Iatrogenic Bile Duct Injuries in Kashmir Valley

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Abstract Cholecystectomy is one of the commonest operations performed throughout the world and bile duct injury is the worst complication of this procedure. In a prospective and retrospective study 25 patients were seen in a tertiary care hospital over a period of 10 years. 72% of patients were referred from other hospitals. 48% of patients presented within one month of injury. Pain was the commonest presentation (92%) followed by jaundice (80%). Liver functions were deranged in 70% of patients, USG revealed biliary dilatation in 69.6% of patients. ERCP was done in 16 patients and revealed cut off of the common hepatic duct in 43.8% of patients. Intraoperative findings revealed adhesions in 96% of patients. 48% of patients had bile duct stricture. Roux-en-Y hepaticojejunostomy was the commonest procedure performed. All patients showed improvement in liver function after surgery. Wound infection was the commonest complication seen in 32% patients. 3 patients died in our series.

Keywords Cholecystectomy · Bile duct injury · Iatrogenic · Hepatico-jejunostomy · Repair

Introduction

A bile duct injury is defined as any clinically evident damage to the biliary system including the cystic duct and extrahepatic duct radicals. Bile duct injuries include excision, division, narrowing and occlusion of these

structures. Bile duct injuries involve, common bile duct in 67%, common hepatic duct in 15%, hilar hepatic ducts in 11% and cystic duct leaks occur in 2.7% [1]. Before the advent of laparoscopic technique the incidence of major bile duct injury after cholecystectomy was thought to be fairly steady at about 1 in 300 to 500 procedures (0.2 to 0.3%) [2]. The incidence of biliary lesions following laparoscopic cholecystectomy has been found to be upto threefold higher than that of open procedure [3]. There are several pathological conditions predisposing to bile duct injury which include acute cholangitis, gangrenous cholecystitis, perforated gall bladder, polycystic disease of liver, sclero-atrophic gall bladder, Mirrizi's syndrome, duodenal ulcer, pancreatic neoplasm, pancreatitis, hepatic neoplasm and infections, fibrosis in triangle of calot, obesity, local haemorrhage, variant anatomy, fat in porta hepatis, presence of anomalous duct or vessel. Bile duct injury can be traced to various errors [4]. Wrong duct is ligated or transected, lumen of bile duct is occluded during flush ligation of cystic duct, the blood supply to the common duct is compromised by excessive dissection, lumen of duct is traumatized by forceful dilatation, application and control of an energy source are inappropriate.

The bile duct injuries include leaks, strictures, transactions or ligation of major bile duct. These injuries most frequently result in tragic consequences for the patients, which may include postoperative fluid collection, stricture of intrahepatic or extrahepatic ducts, biliary peritonitis, sepsis, multiple organ failure, biliary cirrhosis and hepatic failure. Since cholecystectomy is the commonest type of operation performed in different parts of the state, the present study was undertaken with a view to analyse the clinicopathological profile and surgical results of bile duct injuries in our valley.

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Materials and Methods

The study was conducted in the department of General Surgery at Sher-i-Kashmir Institute of Medical Sciences, Srinagar from January 1996 to June 2006. All patients who had iatrogenic bile duct injury were included. Patients with malignancy and who were managed conservatively were excluded. The study was both retrospective and prospective one. Retrospectively records of all patients with bile duct injuries were analyzed and recorded. Prospective study included evaluation of the initial procedure, presenting symptoms of the bile duct lesions, classification and site of the ductal injury, diagnostic procedures including liver function tests (LFT), ultrasonogram (USG) of abdomen, percutaneous transhepatic cholangiography (PTC) and endoscopic retrograde cholangio pancreatography (ERCP). The type of injury was classified according to Way's Classification [5] and in case of biliary strictures, the level of obstruction was classified in relation to confluence of hepatic duct as described by Bismuth [6]. After thorough evaluation, patients were prepared for surgery. Preparation included thorough hydration, correction of coagulation abnormality and blood transfusions. All patients were operated upon by consultants. Type of operative procedure was decided by the type of injury. The various procedures performed included CBD exploration with T-tube drainage, exploratory laparotomy with ooze closed down on needle, drainage of bilioma and Roux-en-y hepaticojejunostomy. The repair of biliary tract injuries in patients who were recognised during surgery was accomplished by primary anastomosis. If a segmental duct less than 3 mm in diameter was injured, simple ligation of the injured duct was done. However, if the duct was 4 mm or longer in diameter, operative repair was done and if the injured segment of the bile duct was short (<1 cm) and the two ends could be brought without tension, an end-to-end anastomosis was done with placement of T-tube through a separate choledochotomy. A narrow T-tube (10–12 F) was used. For proximal injuries or if the injured segment of the bile duct was greater than 1 cm in length the distal bile duct was over sewn and the proximal bile duct debrided of injured tissue and anastomosed in an end to side fashion to a Roux-en-y jejunal loop. Anastomosis was done in one layer using absorbable suture material (vicryl) 4-0, 5-0 with internal/external stenting. The internal stents were made out of 8–12 F PVC tubes with multiple side holes and were fixed with chromic catgut. The external stents were made from T-tube using either a single limb or a standard T-tube brought out through a separate jejunostomy wound and abdominal wall. The jejunostomy site was fixed to the parietal wall by non-absorbable suture material. Stents were removed 6 weeks after doing tube cholangiogram. Abdominal tube drains were removed when

the drainage was less than 20 ml and T-tube removed from third to fifth week postoperatively. The transanastomotic stents were allowed to come out themselves through the gastrointestinal tract. Postoperatively liver function tests, haemogram were done routinely. T-tubes were removed after doing T-tube cholangiogram. The patients were followed up at the outpatient clinic at regular intervals. The observations were recorded in detail and finally analyzed.

Observations

In a prospective and retrospective study in the last 10 years a total of 25 patients had been diagnosed to have iatrogenic bile duct injury and were included in this study. All of them had sustained injury to extrahepatic bile ducts during the primary surgical procedure. Out of these 25 cases, 6 had undergone laparoscopic cholecystectomy, while the remaining 19 had undergone open cholecystectomy. In 7 of the patients, the injury had occurred at our hospital out of the 3950 cases of cholecystectomy performed during the study period and 18 were referred from peripheral institutions. The incidence of bile duct injury in patients operated at our hospital was 0.18% whereas the overall incidence can not be calculated as the exact number of patients operated in periphery during this period is not available. In one of them, the injury was identified during the operation. Age of our patients ranged from 16–65 yrs. Of these 19 patients were female. They had various complaints that started at a variable time after surgery. Time between the first operation and presentation with symptoms ranged from immediately after the first surgery to more than a year (Table 1). Common signs and symptoms were pain RHC, fever, discolouration of eyes, urine discolouration, itching, vomiting, abdominal distension, increased drainage via drain, etc. These findings are shown in Table 2.

Liver functions were deranged in 70% of the patients. The most consistent abnormality being raised bilirubin and ALP (Table 3). Among the radiological investigations, the most commonly performed was USG (23 patients) followed by ERCP (16 patients). T-tube cholangiogram and PTC were done in 4 and 3 patients respectively. HIDA scan, CT scan and MRCP were not done in any of our patients.

On exploration, adhesions were present in 24 patients (96%), peritoneal cavity was filled with bile in 9 patients (36%), one had cirrhotic liver, and one patient had active bile ooze from liver bed. Two patients had type I bile duct injuries, one patient had type II bile duct injury and 6 had type III bile duct injuries. Various surgical procedures performed depending on the type of injury are depicted in Table 4 with Roux-en-Y hepaticojejunostomy performed in majority (72%) of our patients.

Table 1 Time of presentation

Time since surgery	Bile duct strictures(n=12)				Bilioma (n=4)	Bile duct injury (n=9)				Total (n=25)
	Type I stricture n(%)	Type II stricture n(%)	Type III stricture n(%)	Total n(%)		Type I bile duct injury n(%)	Type II bile duct injury n(%)	Type III bile duct injury n(%)	Total n(%)	
≤1 week	–	–	–	–	2(50)	1(11.1)	–	1(11.1)	2(22.2)	4(16)
1 week to 1 month	1(8.3)	–	–	1(8.3)	2(50)	1(11.1)	1(11.1)	3(33.3)	5(55.5)	8(32)
1 month to 3 months	1(8.3)	2(16.6)	–	3(25)	–	–	–	1(11.1)	1(11.1)	4(16)
4 months to 1 year	–	3(25)	1(8.3)	4(33.3)	–	–	–	1(11.1)	1(11.1)	5(20)
>1 year	3(25)	1(8.3)	–	4(33.3)	–	–	–	–	–	4(16)
Total	5	6	1	12	4	2	1	6	9	25

Bile cultures taken at the time of surgery were positive in 32% of the patients with 50% of these showing growth of E-coli. Postoperatively drains were removed within first week in 17 patients and thereafter in 8 patients. T-tubes were removed within 3 weeks in 80% of patients. Internal stenting was done in 8 patients who underwent Roux-en-y hepaticojejunostomy and almost all of them passed these stents simultaneously within three weeks. External stenting was done in 10 patients undergoing Roux-en-y hepaticojejunostomy and they were removed after 6 weeks in almost all the patients.

Post operatively the bilirubin levels showed improvement in all the patients. The alkaline phosphates levels showed similar improvements as shown in Table 3. The various postoperative complications observed in our patients are tabulated in Table 5.

The mean hospital stay in the patients in our study was 26 days, ranging from 14 to 42 days. Out of 25 patients in our study 22 survived and 3 died (overall mortality rate of

12%). One patient died of hepatorenal shutdown with septicemia, second patient died of septicemia and third patient died of upper GI bleed. Patients who died of these complications were diagnosed type II stricture, type III stricture and type III bile duct injury respectively. All the 22 alive patients were followed till June 2007 with a mean follow up of 45.27 months (4 months to 111 months). All these 22 patients who survived are being followed up at our outpatient clinic regularly. Out of these 22 patients three patients (9.1%) developed stricture on follow up, of which two were managed conservatively and one required revision of hepaticojejunostomy.

Discussion

Cholecystectomy is the commonest procedure that leads to bile duct injuries. Although infrequent in expert hands, it is

Table 2 Clinical presentation

Clinical features	Bile duct strictures (n=12)				Bilioma (n=4)	Bile duct injury (n=9)				Total (n=25)
	Type I stricture n(%)	Type II stricture n(%)	Type III stricture n(%)	Total n(%)		Type I bile duct injury n(%)	Type II bile duct injury n(%)	Type III bile duct injury n(%)	Total n(%)	
Pain RHC	4(33)	6(49.6)	1(8.3)	11(88)	4(100)	1(11)	1(11)	6(66)	8(88)	23(92)
Fever	4(33)	5(41.5)	1(8.3)	10(80)	4(100)	–	1(11)	4(44)	5(55)	19(76)
Vomiting	1(8.3)	–	–	1(8.3)	1(25)	–	1(11)	–	3(33)	5(20)
Discolouration of eyes	4(33)	6(49.6)	1(8.3)	11(88)	2(50)	–	1(11)	6(66)	7(77)	20(80)
Abdominal distension	2(16.6)	1(8.3)	1(8.3)	4(33)	1(25)	–	–	–	–	5(20)
Discolouration of urine	2(16.6)	5(41.5)	1(8.3)	8(66)	1(25)	–	1(11)	6(66)	7(77)	15(60)
Clay coloured stools	–	2(16.6)	–	2(16)	–	1(11)	–	3(33)	4(44)	7(28)
Drainage via drain	1(8.3)	1(8.3)	–	2(16)	1(25)	–	–	–	–	3(12)
Itching	2(16.6)	–	1(8.3)	8(66)	–	–	1(11)	3(33)	4(44)	12(48)
Fistula	–	–	–	–	–	–	–	1(11)	1(11)	1(4)
Icterus	3(25)	4(33)	1(8.3)	8(66)	2(50)	1(11)	1(11)	5(55)	7(77)	17(76)
Tenderness	–	4(33)	1(8.3)	5(41)	4(100)	1(11)	1(11)	5(55)	7(77)	16(64)

Table 3 Preoperative and postoperative investigations

Investigations	Bile duct strictures(n=12)						Bilioma						Bile duct injury (n=9)						Total					
	Type I stricture		Type II stricture		Type III stricture		Total		Bilioma		Bile duct injury (n=9)		Total		Type I bile duct injury		Type II bile duct injury		Type III bile duct injury		Total			
	n=5		n=6		n=1		n=12		n=4		n=2		n=9		n=1		n=6		n=9		(n=25)			
	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS	BS	AS		
Hb(g/dL)	11	10.8	10.8	10.7	9.2	9.0	10.3	10.1	10.2	9.4	9.2	9.0	10.2	8.2	9.2	6.9	9.5	8	10.0	8.82				
TLC/ μ L	6	6.5	4	4.2	6	8	5.3	5.5	16	12	14	11	14	10	18	10	15.3	10.3	12.2	11.1				
Lymphocytes/ μ L	20	16	18	14	16	14	18	14.6	20	24	18	22	14	10	12	8	14.6	13.3	17.5	17.3				
Neutrophils/ μ L	60	70	64	68	70	75	64.6	71	80	70	80	70	82	78	70	64	77.3	70.6	73.9	72.2				
Platelets(10^9 /L)	190	180	194	200	176	175	186	185	184	180	200	168	210	200	168	174	192.6	180.6	187.5	181.8				
Bilirubin(mg/Dl)	3.4	3.0	3.6	2.8	4.9	2.0	3.9	2.6	17	8.4	14	8	12	8.2	16	7	14	8.4	11.65	6.46				
Protein(g/dL)	6.9	6.4	6.4	6.0	6.2	6.0	6.5	5.4	5.9	3.2	7.0	4.0	6.2	6.1	6.0	4.0	6.06	5.4	6.15	4.66				
Albumin(g/dL)	4.2	4.1	3.5	3.0	3.6	3.4	4.7	3.5	4.0	3.0	4.0	3.0	4.2	2.8	6.1	3.1	4.7	5.0	4.46	3.38				
ALP(IU/L)	500	200	620	400	500	210	540	270	680	400	800	400	820	300	720	152	780	284	666.6	318				

BS = before surgery

AS = after surgery

usually encountered when comparatively inexperienced surgeons are operating. The majority of bile duct injuries are recognised during the early postoperative period and with appropriate management, the long term results are acceptable. However, with unrecognized or inappropriately managed strictures recurrent cholangitis, jaundice and even biliary cirrhosis may develop and if they are recognised at the time of initial surgery it may be appropriate for the initial surgeon to repair it, if experienced in doing so, otherwise the patient should be referred to a centre that has experience with these injuries.

The incidence of bile duct injuries in our hospital is comparable with those reported in various studies [2, 3]. The mean age of our patients was 41.48 years, very similar to that reported by others [7, 8]. The finding may be related to the higher incidence of cholecystitis in patients of these ages. A proposed risk factor in the occurrence of biliary tract injuries in middle age patients is the presence of inflammatory changes in the area of the portal triad that obscure normal anatomic features. Patient sustaining a bile duct injury after cholecystectomy present in early postoperative period whereas bile duct stricture present months to years after original operation with symptoms of cholangitis. Most of the bile duct injuries are not recognised at the time of cholecystectomy. Clues to possible intraoperative injury include persistent abdominal pain, unexpected bile leak, abdominal distension, vomiting, fever, itching and these should be evaluated accordingly. Riggs et al. [9], Davidoff et al. [10] and Trerotola et al. [11] have conducted studies and have emphasized the importance of early aggressive investigations in diffuse abdominal pain, fever, malaise or liver function abnormalities after laparoscopic cholecystectomy. In a study of laparoscopic cholecystectomy injuries conducted by Maderiaga et al. [12], they found that the most common clinical manifestation was abdominal pain as a result of bile peritonitis (40%), followed by fever and jaundice as a result of obstructive cholangitis (26%). In our study 76% of patients were jaundiced, this variation is because only one patient was recognised on table in our study compared to 26% recognised intraoperatively in the study conducted by Maderiaga et al. [12].

In the study by Raute et al. [13], of the 64 patients of bile duct injury, 48 were referred patients and out of 16 patients that occurred in their hospital 14 injuries were recognized intraoperatively. In our study only one patient was recognized intraoperatively and jaundice was present in 76% of patients, this difference may be due to routine intraoperative cholangiography done in their study. The most common diagnostic modality for diagnosis of bile duct injury was ERCP in 73%, followed by USG abdomen in 27% in a study by Asbun et al. [14] USG, ERCP, P.T.C was done on 92%, 64%, and 12% respectively in our study. Helmy et al. [15] conducted a study on 22 patients of bile

Table 4 Operative procedures performed

Diagnosis	Surgery performed			
	CBD exploration with T-tube drainage <i>n</i> (%)	Exploratory laparotomy with on needle closure of ooze <i>n</i> (%)	Exploratory laparotomy with drainage of bilioma <i>n</i> (%)	Roux-en-Y hepaticojejunostomy <i>n</i> (%)
Stricture (<i>n</i> =12)	1(20)	0(0)	0(0)	11(61.1)
Bilioma (<i>n</i> =4)	2(40)	1(100)	1(100)	0(0)
Bile duct injury (<i>n</i> =9)	2(40)	0(0)	0(0)	7(38.9)
Total	5	1	1	18

duct injury. The diagnostic modalities were USG abdomen, ERCP, P.T.C, T-tube cholangiography, CT, HIDA scan in 100%, 82%, 32%, 9%, 4%, 4% respectively. USG abdomen is the commonest and first diagnostic modality for bile duct injuries but ERCP, PTC, HIDA scan defines the level and confirms the diagnosis. ALP and bilirubin levels are raised in bile duct strictures due to cholestasis and in case of above normal levels in postoperative period, should raise the doubt of bile duct injury [16].

Our study revealed overall dilatation of IHBR in 69.6%, similar to study conducted by Bergman et al. in 1996 [1]. In their study dilatation occurred in 89% of patients of biliary stricture and 29% in patients with bilioma. Fluid collection was noted in 20% of patients. In their study on 47 patients, ERCP was performed in 45 patients and established the diagnosis of bile leakage or stricture. Although in biliary strictures retrograde cholangiography showed a total stop and this was of diagnostic importance, the exact proximal extent of the lesion could not be determined and requires PTC [1].

Intra-operative findings in our study were similar to those reported by Way et al. [17] and Bergman et al. [1]. Less number of laparoscopic operations are done in Kashmir valley, so fewer patients with laparoscopic CBD injuries occur in relation to open cholecystectomy. Way et al. [17] in his study had noted class I type of bile duct injury in 7%, class II in 22%, class III in 61%, and class IV in 10%, as seen in our study. Bergman noted minor bile duct leaks in 33%, major bile duct leaks in 20%, complete transection in 28% and strictures in 17% of patients in his study [1].

The goal of operative management of bile duct injuries is establishment of bile flow into the proximal gastrointestinal tract. This has to be achieved in a manner that prevents cholangitis, sludge or stone formation, stricture/restriction and biliary cirrhosis. This goal is best accomplished with a tension-free anastomosis between healthy tissues. A number of surgical alternatives exist; these include end-to-end repair, choledochojejunostomy/hepaticojejunostomy. Roux-en-y hepaticojejunostomy was done in majority of our patients. Henry et al. [18] compared surgery and balloon dilatation and found a successful outcome was achieved in 88% of surgery and 55% of balloon dilatation patients. Of the 25 patients

managed surgically, recurrent strictures occurred in 3(12%) at 20, 30, 78 months of follow up. Nine of 20 patients (45%) managed with balloon dilatation have developed recurrent strictures. All of these nine recurrent problems became apparent within 36 months of the initiation of balloon dilatation [18]. Csendes A et al. [19] reported poor results in one series, in which 29 of 36 patients with primary end-to-end repair developed postoperative strictures within 4 years. Although a number of alternatives for repair of bile duct strictures exist, the best results have been achieved with choledochojejunostomy or hepaticojejunostomy [6, 7, 20, 21]. Lygia et al. [22] conducted a study and found that out of a total of 64 reparative operation performed by the primary surgeon or another surgeon with similar experience, only 11 (17%) were successful and out of 46 repairs performed by tertiary care biliary surgeons, 43(94%) were successful and in cases of successful anastomosis, absorbable suture material was used in 96% of patients. Restructure rate in our study is comparable with those reported in earlier studies [18, 22].

In a study by Pitt et al. [20] the organisms cultured most frequently at biliary surgery were *E. coli*, *Enterococcus*, *Klebsiella* and *Pseudomonas* in that order, which is in accordance with that seen in other studies. In our study, T-tubes were removed at about 3 weeks in 80% of patients. If the duration is less than two weeks there is not enough time to form a strong fibrous tract. Moreaux J [23] recommended leaving the T-tube in for three weeks to minimise intraperitoneal leakage [23]. All patients had normal T-tube cholangiogram before removal of T-tube. Abdominal drains were removed from 5th to 28th postoperative day. In our study internal stenting was done in all the cases of hepaticojejunostomy and they were allowed to pass themselves through GIT of their own. Stenting after Roux-en-y hepaticojejunostomy remains controversial, there is an increasing trend away from stenting if an adequately wide anastomosis is done, and whether their use contributes to prevention of restriction is still unsettled. The higher incidence of wound infection in our patients (32%) in comparison to other studies can be attributed to low albumin and protein levels in our patients [15]. Improve-

Table 5 Postoperative complications

Complication	Diagnosis			
	Stricture (n=12) n(%)	Bilioma (n=4) n(%)	Bile duct injury (n=9) n(%)	Total (n=25) n(%)
Wound infection	5(41.7)	2(50)	1(11.1)	8(32)
UTI	2(16.7)	0	1(11.1)	3(12)
Bile leak	1(8.3)	0	0	1(4)
Cholangitis	0	0	0	0
Intraabdominal collection	0	0	0	0
Total	8(66)	2(50)	2(22)	12(48)

ment in liver functions was seen in all patients following repair of CBD injury and on follow up the general condition and nutritional status of all these patients showed significant improvement.

From April 1993 to July 1995 altogether 3860 procedures were enrolled in the Norwegian National Cholecystectomy registry [24]. The various postoperative complications were sepsis, wound infection, bleeding, pancreatitis, RTI, thrombosis in 7(12%), 4(7%), 2(3.5%), 3(5%), 8(14%), 1(1.75%) patients respectively. Rossi et al. [25] noted in their series of 11 patients with post laparoscopic cholecystectomy bile duct injuries that there was an average total hospital stay of 28.6 days. The study entitled “long term follow up after bilioenteric anastomosis for benign bile duct stricture was conducted by William H et al. [26] and found overall length of hospital stay for entire group was 7.6 days (range 6–8 days) and overall mean post surgical stay was 6.2 days (range 5–16 days). This is in contrast to the duration of 26 days in our study, this difference may be due to fact that our patients are from far flung areas and are kept in hospital for a longer period of time till they recover completely. Out of 25 patients in our study 22 survived and 3 died. This is similar to studies by Stewart et al. [22] and Henry AP et al. [18]. In a study conducted by Raute et al. [13] on 64 patients, 54 were managed surgically and 10 patients were managed conservatively, there were 9 deaths (16%) observed postoperatively, 7% were related to surgery and 9% were unrelated deaths. There were deaths in those patients where strictures had developed after cholecystectomy and primary repair was done. All deaths in our study were related to sepsis and multiple organ failure and were not related to procedure performed. These findings are similar to study by Helmey et al. [15] and Buanes et al. [24] in their study out of 57 patients of bile leak, 5(8.7%) died because of postoperative complications. One patient died during hospital stay due to pulmonary embolism, another died of liver metastasis 6 months later due to ovarian carcinoma.

Since bile duct injury is associated with life long morbidity, it is always advisable to delineate the anatomy at callot's triangle clearly and in case of doubt it is better to

come out with cholecystostomy or subtotal cholecystectomy or call a senior surgeon for help. Injury detected and repaired at the time of initial surgery carries the best results. Post operatively detected injuries should be referred to surgeons experienced in the field.

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