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ENDOSCOPIC MANAGEMENT OF BILIARY LEAK AFTER CHOLECYSTECTOMY. AN INITIAL STUDY

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Biliary leak after cholecystectomy ranges from 0.1% to 3% and is more common with laparoscopic choleystectomy than with open procedure. Endoscopic management for postcholecystectomy biliary leak was developed to avoid the high morbidity and mortality rates associated with surgical therapy. The aim of this prospective study was to evaluate the initial results of endoscopic management of patients with biliary leak after cholecystectomy. Between July 1999 and July 2002, 31 patients (18 men and 13 women, aged from 16 to 67 with mean age 49 + 12.1 years) underwent endoscopic management for postcholecystectomy bile leak in the Endoscopy Unit of El-Minia University Hospital. The mean time from cholecystectomy to ERCP was 6.9 + 3.2 days. Presenting clinical features included abdominal pain in 25 patients (80.6%), jaundice in 7 patients, biliocutaneous fistula in 8 patients (25.8%) and biloma in 7 patients (22.6%). ERCP successfully demonstrated the precise location of the leak in all cases. The leak originated from the cystic duct in 16 patients (51.6%), the common bile duct (CBD) in 10 patients (32.2%), and the right hepatic duct in 5 patients (16.1%). Methods of endoscopic treatment included endoscopic sphincterotomy (ES) in 4 patients (12.9%), endoscopic stenting in 8 patients (25.8%), endoscopic sphincterotomy and stenting in 14 patients (45.1%), endoscopic sphincterotomy and naso-biliary drainage tube (NBDT) in 3 patients (9.6%). Endoscopic management was effective in 29 of 31 patients (93.5%), safe, without mortality and the reported complications were treated effectively by endoscopic management. The mean hospital stay for treatment of the leak was 6.1 + 4.3 days. The patients were free of biliary symptoms at a mean follow-up period of 12 + 6.2 months (range 9 – 30 months) after completion of endoscopic therapy. Surgical therapy was done in two patients of complete transection of CBD.

Conclusion: ***ERCP and endoscopic procedures are safe and effective in the diagnosis and treatment of biliary leak after cholecystectomy. Long-term follow-up is required in patients who undergo endoscopic drainage for detection of subsequent biliary stricture formation. Surgical repair of completely transected CBD is still the standard treatment.***

Key words: Endoscopic management- biliary leak- cholecystectomy.

INTRODUCTION

Bile leakage is a well-recognized complication of cholecystectomy with a reported incidence of 0.1% to 0.5% after conventional cholecystectomy [1,2,3] and 0.5% to 3% after laparoscopic cholecystectomy [1,4]. The majority of postcholecystectomy leaks occur from the cystic duct stump [4,5]. ERCP plays a definite role in establishing the diagnosis of biliary leak, and as a therapeutic modality by enabling endoscopic procedures such as sphincterotomy, nasobiliary drainage, stenting, or a combination of any of the above [6,7].

In this prospective study, the aim was to evaluate the initial results of endoscopic management of patients with biliary leak after cholecystectomy.

PATIENTS AND METHODS

Between July 1999 and July 2002, 31 patients with post cholecystectomy biliary leak were admitted to El-Minia University Hospital and included in this prospective study. Patients with post traumatic biliary leak were excluded from the study. A detailed informed consent was taken from all patients.

The mean time from cholecystectomy to ERCP was recorded. Clinical sheets were done for all patients. Relevant symptoms, signs, and biochemical test results were recorded, as well as the results of noninvasive imaging investigations (abdominal ultrasonograpy and/or CT scanning).

Antibiotic (third generation cephalosporin) was given intravenously one hour prior to the procedure and then every 12 hours for 2 days, or for 5 days if biloma was present. Patients were kept fasting for at least 6 hours before the procedure. An intravenous line was established in the right arm since the patients were positioned partially on the left arm and appropriate monitoring was initiated. Endoscopic procedures were performed with the TJF 200 side-viewing duodenoscope (Olympus Corp., Japan). A cholangiogram was performed in each case. Endoscopic sphincterotomy (ES) was performed with a standard papillotome and the size of leak was estimated to be small or large based on the amount of extravasated contrast noted to flow from the ductal disruption. ES was performed if needed to remove stones or to facilitate stent placement.

If access to the bile duct could not be achieved by conventional methods, a needle knife papillotome was used for sphincterotomy. Stents or nasobiliary drainage tube (NBDT) were inserted according to standard techniques.

Stents or NBDT were removed after a follow-up cholangiogram to confirm healing of the leak. Patients were followed up after endoscopic therapy for a period of 9 to 30 months, with a mean of 12 + 6.2 months by serum bilirubin, alkaline phosphatase and abdominal ultrasonography.

Surgical treatment was performed if endoscopic treatment failed. Bismuth[8] classification for extrahepatic biliary injury was used in the operative cases as follow: Level 1, injuries involved the common duct with a normal hepatic duct stump of 2cm or greater; level II, injuries with a hepatic duct stump length of less than 2 cm; level III, high stricture with a preserved ductal confluence; level IV, destruction of confluence; level V injuries of the right sectorial duct with or without involvement of the common duct.

An injury with a long segment of preserved common duct (Bismuth I) was reconstructed with a Roux limb of jejunum. An end-to- side single- layered anastomosis was created to the proximal end of the Roux limb. Fine-caliber interrupted absorbable sutures were employed. The anastomosis was drained through the liver or with a T tube if adequate healthy proximal hepatic duct was available. A 60 cm jejunal loop was constructed. If this was difficult, an alternative was to pass a catheter through the anastomosis via the Roux limb and then secured to the anterior abdominal wall. The left duct was used for anastomosis if the common bile duct length was insufficient (Bismuth II-V). The left hepatic duct was opened in its long axis on the anterior surface, and a side-to-side hepaticojejunostomy was created then stenting of the hepaticojej-unostomy was achieved.

Statistical analysis

Descriptive data were expressed as mean + standard deviation or medians and ranges for continuous variables and as number and percent for categorical variables.

RESULTS

Study population

Between 1999 and 2002, 31 patients underwent ERCP for post cholecystectomy bile leak. The patients were 18 men and 13 women, with a mean age of 49 + 12.1 years, range 16-67 years. The bile leak followed open cholecystectomy in 18 patients (58.1%) and followed laparoscopic cholecystectomy in 13 patients (41.9%). Seventeen patients (54.8%) were referred from other general hospitals, 15 patients (48.4%) followed open and 2 patients (6.4%) followed laparoscopic cholecystectomy. In our department, we had 14 patients (45.1%) subjected for the initial cholecystectomy, 8 patients (25.8%) had laparoscopic cholecystectomy, and 6 patients (19.4%) had open cholecystectomy.

Clinical presentations and investigations:

The mean time from cholecystectomy to ERCP was 6.9 +3.2 days (range 1-53 days). Fifteen patients (48.4%) presented within 3 days of surgery, whereas 11 patients (35.5%) presented from 6 days to one month after the operation. Five patients (16.1%) were referred more than 1 month after cholecystectomy.

The presenting clinical features were shown in (Table1). Abdominal pain was the main presenting symptom being encountered in 25 patients (80.6%).

Transabdominal imaging with US and/ or CT scanning revealed subhepatic fluid collections in 7 patients (22.6%). Exploratory laparotomy was undertaken in 4 patients (12.9%) before referral, that failed to identify the site of leakage in each case.

Biochemical test results immediately before ERCP were as follows: total bilirubin 0.9 to 12.8 mg/dl, with a mean of 5.8 + 2.8 mg/dl (normal is less than 1.2 mg/dl), alkaline phosphatase 59 to 1021 IU/L, mean 243 + 119.5 IU/L (normal, 35 to 125 IU/L), aspartate aminotransferase 17 to 321 IU/L, mean 73 + 31.5 IU/L (normal less than 41 IU/L), and WBC count 5300 to 20,000 cells/dl, mean 11.443 + 4.6 cells/dl (normal, 4000 to 11,000 cells /dl) (Table 2).

Endoscopic management

ERCP successfully demonstrated the precise location of the leak in all cases. Extravasation of contrast originated from the cystic duct was noticed in 16 patients (51.6%), the CBD in 10 patients (32.3%), and from the right hepatic duct in 5 patients (16.1%) (Table 3). The size of the leak was estimated during cholangiography to be small in 22 patients (70.9%) and large in 9 patients (29.1%). Eleven patients (35.48%) had concomitant biliary tract stones that were treated endoscopically. The CBD diameter was normal in 20 patients (64.5%) and dilated in 11 patients (35.5%). The methods of endoscopic treatment and subsequent outcome for patients are shown in (Table 3).

Endoscopic sphincterotomy was done in 4 patients (12.9%) (Fig.1), endoscopic stenting in 8 patients (25.8%), combined sphincterotomy and stenting in 14 patients (45.2%) (Fig. 2), sphincterotomy and NBDT in 3 patients (9.7%). Sizes of stents were 10 F in 10 patients (32.3%), and 7F in 12 patients (38.7%) (one patient received two 7F stents); a 7F NBDT was placed in 3 patients. Bilomas were detected in 7 patients (22.6%) and was evacuated by percutaneous drainage in 5 cases (16.1%) and open drainage in one patient (3.2%). In one patient no specific therapy was directed at the biloma itself and the treatment of the biliary leak was the only treatment used.

The 3 patients treated with ES and NBDT had the device in place for 1 week to monitor drainage from the duct leak. The follow-up nasobiliary cholangiogram showed cessation of the leak and the tube was then removed.

Stents were left in place for 1 to 16 weeks, (mean 4.2 + 2.6 weeks). Four patients (12.9%) were successfully treated with ES alone (Table 3).

The length of hospitalization after ERCP for treatment of leak ranged from same day discharge to 42 days with a mean length of hospital stay 6.1 + 4.3 days.

In total, 29 of 31 patients (93.5%) underwent successful endotherapy and were free of biliary symptoms at a mean follow-up of one year after completion of endoscopic therapy. In addition, no evidence of ductal dilatation or serum liver enzymes elevations has been noted in any of these patients.

Endoscopic approach was safe and without mortality. The reported complications were treated effectively by endoscopic management. Bleeding at site of sphincterotomy occurred in 2 cases (6.4%) and was controlled by coagulation current. Stent occlusion occured in 1 case (3.2%) and was treated by stent exchange. Failure of endoscopic management was recorded in 2 cases (6.4 %), due to completely transected CBD (Fig. 3) and surgical intervention was done.

The first patient had a long segment of preserved common bile duct (Bismuth I), and was treated by a Roux-en-Y choledochojejunostomy with stent for the anastomosis and drainage for the subhepatic space. This patient had successful outcome. The second patient had insufficient duct length for anastomosis, so left duct was used for anastomosis and hepaticojejunostomy was created. The patient developed biliary and enteric leakage and died from sepsis.

Table (1)*: Clinical presentation*

Clinical presentation	Number	Percentage
Abdominal pain	25	80.6
Nausea, vomiting	11	35.5
Biliocutaneous fistula	8	25.8
Jaundice	7	22.6
Biloma	7	22.6
Fever	7	22.6
Vomiting	6	19.3

Table (2): *Biochemical tests results in 31 patients*

Test	Range	Mean ± SD
BR (mg/dL)	0.9- 12.8	5.8 ± 2.8
AP(U/L)	59 - 1021	243 ± 119.5
AST (U/L)	17 - 321	73± 31.5
ALT(U/L)	25 - 365	82 ± 36.5
WBC (cell/dL)	5300 - 20000	11.443 ± 4.6

BR= bilirubin; AP= Alkaline phosphatase; AST= Aspartate aminotransferase; ALT= Alanine aminotransferase WBC= white blood cell count.

Table (3): ***Methods of endoscopic treatment and subsequent outcome for 31 patients with a post cholecystectomy biliary leak***

Method of treatment	No. of patients	Site of leak Cystic duct	Common bile duct	Right hepatic duct	Technical success (%)	Leak healed (%)
ES alone	4	1	1	2	100%	100%
Stent alone	8	5	3	0	100%	100%
ES and stent	14	7	4	3	100%	100%
NBDT*	3	3	0	0	100%	100%
Diagnostic ERCP only**	2	-	2	-	-	-
Total	31	16	10	5	93.5%	93.5%

**** NBDT, Naso-biliary drainage tube. ** Two cases of complete transection of CBD with failure of endoscopic management***

Fig. (1): Endoscopic sphincterotomy with a standard papillotome

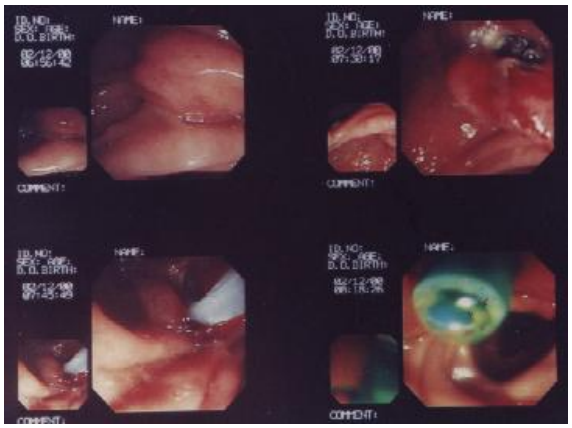

Fig. (2): Continuous bile flow through large sized stent 10 French

Fig. (3): Complete transection of CBD with leakage of the contrast

DISCUSSION

Cholecystectomy is the preferred method for treatment of symptomatic gallstone disease. The incidence of bile injury occuring in association with cholecystectomy ranges from 0.1% to 3% and is more common with laparoscopic cholecystectomy than with open procedure[9]. In the present study, the majority of biliary leak (58.06%) was after open cholecystectomy. This may be due to wide practice of open cholecystectomy in General Hospitals from which 17 cases (54.8%) were referred. However, in our department, we had 8 of 14 cases (57.1%) which were after laparoscopic cholecystectomy due to the wide practice of the laparoscopic technique in our department.

The clinical presentation of postoperative bile duct injury includes symptoms such as pain, fever, cholestasis, jaundice, persistent bile drainage through drains [10] which may persist for a few days to weeks [11]. In a study by Mergener et al., [12] abdominal pain was the commonest symptom (93%). Similarly, in this study, the commonest clinical presentation was the abdominal pain (80.6%). Of the total 31 studied patients, 12 had hyperbilirubinemia, the mean value of which was 5.8 + 2.8 mg/dl at the time of presentation. The rise in bilirubin was mild, being consistent with other reports[11].

Imaging studies are helpful for confirming the diagnosis and helping to decide upon subsequent therapy [13]. Abdominal ultrasonography and CT scan can detect intraabdominal bile collection [14,15] while ERCP provides an accurate diagnosis of the site of leak in the majority of cases. Percutaneous transhepatic cholangiography (PTC) may be performed to delineate the site of injury in cases of complete transection of CBD[16]. In the present study, PTC was done for two cases to better define the biliary anatomy in case of complete transection of CBD.

Abdominal CT demonstrated a fluid collection in 7 patients (22.6%) with a drainage procedure eventually being performed in 6 patients (19.4%) while no specific therapy was undertaken in one patient, who did well with the drainage of biliary tree only and this was similar to other series [5,15].

In the present study, an interesting finding was the delay in referral for endoscopic therapy of bile leaks. Although 15 patients (48.4%) presented within 3 days, 11 patients (35.5%) presented from 6 days to one month after the operation and 5 patients (16.1%) presented more than one month after cholecystectomy. So the mean duration before presentation was 6.9 + 3.2 days after cholecystectomy.

Once recognized, bile duct leak can be managed in several ways. Although laparotomy was the standard treatment in the past, endoscopic procedures have now replaced this procedure as the first line of management [17,18].

Our study confirmed the findings of others[17,18] that endoscopic therapy in general is both safe and effective in management of post cholecystectomy biliary leak. All specific treatments were completed without major morbidity and permanent closure of the leak occurred in 29 of 31 cases (93.54%). While the results for surgical repair of bile duct injuries are less favourable and the associated morbidity and mortality rates are high [19,20,21]. In the present study, surgical treatment was done in two cases with successful outcome in the first patient and fatal outcome in the second patient. Fistulas that occur after reoperation are noted in approximately one third of cases, and strictures which are usually manifest within 3 years of injury may occur in up to 37% to 50% of surgically treated patients [19,21,22,23]. It is too early to know whether stricture formation will be an important problem in our patients because mean follow-up has been relatively short (12 months). However, this complication is unlikely because it has not been reported in other endoscopic series[19,21,22] and most of our patients had cystic duct rather than common bile duct leaks.

In our study, all specific endoscopic treatments achieved equally good results. ES or stents used alone and ES in combination with stents orNBDT were similarly effective. This observation tends to support the application of the simplest and least invasive method of management. The presumed benefit of an endoprosthesis or sphincterotomy is to reduce or eliminate the intraductal pressure gradient maintained by the sphincter of Oddi and to divert bile into the duodenum and away from the site of leakage. It is not known which method best achieves this goal. ES may fail when leaks are large or ductal transection has occurred. The CBD in 64.5% of our patients was not dilated as a result of decompression from the leak, and this has been considered a consistent observation made by others [24,25]. Sherman et al., [26] reported a high complication rate (11%) for ES performed in patients with normal caliber bile ducts. In our study, ES was not performed in cases of normal caliber CBD to avoid such a high complication rate.

The use of NBDT in patients with biliary leaks gave favourable results. This treatment theoretically could provide maximal decompression by the application of suction rather than simple reduction in the ampullary pressure gradient. These catheters are easily placed without ES and can be removed without endoscopy, and serial cholangiography can be used to monitor the status of the leak.

Our results show that stents are effective in the treatment of patients with post-cholecystectomy biliary leak. In most reported series stents were inserted with the proximal end positioned above the site of leakage [27,28,29,30]. It

is assumed without proof that mechanical occlusion of the breach in the bile duct by the physical presence of the stent is an added advantage for this method [30]. In our study two patients with intrahepatic duct leaks were successfully treated with relatively short stents positioned below the leak, and others have treated similar patients with this technique with favourable results [31]. Biliary decompression through elimination of trans-papillary resistance is probably the most important function served by the stent. Long stents inserted for the purpose of physically occluding the leak site may not be necessary.

It appears that the type of treatment chosen was influenced largely by the size of the leak and the associated CBD stones. Endoscopic stenting (7F) or NBDT was effective for closing small size leaks. The use of ES and placement of stent (10F) was effective for closing large size leaks, ES being performed largely to facilitate stent placement in these patients. ES alone or with stenting was performed for associated CBD stones.

The length of time to closure of the bile leak was from 4 to 6 weeks which appeared to be a reasonable period for healing in most patients and this was consistent with findings of others [5,15,32,33,34].

Finally, the mean hospital stay for treatment of the leak was 6.1 + 4.3 days. The need for percutaneous or surgical drainage of a biloma was the primary reason for prolongation of hospital stay. Patients who have undergone endotherapy for biliary injuries require long-term follow-up [34]. This should, at a minimum, include serum liver function tests every 6 to 12 months and liberal use of ultrasound examinations in patients in whom recurrent biliary colic or serum liver test abnormalities develop. Although the successfully treated patients are symptoms-free at a minimum of 1 year of follow-up after therapy, previous surgical and radiological data suggest that bile duct strictures can recur for up to 7 years after apparently successful treatment [35,36]. Thus, it is possible that endotherapy for biliary leak may need to be repeated years after the initial insult.

CONCLUSION

ERCP and endoscopic procedures are safe and effective in the diagnosis and treatment of biliary leak after cholecystectomy. Long-term follow-up is required in patients who undergo endoscopic drainage for detection of subsequent biliary stricture formation. Surgical repair of completely transected CBD is still the standard treatment.

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