ORIGINAL ARTICLE

Factors Affecting Short-Term and Long-Term Outcomes After Bilioenteric Reconstruction for Post-cholecystectomy Bile Duct Injury: Experience at a Tertiary Care Centre

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Abstract Bile duct injury following cholecystectomy is an iatrogenic catastrophe associated with significant perioperative morbidity, reduced long-term survival and quality of life. There has been little literature on the long-term outcomes after surgical reconstruction and factors affecting it. The aim of this study was to study factors affecting long-term outcomes following surgical repair of iatrogenic bile duct injury being referred to a tertiary care centre. Between January 2005 to December 2011, 138 patients with bile duct injury were treated in a single surgical unit in a tertiary care referral hospital. Preoperative details were recorded. After initial resuscitation, any intra-abdominal collection was drained and an imaging of biliary anatomy was done. Once the general condition of the patient improved, patients

were taken up for a side-to-side extended left duct hepaticojejunostomy. The post-operative outcomes were recorded and a hepatobiliary iminodiacetic acid scan and liver function tests were done, and then the patients were followed up at regular intervals. Clinical outcome was evaluated according to clinical grades described by Terblanche and Worthley (Surgery 108:828–834, 1990). The variables were compared using chi-square, unpaired Student's *t* test and Fisher's exact test. A two-tailed *p* value of <0.05 was considered significant. One hundred thirty-eight patients, 106 (76.8 %) females and 32 (23.2 %) males with an age range of 20–63 years (median 40.8±SD) with bile duct injury following open or laparoscopic cholecystectomy, were operated during this period. Majority of the patients [83 (60.1 %)] had a

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delayed presentation of more than 3 months. Based on imaging, Strasburg type E1 was seen in 17 (12.5 %), type E2 in 30 (21.7 %), type E3 in 85 (61.5 %) and type E4 in 6 (4.3 %). On multivariate analysis, only level of injury, longer duration of referral and associated vascular injury were independently associated with an overall poor long-term outcome. This study demonstrates level of injury at or above the confluence; associated vascular injury and delay in referral were associated with poorer outcomes in long-term follow-up; however, almost all patients had excellent outcome in long-term follow-up.

Keywords Bile duct injury · Post-cholecystectomy · Hepaticojejunostomy · Outcome

Introduction

Bile duct injury following cholecystectomy is an iatrogenic catastrophe associated with significant perioperative morbidity, mortality, reduced long-term survival and quality of life and high rates of subsequent litigations and converting a healthy subject to what can be called as a 'biliary cripple'. The traditional management of these patients has been billioenteric reconstruction, but recent literature has shown promising results with endoscopic management [1]. There has been little literature on the long-term outcomes after surgical reconstruction. Reports have shown that more than 90 % of patients following surgical reconstruction have good outcomes in the long term also [2], but the factors predicting the outcomes of these patients have not been studied extensively. We retrospectively analyzed our prospective data of incidence, management and factors affecting long-term results of bile duct injuries sustained during cholecystectomy being referred to our centre.

Materials and Methods

Between January 2005 to December 2011, 138 patients with bile duct injury (BDI) were treated in a single surgical unit in a tertiary care referral hospital. All the patients were operated outside and were referred for management of the bile duct injury. The data were entered into a computerized database, and patients were followed prospectively. The demographic profile, presenting symptoms, indication for surgery, details of previous surgery if available, haematological and biochemical parameters, diagnostic evaluation, classification of bile duct injury, surgical or radiological interventions, intra-operative variables and post-operative outcomes were recorded. Patients with BDI who did not require surgical intervention were not included. Based on the time of presentation from index surgery, the patients

were divided into following groups: (1) within 10 days of injury, (2) 10 days to 3 months of injury, (3) after 3 months of injury and (4) prior repair before referral.

The patients were resuscitated depending on their time and mode of presentation. Routine laboratory (haematological and biochemical) investigation as well as ultrasonography of the abdomen was done. Any intra-abdominal collection was drained, and an imaging of biliary anatomy and level of injury was done using endoscopic retrograde cholangiography, magnetic resonance cholangiopancreatography (MRCP) or fistulogram.

Once the general condition of the patient improved, patients were taken up for definitive surgical management. An end-to-side extended left duct hepaticojejunostomy was performed in a single layer with interrupted 3–0 or 4–0 polyglactin 910 suture.

The post-operative outcomes were recorded and a hepatobiliary iminodiacetic acid (HIDA) scan was done at 7 days post-operatively, and then the patients were followed up at regular intervals in the follow-up clinic. Liver function tests and HIDA scan were repeated at 3 months. Patient were followed up every 3 months for the first year and then after every 6 months for 3 years and then yearly. Any symptoms and clinical examination were done, and any derangements in liver function tests were recorded. Clinical outcome was evaluated according to clinical grades described by Terblanche and Worthley [3].

The outcomes were analyzed in terms of time of presentation from index surgery, level of injury, post-operative complication and long-term outcomes. A univariate and multivariate analyses of various factor and their effect on post-operative complication and long-term outcomes were performed.

Results

Presentation and Symptoms

Of the 138 patients, 106 (76.8 %) were females and 32 (23.2 %) were males with an age range of 20–63 years (median 40.8±SD). Obstructive jaundice was the most common presentation seen in 96 (69.50 %) patients. Twenty-four (17.2 %) patients presented with cholangitis and sepsis, and 46 (33.3 %) patients presented with biliary fistula. The serum bilirubin concentration ranged from 0.3 to 32 mg/dl. The serum albumin levels ranged from 2.6 to 5.1 g/dl (median 3.68±).

Time of Presentation and Index Surgery

Majority of the patients [83 (60.1 %)] had a delayed presentation of more than 3 months. Only eight (5.8 %) patients



presented within 10 days of index surgery. Forty-two (34.1 %) patients presented within 3 months of surgery. The median time to presentation was 3.2 months with a range of 7 days to 84 months. One hundred eight (78.26 %) patients had bile duct injury following open cholecystectomy. The BDI could be recognized in only five (3.6 %) patients during index surgery. Two of these patients underwent attempted Roux en-Y hepaticojejunostomy and one patient choledochojejunostomy all of which had failed. Two patients were referred with drain placement only in the divided bile duct after recognition of injury during surgery. One among these died after admission 2 weeks from index surgery with uncontrolled biliary fistula and biliary peritonitis with sepsis.

Classification of Bile Duct Injuries

The BDI was defined according to the Strasberg classification [4] (Table 1). The final classification was done after reviewing the operative findings, endoscopic retrograde cholangiopancreatography (ERCP) films, fistulogram films and MRCP films. Based on the above imaging, Strasburg type E1 was seen in 17 (12.5 %), type E2 in 30 (21.7 %), type E3 in 85 (61.5 %) and type E4 in 6 (4.3 %). None of the patients had E5 injury. Computed tomography (CT) angiography and coil embolization of pseudo-aneurysm with bleeding were done pre-operatively in two patients. Both of them underwent surgery uneventfully after this. Three patients had concomitant vascular injury also.

Initial Assessment and Management

All the patients were assessed and resuscitated after referral from the peripheral centre. After admission, patients in sepsis or with biliary fistula were managed with intravenous antibiotics, aggressive nutritional management and drainage of intra-abdominal collections or ERCP. Forty-one (29.7 %) patients underwent ultrasound-guided drainage of intraabdominal collection, and ten (7.2 %) patients had multiple attempts at drainage. Only one patient underwent exploratory laparotomy and peritoneal lavage and placement of drains for uncontrolled sepsis before definitive repair. Twenty-four (17.3 %) patients underwent ERCP and placement of stent before finally being taken up for definitive repair. All the patients were operated after a period 4-12 weeks (median 7.2 weeks±SD) once their general condition had improved and the sepsis was under control. At the time of surgery, 26 (18.3 %) patients still had a drain in the sub-hepatic space draining bile.

Surgical Technique

Extended right subcostal incision was used in all patients. Dense intra-abdominal adhesions were encountered in 44 (31.82 %) patients with 38 (27.27 %) patients having multiple intra-abdominal abscesses which were drained. An extended left hepaticojejunostomy end-to-side, single-layer interrupted 4–0 polyglactin suture was done within all patients. Three patients had concomitant right hepatic artery

Table 1 Comparison of patient demographics profile and post-op complications according to Strasberg level of injury

	E1	E2	E3	E4
Number	17	30	85	6
Females/males	14:3	25:5	78:7	5:1
Age	42.3 (24–56 years)	40.1 (20-62 years)	44.2 (22-63 years)	41.6 (20-63 years)
Jaundice	12 (70.5 %)	20 (66.7 %)	58 (68.2 %)	6 (100 %)
Bile leaks	6 (35.3 %)	13 (40.3 %)	22 (25.8 %)	5 (83.3 %)
Sepsis/cholangitis	2 (11.7 %)	3 (10 %)	15 (17.6 %)	4 (66.7 %)
Within 10 days	2 (11.7 %)	2 (6.7 %)	3 (3.5 %)	1 (16.7 %)
10 days-3 months	4 (23.5 %)	10 (33.3 %)	31 (36.4 %)	2 (33.3 %)
After 3 months	11 (64.7 %)	18 (60 %)	51 (60 %)	3 (50 %)
Prior repair before referral	0	0	4 (4.7 %)	11 (16.7 %)
LC	3 (17.6 %)	4 (13.3 %)	10 (11.7 %)	1 (16.7 %)
OC	13 (76.4 %)	24 (80 %)	67 (75.2 %)	4 (66.7 %)
Lap>open	1 (6 %)	2 (6.7 %)	8 (9.4 %)	1 (16.7 %)
Drainage	2 (11.7 %)	8 (29.3 %)	26 (30.5 %)	5 (83.3 %)
Multiple drainage	1 (5.8 %)	1 (3.3 %)	17 (20 %)	5 (83.3 %)
Laparotomy	0	0	0	1 (16.7 %)
ERCP	5 (29.4 %)	6 (20 %)	11 (12.9 %)	2 (33.3 %)
RHA aneurysm	0	1 (3.3 %)	2 (2.3 %)	2 (33.3 %)



pseudo-aneurysm which resulted in bleeding. Bleeding vessel was ligated in all the patients. In two patients with type IV stricture, the anastomosis of both the ducts was done with a single loop of jejunum only. In two patients with previous hepaticojejunostomy and stricture with complete occlusion of the anastomosis, the anastomosis was dismantled and a new anastomosis created.

Operative Findings and Intra-op Complications

The operative time ranged from 90 to 240 min (Table 2). Multiple interloop adhesions were found in 36 (26.14 %) patients and pelvic collection in 24 (17.05 %) patients. Almost all patients required blood transfusion ranging from three to six units with an average blood loss of 565 ml (200–1,500 ml).

Post-op Period (Table 2)

Three (2.2 %) patients required ventilator support in the immediate post-operative period but were weaned successfully. One patient with pseudo-aneurysm of right hepatic artery had massive bleed in the post-operative period and was re-explored. She died after the second surgery. Two patients were re-explored for bleeding. Of these, one had bleed from anastomotic site and another had generalized ooze. Both patients made uneventful recovery. The other post-operative complications included biliary leak which was transient (<72 h) in 22 (15.9 %) and prolonged in 13 (9.09 %) patients. Wound infection was seen in 26 (18.8 %). Pulmonary

complication was seen in 16 (11.5 %) patients. Thirteen patients developed cholangitis which was managed conservatively with intravenous antibiotics and did not require any operative intervention. The median hospital stay was 9.5 days with a range of 5 to 20 days.

Follow-up and Outcome

After a mean follow-up of 54 months (range from 6 to 83 months) (Table 3), the liver function test normalized in majority of the patients in the follow-up. Fifty-six (40.90 %) patients were followed up for more than 40 months. However, alkaline phosphatase was raised in 24 (17.4 %) patients, in the follow-up. But these patients were asymptomatic on regular follow-up. HIDA scan was done in the follow-up period for 88 (63.8 %) patients after a period of 6-9 months. The findings recorded were slightly delayed clearance in five (3.6 %) patients, but these patients were asymptomatic so no further intervention was done and then are on follow-up. The HIDA scan showed good clearance in the rest of patients. One patient had severe cholangitis 3 months after the repair, was managed outside for 10 days and was referred. At referral, she was in multiple organ dysfunction syndromes and succumbed after 7 days of admission. Four patients had minor episodes of cholangitis in initial period up to 12 weeks and settled on conservative management. The outcome according to Terblanche and Worthley grading is given in Table 3. The outcome after surgery was excellent (grade I/II) in 92 % patients, fair (grade III) in 5.8 % and poor in only 2.2 % patients.

Table 2 Comparison of intra-operative and post-operative complications according to Strasberg level of injury

	E1	E2	E3	E4
Operative time	90–200 min	95–210 min	102–230 min	110–240 mir
Mean blood loss	465 ml	550 ml	590 ml	600 ml
Post-op mortality	0	0	1 (1.1 %)	1 (16.7 %)
UGI haemorrhage	0	0	2 (2.3 %)	1 (16.7 %)
LGI haemorrhage	0	1 (3.3 %)	0	0
Transient Bile leak	2 (11.7 %)	4 (13.3 %)	11 (12.9 %)	5 (83.3 %)
Prolonged bile leak	0	1 (3.3 %)	9 (10.5 %)	3 (50 %)
Respiratory tract infections	2 (11.7 %)	3 (10 %)	8 (9.4 %)	3 (50 %)
Urinary tract infections	0	1 (3.3 %)	9 (10.5 %)	1 (16.7 %)
Jaundice	0	0	2 (2.3 %)	1 (16.7 %)
Cholangitis	0	2 (6.7 %)	8 (9.4 %)	3 (50 %)
SAIO	1 (5.8 %)	3 (10 %)	8 (9.4 %)	1 (16.7 %)
Burst abdomen	0	1 (3.3 %)	3 (3.4 %)	1 (16.7 %)
SSI	2 (11.7 %)	5 (16.6 %)	17 (20 %)	2 (33.3 %)
Pneumonia	1 (5.8 %)	3 (10 %)	10 (11.8 %)	2 (33.3 %)
Intra-abdominal collection	1 (5.8 %)	1 (3.3 %)	3 (3.4 %)	4 (66.7 %)



Table 3 Comparison of outcome grading as per Terblanche grading system

Grade	E1	E2	E3	E4
Grade I	15 (88.7 %)	28 (93.3 %)	74 (87.2 %)	3 (60 %)
Grade II	2 (11.3 %)	2 (6.7 %)	5 (5.8 %)	1 (16.7 %)
Grade III	0	0	4 (4.7 %)	1 (16.7 %)
Grade IV	0	0	2	1 (16.7 %)

Outcomes Analysis

On performing univariate analysis, six factors were found to be associated with development of post-operative complications (Table 4). These included prior open cholecystectomy (p= 0.007), injury at or above the level of confluence (p<0.001), time of presentation >3 M from index surgery (p=0.02), prior attempts at repair (p=0.028), prior ERCP (p=0.03) and those with associated vascular injuries (p=0.033). However, on multivariate analysis with stepwise logistic regression, only the level of injury, time of presentation >3 M from index surgery, prior attempted repair and associated vascular injury were found to be independent risk factors for post-operative outcomes (p=0.002, p=0.003, p=0.001, respectively).

Predictors of Long-Term Outcome in Terms of Terblanche Grading

On performing univariate analysis, previous laparoscopic cholecystectomy, higher level of injury, longer duration of referral from time of index surgery, prior attempted repair, prior ERCP and associated vascular injury were associated with a poor long-term outcome; however, on multivariate analysis, only level of injury, longer duration of referral and associated vascular injury were independently associated with a overall poor long-term outcome (Table 5).

Discussion

Over the last decade, BDI following LC has been recognized as a major health problem. Despite expectations that

Table 4 Univariate and multivariate analysis of predictors of post-operative complications

Predictors of post-	Proportion with post-	p value	p value	
operative complications	operative complication	(univariate analysis)	(multivariate analysis)	
Laparoscopic cholecystectomy	8 out of 18	0.667		
Open cholecystectomy	88 out of 138	0.007	0.043	
Injury at or above bifurcation (E3/E4)	70 out of 91	< 0.001	0.002	
Duration of presentation <10 days	4 out of8	0.7	0.065	
Duration of presentation >3 months	59 out of 83	0.002	0.023	
Previous attempted repair	4 out of 5	0.028	0.002	
ERCP attempted	17 out of 24	0.03	0.07	
Associated vascular injury	5 out of 5	0.033	0.001	

the rate of BDI would decrease over time as the "learning curve" of LC flattened, the rates appear to have reached a plateau, as evidenced by a recent review of nearly 1.6 million cholecystectomies performed among Medicare beneficiaries [5]. Despite improvements in technology, BDI continues to pose a significant clinical challenge. There has been only very little literature published on the factors affecting the outcome of these patients undergoing a surgical repair. Only few series have previously reported the long-term outcomes following repair of laparoscopic BDI and the factors affecting it.

The surgical approach for repairing post-cholecystectomy bile duct stricture is the most important determinant of postoperative complications and long-term outcomes. Hepaticojejunostomy for postcholecystectomy benign bile duct strictures offers the best possible long-term results [6]. Compared with earlier reports, there has been a considerable decline in the operative mortality with many large series reporting zero perioperative deaths [7]. Recurrence of the stricture is a known complication of the procedure, and Pitt [8] reported that 68 % of recurrences occur within 3 years of the most recent repair and 80 % within 5 years. Nevertheless, in all our experience, we have always done Roux en Y hepaticojejunostomy. In fact using the approach of extended left hepaticojejunostomy based on the anatomical work of Hepp and Couinaud [9], a direct sutured anastomosis was possible in all our cases. No end-to-end anastomosis of the transected duct or hepatoduodenostomy was done. None of our patients has developed anastomotic stricture over a follow-up of 54 months. The outcome success in our study group was 97.8 % with excellent results in 92 % cases. Our results our consistent if not better than the results with earlier



Table 5 Univariate and multivariate analysis of predictors of outcome: outcome grading according to Terblanche

Predictors of long-term outcome	Proportion with poor outcome (grades III and IV)	p value (univariate analysis)	p value (multivariate analysis)
Laparoscopic cholecystectomy	2 out of 8	0.74	0.88
Open cholecystectomy	5 out of 8	0.03	0.06
Injury at or above bifurcation (E3/E4)	8 out of 8	< 0.001	<0.001
Duration of presentation <10 days	2 out of 8	0.74	0.88
Duration of presentation >3 months	5 out of 8	0.03	0.01
Previous attempted repair	4 out of 8	0.04	0.06
ERCP attempted	3 out of 8	0.04	0.32
Associated vascular injury	5 out of 8	0.03	0.01

study which report a success rate between 84 and 98 % following hepaticojejunostomy [10]. The reason for this excellent outcome in our series is due to the wide anastomosis with an extended left duct approach with a healthy duct and performance of surgery by surgeons well experienced in biliary tract surgery.

Recently, a number of studies have reported that the timing of biliary reconstruction influences outcomes [11–14]. In the current study, majority of the patients presented to us 3 months after the injury with only eight patients presenting within 10 days of surgery. Those patients who were found to have intra-abdominal collections and signs of active sepsis underwent percutaneous drainage and control of sepsis before surgical repair usually 4 weeks after the admission as per our standard policy. We found no correlation between timing of biliary reconstruction and successful repair. However, in cases referred early, with good control of intra-abdominal inflammation, we found no need to delay operative repair. There has been no study in literature on the effect of timing of referral from index surgery and surgical repair. In our study on both univariate and multivariate analysis, longer delay of presentation (>3 months) from index surgery was associated with a poor outcome in terms of higher rate of post-operative complication as well as poorer longterm outcome following successful surgical repair. Interestingly, those who were referred earlier (<10 days) had better outcomes most probably due to earlier control of sepsis and earlier drainage of intra-abdominal collection and better care at a tertiary care centre. Thus, early referral to tertiary care centres with expertise in biliary surgery may limit further operations, complications, time to definitive repair and mortality.

The number of attempts at repair following recognition of BDI before referral to a tertiary care centre is also a significant predictor of poor outcome. Heise [15] studied 175 patients with BDI and determined that the

number of attempted repairs before referral was associated with poor outcome. In our study, though the number of patients undergoing repair prior to referral was small (n=5 (3.6 %)), all these patients were found to have a higher level of injury and were found to have significantly more post-operative complications. The long-term outcome was also found to be compromised in all these patients as found on univariate and multivariate analysis. The expertise of an experienced hepatobiliary surgeon would appear to be important to insure optimal results following repair of BDI.

Most studies comparing LC with OC have been performed shortly after the introduction of LC. After the introduction of LC, the spectrum of BDI has remained generally the same, but proportion of major injuries has risen substantially [16–19]. Though the overall incidence of BDI is more after laparoscopic cholecystectomy, however, in our studies, there were a significantly larger number of patients with BDI following open cholecystectomy (78.3 %). This can be explained by the simple fact that open cholecystectomy is being performed far more commonly in the peripheral centres in the Indian scenario and clearly outnumber the number of cholecystectomy being performed laparoscopically. There has been no study of the technique of initial cholecystectomy (LC vs. OC) and the long-term outcome following surgical repair of BDI sustained during the procedure. There is also a suggestion in literature that BDI following LC are more severe and proximal [20]. However, in our study, we found that prior open cholecystectomy was associated with a higher incidence of postoperative complications on univariate analysis but was not found to be independent predictor of long-term outcomes. Therefore, the type of index cholecystectomy does not affect the overall outcome of these patients.

BDI are associated with vascular injuries, the most common being right hepatic artery injury seen in 26–32 % of cases of BDI [21]. Gupta et al. [22] reported



three patients with right hepatic arterial occlusion combined with BDI during LC in whom arterial reconstruction was not performed. They showed that the arterial occlusion is a crucial risk factor for post-operative morbidity because liver necrosis, liver abscess or ischemic injury of the intra-hepatic bile duct can occur after reconstructive hepaticojejunostomy. Stewart and Crystine [23] observed combined biliovascular injury in 32 % of patients, but there was no difference in the morbidity and long-term outcome in patients with or without concomitant vascular injury. This incidence of vascular injuries in our patients was around 4 % which is lower than the incidence reported by others. Because more than 60 % of our patients had undergone an open cholecystectomy, these results suggest that the open approach is not associated with an additional risk of arterial injury. In our study, associated vascular injury was found to be an independent predictor of significantly more post-operative complications and poorer overall long-term outcome

Numerous studies have noted that level of injury correlates with surgical outcome, with worse outcomes in patients with higher levels of biliary injury [24, 25]. We found that the level of injury correlated with outcome on both univariate and multivariate analysis. Higher-level injuries are more difficult to repair and thus an independent predictor of outcomes. Outcomes for primary surgeons correlated with the Stewart–Way class of injury [26]. Primary surgeons generally had better success rates in class I and II injuries, but were usually unsuccessful in repairing class III and IV injuries.

Before the introduction of laparoscopic cholecystectomy, successful long-term outcomes were reported in 80-95 % of patients undergoing operative repair for biliary stricture at tertiary care centre [27]. However, similar results have been obtained in patients following laparoscopic cholecystectomy. In the present series, successful outcome (Terblanche grade I/II) was seen in 92 % cases which is consistent with the present literature. Excellent results in our series and those of others for long-term biliary function underscore the advantage that present-day surgeons with expertise in biliary surgery have over the surgeons of by gone era when repair was attempted in an environment of uncontrolled sepsis, biliary peritonitis, long-standing jaundice or cholangitis. We are now equipped with tools for better delineation of biliary anatomy. Bile leaks are better controlled with CT-guided abdominal drainage and decompression of biliary tree with endotherapy or percutaneous techniques which give time for resolution of peritoneal inflammation and sepsis and better outcomes.

In conclusion, this study demonstrates that the most important factors associated with the success of biliary reconstruction include the complete eradication of intra-abdominal infection (drainage of all bile and fluid collections), complete characterization of the injury, repair performed by an experienced biliary surgeon and using the extended left Roux en Y hepaticojejunostomy for reconstruction. Level of injury at or above the confluence, associated vascular injury and delay in referral were associated with poorer outcomes in long-term follow-up; however, almost all patients had excellent outcome in long-term follow-up.

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