and left ducts. (E5) Stricture of the main duct and the right posterior sectoral duct.

All patients who underwent surgical repair of BDI at our institute were included in the study. Other patients who had nonoperative management either conservatively or endoscopically were excluded from the study.

Diagnostic workup

Full medical history, including operative details of previous cholecystectomy, and clinical examination were done. Initial laboratory tests (complete blood count, kidney function tests, liver function tests, etc.) were done.

Abdominal ultrasound (US) was done to assess presence of abdominal collections and any dilatation of the biliary system. The patients who had abdominal collections were subjected to drainage procedure by either percutaneous drain under US guidance or surgical drainage.

The patients presented with biliary fistula underwent endoscopic retrograde cholangiopancreatography first to detect type of injury and possible stenting if there is preserved continuity of the biliary system or partial BDI.

All patients were subjected to magnetic resonance cholangiopancreatography (MRCP) before surgery to assess BDI (level and degree). BDI was classified according to Strasberg classification, which is used in most publications [10] (Fig. 1).

Surgical technique

All patients underwent surgical repair by doing RYHJ with end-to-side anastomosis.

(1) Under general intubation anesthesia, a generous right subcostal incision is performed and could be

extended on demand upward to the xiphoid process and/or to the left subcostal area. Thorough dissection and adhesiolysis is performed to reach the CBD and prepare the unaffected proximal part for anastomosis. In case of high injuries, Hepp–Couinaud technique or hepatic ductoplasty is used to ensure a wide bilioenteric anastomosis. The Roux jejunal loop is prepared and passed retrocolic to reach the porta hepatis.

- (2) Then, the hepaticojejunostomy is done via end-to-side anastomosis using interrupted sutures of PDS of 4–0 size. A biliary stent may be optionally placed according to operative circumstances/surgical preference.
- (3) Enteroenterostomy is done in the form of single-layer continuous sutures of polyglactin of 3–0 size. An intraperitoneal drain was left in the hepatorenal pouch before closing the incision in layers.

Grouping of patients

According to the time interval between previous surgery and surgical repair, patients were divided into two groups (early <6 weeks and delayed >6 weeks).

Follow-up

Follow-up was scheduled at 3 months, 6 months, 12 months, 2 years, and 3 years by liver function test and abdominal US to detect any abnormality. MRCP was done for patients if there was any derangement in liver functions tests (LFT) and/or dilated biliary channels on US.

Anastomotic stricture was evident by repeated episodes of cholangitis, jaundice, increased bilirubin or alkaline

phosphatase on LFTs, and/or biliary dilatation on US during follow-up after surgical repair.

Data such as age, sex, pattern of presentation, time of previous operation, time of surgical repair, length of hospital stay, postoperative bile leak, wound complications, and anastomotic stricture were collected and analyzed.

Statistical analysis

The data were tested for normality using the Kolmogorov–Smirnov test and for homogeneity variances before further statistical analysis. Categorical variables were described by number and percent, whereas continuous variables were described by mean and SD. χ^2 test was used to compare between categorical variables, whereas comparison between continuous variables was done by analysis of variance test. Logistic regression analysis was done to test for significant association. A two-tailed *P* value less than 0.05 was considered statistically significant. All analyses were performed with the IBM SPSS 24.0 software (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY, USA: IBM Corp.).

Results

Our study included 43 patients with postcholecystectomy BDI who underwent surgical repair in the time period between October 2014 and November 2018. There were 31 females and 12 males, with mean age of 37.2 ± 7.3 years.

Clinical presentation of the patients varies from intra-abdominal collections (biloma and/or biliary peritonitis), external biliary fistula from the drain of previous cholecystectomy, obstructive jaundice, to cholangitis.

Obstructive jaundice was the most presenting symptom in 15 (34.9%) patients, eight patients had localized collection in the form of biloma (18.6%), 11 patients had external biliary fistula (25.6%), six (14%) patients had cholangitis, and only three (7%) patients presented with biliary peritonitis.

Regarding laboratory investigations, the mean white blood cell count was 8.7 ± 2.6 , total bilirubin was 43.3 ± 11.7 , direct bilirubin was 33.3 ± 11.2 , alkaline phosphatase was 179.5 ± 28.5 , and albumin was 32.6 ± 2.9 .

Abdominal US revealed collections in 10 (23.3%) patients. Endoscopic retrograde

Table 1 Clinicoepidemiologic data of patients

	<i>n</i> (%)
Age (mean±SD)	37.2±7.3
Sex	
Male	12 (27.9)
Female	31 (72.1)
Clinical presentation	
Obstructive jaundice	15 (34.9)
Cholangitis	6 (14.0)
Biliary fistula	11 (25.6)
Biloma	8 (18.6)
Biliary peritonitis	3 (7.0)
WBCs (mean±SD)	8.7±2.6
Total bilirubin (mean±SD)	43.3±11.7
Direct bilirubin (mean±SD)	33.3±11.2
ALP (mean±SD)	179.5±28.5
Albumin (mean±SD)	32.6±2.9
ERCP	
Not done	18 (41.9)
Done	25 (58.1)
Type of drainage	
Not done	33 (76.7)
Done	10 (23.3)
Stenting	
Not done	36 (83.7)
Done	7 (16.3)
Class of injury	
Class E2	5 (11.6)
Class E3	30 (69.8)
Class E4	8 (18.6)

ALP, alkaline phosphatase; ERCP, endoscopic retrograde cholangiopancreatography; WBC, white blood cell.

cholangiopancreatography was done in 25 (58.1%) patients. Percutaneous drainage under US guidance was done in seven (16.3%) patients whereas surgical drainage was done in only three (7%) patients.

According to MRCP done before surgical repair, type E3 injury was the most common injury occurring in 30 (69.8%) patients, type E4 in eight (18.6%) patients, and finally type E2 in only five (11.6%) patients (Table 1).

Surgical repair and anastomosis was done over biliary stents in only seven (16.3%) patients, whereas other repairs were done without stenting (Table 1).

In early postoperative period, there was wound infection in six (14%) patients. Moreover, bile leak occurred in five (11.6%) patients, and all of them were managed conservatively without intervention (Table 2).

During the follow-up period, only six (14%) patients had evidence of anastomotic stricture. Two patients developed gradually progressive biliary stricture and

underwent redo-hepaticojejunostomy. Other three patients experienced attacks of cholangitis, which was managed by radiological intervention. The last patient had abnormal liver function in the form of slight increased bilirubin and alkaline phosphatase but without clinical manifestations. This patient was managed conservatively with ursodeoxycholic acid.

According to the time interval between previous surgery and surgical repair, 18 (41.9%) patients underwent early repair (<6 weeks), whereas 25 (58.1%) patients underwent delayed repair (>6 weeks). Tables 3 and 4 show the different clinicoepidemiologic factors along with short-term and long-term outcome data in relation to the timing of intervention.

Table 2 Short-term and long-term follow-up data of patients

	n (%)
Wound complications	
No	37 (86.0)
Yes	6 (14.0)
Postoperative biliary leakage	
No	38 (88.4)
Yes	5 (11.6)
Hospital stay (mean±SD)	4.7±1.6
Bilirubin normalization (mean±SD)	1.8±0.8
Timing of intervention	
Early	18 (41.9)
Delayed	25 (58.1)
Stricture	
No stricture	37 (86.0)
Stricture	6 (14.0)

By doing comparative analysis, none of the preoperative, intraoperative, or postoperative factors were found to affect the outcome of surgical repair except time interval between previous cholecystectomy and surgical repair and bilirubin level. There was a statistically significant difference ($P=0.026$) regarding developing anastomotic stricture between first group (repair <6 weeks) and the second group (repair >6 weeks) (Tables 5 and 6).

By using logistic regression analysis, the factors found to be statistically significant affecting the outcome of the surgical repair of BDI were timing of repair, level of direct bilirubin, and timing of bilirubin normalization (Table 7).

Table 3 Comparative analysis of epidemiologic and clinical factors with timing of surgical intervention

	Early (N=18) [n (%)]	Delayed (N=25) [n (%)]	P value
Age (mean±SD)	37.6±8.8	36.8±6.1	0.719
Sex			
Male	4 (22.2)	8 (32.0)	0.481
Female	14 (77.8)	17 (68.0)	
Clinical presentation			
Obstructive jaundice	6 (33.3)	9 (36.0)	0.209
Cholangitis	1 (5.6)	5 (20.0)	
Biliary fistula	6 (33.3)	5 (20.0)	
Biloma	5 (27.8)	3 (12.0)	
Biliary peritonitis	0	3 (12.0)	
WBCs (mean±SD)	8.4±2.4	8.9±2.8	0.563
Total bilirubin (mean±SD)	40.6±11.9	45.2±11.4	0.204
Direct bilirubin (mean±SD)	30.3±10.9	35.4±11.1	0.145
ALP (mean±SD)	177.9±30.2	180.6±27.8	0.762
Albumin (mean±SD)	33.1±3.2	32.2±2.6	0.313
ERCP			
Not done	6 (33.3)	12 (48.0)	0.551
Done	12 (66.7)	13 (52.0)	
Type of drainage			
Not done	13 (72.2)	20 (80.0)	0.336
Done	5 (27.8)	5 (20.0)	
Class of injury			
Class E2	2 (11.1)	3 (12.0)	0.419
Class E3	11 (61.1)	19 (76.0)	
Class E4	5 (27.8)	3 (12.0)	
Stenting			
Not done	14 (77.8)	22 (88.0)	0.370
Done	4 (22.2)	3 (12.0)	

ALP, alkaline phosphatase; ERCP, endoscopic retrograde cholangiopancreatography; WBC, white blood cell.

Table 4 Comparative analysis of operative factors with timing of surgical intervention

	Early (N=18) [n (%)]	Delayed (N=25) [n (%)]	P value
Wound complications			
No	16 (88.9)	21 (84.0)	0.648
Yes	2 (11.1)	4 (16.0)	
Postoperative biliary leakage			
No	17 (94.4)	21 (84.0)	0.292
Yes	1 (5.6)	4 (16.0)	
Hospital stay (mean±SD)	5.0±1.1	5.2±1.6	0.650
Bilirubin normalization (mean±SD)	2.7±1.1	2.7±0.9	0.964
Stricture			
No stricture	13 (72.2)	24 (96.0)	0.026
Stricture	5 (27.8)	1 (4.0)	

All bold values = Significant results *P*-value = <0.05.

Table 5 Comparative analysis of epidemiologic and clinical factors with stricture

	Stricture (N=6) [n (%)]	No stricture (N=37) [n (%)]	P value
Age (mean±SD)	34.1±7.0	37.6±7.3	0.281
Sex			
Male	3 (50.0)	9 (24.3)	0.193
Female	3 (50.0)	28 (75.7)	
Clinical presentation			
Obstructive jaundice	0	15 (40.5)	0.249
Cholangitis	1 (16.7)	5 (13.5)	
Biliary fistula	3 (50.0)	8 (21.6)	
Biloma	2 (33.3)	6 (16.2)	
Biliary peritonitis	0	3 (8.1)	
WBCs (mean±SD)	8.5±3.3	8.7±2.6	0.869
Total bilirubin (mean±SD)	30.8±6.4	45.3±11.1	0.004
Direct bilirubin (mean±SD)	20.6±4.7	35.3±10.6	0.002
ALP (mean±SD)	172.0±19.0	180.7±29.8	0.495
Albumin (mean±SD)	32.5±3.2	32.6±2.9	0.942
ERCP			
Not done	2 (33.3)	16 (43.2)	0.648
Done	4 (66.7)	21 (56.8)	
Type of drainage			
Not done	4 (66.7)	29 (78.4)	0.529
Done	2 (33.3)	8 (21.6)	
Class of injury			
Class E2	0	5 (13.5)	0.604
Class E3	5 (83.3)	25 (67.6)	
Class E4	1 (16.7)	7 (18.9)	

ALP, alkaline phosphatase; ERCP, endoscopic retrograde cholangiopancreatography; WBC, white blood cell. All bold values = Significant results *P*-value = <0.05.

Discussion

BDI is considered the most serious complication following cholecystectomy. The incidence of BDI varies in reports from 0.1 to 0.2% for open cholecystectomy to 0.4–0.6% for laparoscopic cholecystectomy [11]. BDI is a devastating complication, which is associated with increased hospital stay, high cost, and short-term and long-term morbidity that may result in reduced survival and an impaired quality of life [12,13].

Surgical repair of BDI is a technically demanding procedure, which should be best performed in a tertiary referral hepatobiliary center [13]. Although many different procedures are used for repair of a BDI, RYHJ repair is still considered by most authors the procedure of choice for major duct injury. All patients in our study underwent RYHJ for BDI. In addition to being the preferred procedure in our center, all injuries were of E2-4 type, making other options of repair unfeasible.

Table 6 Comparative analysis of operative factors with incidence of stricture

	Stricture (N=6) [n (%)]	No stricture (N=37) [n (%)]	P value
Stenting			
Not done	6 (100.0)	30 (81.1)	0.244
Done	0	7 (18.9)	
Wound complications			
No	5 (83.3)	32 (86.5)	0.836
Yes	1 (16.7)	5 (13.5)	
Postoperative biliary leakage			
No	5 (83.3)	33 (89.2)	0.678
Yes	1 (16.7)	4 (10.8)	
Hospital stay (mean±SD)	4.7±1.6	5.2±1.4	0.403
Bilirubin normalization (mean±SD)	1.8±0.8	2.8±0.9	0.017
Timing of intervention			
Early	5 (83.3)	13 (35.1)	0.026
Delayed	1 (16.7)	24 (64.9)	

All bold values = Significant results P -value = <0.05.

Table 7 Logistic regression analysis of different factors in relation to stricture

	P value	Exp(B)	95% CI for Exp(B)	
			Lower	Upper
Age	0.281	0.923	0.798	1.068
Sex	0.208	3.111	0.531	18.224
Clinical presentation	0.189	1.580	0.798	3.126
WBCs	0.865	0.972	0.696	1.356
Total bilirubin	0.012*	0.849	0.747	0.965
Direct bilirubin	0.009**	0.783	0.651	0.941
ALP	0.485	0.989	0.957	1.021
Albumin	0.940	0.988	0.730	1.338
US/CT	0.859	1.182	0.188	7.426
ERCP	0.650	1.524	0.247	9.383
Drainage procedure	0.791	0.817	0.183	3.639
Classification of injury	0.640	1.461	0.299	7.141
Stents (internal/external)	0.999	0.000	0.000	
Length of hospital stay	0.405	0.685	0.282	1.669
Wound infection	0.837	1.280	0.123	13.352
Postoperative bile leak	0.681	1.650	0.152	17.911
Timing of bilirubin normalization	0.028*	0.268	0.083	0.866
Timing of intervention	0.049*	0.978	0.928	1.031

ALP, alkaline phosphatase; CI, confidence interval; CT, computed tomography; ERCP, endoscopic retrograde cholangiopancreatography; US, ultrasound; WBC, white blood cell. All bold values = Significant results P -value = <0.05. *Significant results <0.05. **Highly significant <0.01.

Although many factors can lead to this complication, we believe that misinterpretation of anatomy is the most important factor, with the common bile duct, the common hepatic duct, or an aberrant right hepatic duct misidentified as cystic duct. This explains why type E injuries are the most frequent in most publications.

In our study, type E3 was reported to be the commonest injury type (69.8%), which was also reported by other authors to be the commonest injury type [14,15]. Interestingly, type E1 was not present in our cases. Felekouras *et al.* [16] analyzed 92 patients between 1991 and 2011 and reported type E2 (28.3%) as the commonest type, followed by type E3 (23.9%).

Moreover, AbdelRafee *et al.* [17] reported the type of injury in their study of 120 patients as follows: E1 (18.3%), E2 (63.3%), and E3 (14.2%). We noted that the level of injury had no effect on the incidence of stricture ($P=0.604$) or bile leak, which is inconsistent with some studies that reported association between injury level and incidence of stricture [18,19].

Incidence of wound complications in our study was 14%. There is no statically significant difference present between early and late groups. Moreover, we cannot detect any association between the incidence of wound complication and other factors. Felekouras [16] also reports no statistically significant difference in the

incidence of wound complications between early and delayed interventions ($P=0.310$).

Postoperative bile leak occurred in 11.6% of patients in this study. All patients were managed conservatively. This incidence is within the range of other studies, which is between 0.8 and 12% [17,20]. We found no association between the incidence of bile leak and other factors. However, de Castro *et al.* [21] in their multivariate analysis reported a body mass index greater than 35 kg/m², endoscopic biliary drainage, and an anastomosis on the segmental bile ducts to be independent predictors of leakage.

Moreover, the postoperative bile leak had no influence on the incidence of anastomotic stricture ($P=0.678$). This is in contrast with the study reported by AbdelRafee *et al.* [17], where the postoperative bile leak – which was reported in up to 19.2% of cases – was associated with poor outcome.

The main concern of long-term complication following hepaticojejunostomy is the incidence of anastomotic stricture. Hepaticojejunostomy stricture is a serious complication that can lead to repeated cholangitis, intrahepatic stones formation, and progressive biliary cirrhosis. In literature, the incidence of stricture following hepaticojejunostomy ranges from 5 to 22% [14,19,20,22].

The incidence of stricture in our study after 3-year follow-up was 13.95%. We believe that this incidence may increase with longer follow-up, as studies showed that most (65%) of recurrent biliary strictures develop within 2–3 years after the operation, 80% within 5 years, and 90% within 7 years. Occurrence of strictures after 10 years following the surgical procedure is also described in the literature [14,17].

In our study, other than time interval between the previous cholecystectomy and hepaticojejunostomy and bilirubin level, no association is detected between stricture and other factors. The lowest incidence in the delayed group can be explained by presence of more dilated ducts in the patients of this group which can also account for lower incidence of stricture in patients presented with significantly higher bilirubin level.

Many hepatobiliary surgeons believe that early surgical reconstruction performed early within 6 weeks after injury, on nondilated bile ducts and inflamed tissues, is associated with poorer outcomes. However, this is a matter of debate, and many studies have failed to

identify early repair as an individual risk factor and support this concept [18,19,23,24].

In a retrospective national French survey, which analyzed the data from 47 centers including more than 500 cases of BDI following cholecystectomy, to compare the results of surgical repair for BDI and effect of timing of intervention, authors categorized patients into three groups: immediate (at time of cholecystectomy) (194 patients), early (within 45 days after a cholecystectomy) (216 patients), and late (beyond 45 days after a cholecystectomy) (133 patients). They reported the need for second procedure in 56.7% for immediate repair, 40.7% for early repair ($P<0.05$), and in 6.8% for late repair ($P<0.001$). Conclusions were drawn that the timing of surgical repair influences significantly the rate of a second procedure and a late repair should be the preferred option [11]. In another large study, authors concluded that patients operated in the acute phase had more perioperative morbidity and more stricture rate than patients operated in the delayed and late phase [18]. These findings were supported by other publications reporting a higher rate of stricture with early repairs (within days to weeks) [19,23,24].

In contrast, Dageforde *et al.* [25] demonstrated that early repair by a hepatobiliary surgeon (<6 weeks) was associated with lower costs, earlier return to normal activity, and better quality of life. Thomson *et al.* [26] found that early repair resulted in similar outcome to that of delayed repair (beyond 2 weeks).

Beside these contradictable results regarding the effect of time of intervention on surgical outcome, definitions of timing used in studies are not universal. Some authors divided groups into immediate (within 72 h), early (<6 week), and delayed (>6 weeks). Therefore, we should not only compare early versus delayed repair but also consider different patient circumstances in the timing for surgery.

It should be noted that all patients presented with biliary peritonitis in our study were subjected to delayed repair. Our practice in these cases was to initially control sepsis via percutaneous or surgical drainage and operate on patients at a later date (after 6 weeks), when the patient condition improved and inflammation had subsided.

The major limitations of this study are being retrospective with small number of cases and relative short period of follow-up.

Conclusion

We believe that timing of repair of BDI following cholecystectomy has a significant effect on the outcome of repair. It is better to do delayed repair after 6 weeks (unless there is a factor which necessitate direct intervention as obstructive jaundice) to give a chance for improvement of general condition of the patient, nutritional status, resolution of inflammatory process, control of sepsis, and get more healthy tissues for repair. All those factors will lead to better outcome.

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Conflicts of interest

There are no conflicts of interest.

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