

Endoscopic management of post operative bile duct injuries

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Abstract

Objective: To evaluate the pattern of post-operative bile duct injuries and their subsequent endoscopic management.

Methods: The prospective, non-randomised, cross-sectional study was conducted at the endoscopic suite of Surgical Unit-IV of the Civil Hospital, Karachi, over a period of three years. A total of 97 patients were included in the study. Post-procedure patients were followed up for resolution of symptoms and cessation of the bile leak. Patients with complete biliary cutoff or transection on Endoscopic Retrograde Cholangio-Pancreatography (ERCP) were advised Magnetic Resonance Cholangio-Pancreatography (MRCP). Average followup of patients in our study was for 3 months. Mann Whitney U test was applied for non-parametric data.

Results: Out of 97 patients in the study, 82(84.5%) presented with post-operative bile leakage and 15(15.5%) with obstructive jaundice. The age of the study population ranged between 20-70 years with a mean age of 40.80 ± 13.45 years. Male-to-female ratio was 1:3. ERCP findings in our study included 41 (42.26%) patients with bile leakage out of which 27 (27.8%) had high-grade leak and 5 (5.1%) had low-grade leak, while 9 (9.3%) patients had Common Bile Duct (CBD) stones. Among the patients, 39 (40.2%) had complete cutoff of CBD. There were 15 patients with strictures and 6 with normal ERCP. As for the bile leaks, 36/41 (87.8%) patients were managed successfully by endoscopic stenting, stone removal or simple sphincterotomy. Of the 41 patients, 5 (12.2%) with bile leak developed biliary stricture on subsequent ERCP. Nine of the 15 patients (60%) with complete cutoff on initial endoscopy were successfully stented on subsequent ERCP after demonstration of biliary continuity on MRCP. Six (40%) patients were referred for surgery.

Conclusion: Patients with postoperative biliary leaks fare much better than those with complete cutoff or strictures. MRCP should be done in all patients where ERCP shows loss of biliary continuity. Re-exploration should be deferred till all other non-invasive modalities have been tried.

Keywords: Bile leakage, CBD injury, ERCP, MRCP, Biliary strictures (JPMA 62: 257; 2012).

Introduction

Iatrogenic bile duct injuries following surgery are a major problem and can be associated with life-threatening complications. Bile duct injuries may follow after several types of abdominal operations e.g. liver surgery, gastrectomy, common bile duct exploration etc. However, majority of post-operative bile duct injuries result from open or laparoscopic cholecystectomy. The incidence of injury has risen with the advent of laparoscopic cholecystectomy from 0.1-0.2% for open to 0.5-2.7% for laparoscopic cholecystectomy.¹

Only 30% of injuries are recognised at the time of operation.² The remaining present as bile leakage, bilioma, peritonitis or abscess formation.³ Late presentation of bile duct injuries is in the form of benign biliary strictures which are usually associated with a broad spectrum of presentations from mild alteration of liver function tests to deep jaundice with complete biliary obstruction, recurrent cholangitis, secondary biliary cirrhosis and liver failure. These injuries

can result from inadvertent surgical damage to bile ducts, inadequate closure of cystic stump, leakage from gall bladder bed or leakage from T-tube site. There is often distal obstruction of common bile duct because of either residual stones and/or strictures.

Post-surgical bile duct injuries have a marked influence on the patient's physical and mental quality of life even at long-term followup. Adequate management of these injuries requires early post-operative diagnosis with a low threshold for performing an ERCP. In the past these injuries have been treated by surgical repair. Advances in endoscopic procedures have provided an alternative option. Injuries diagnosed at the time of surgery are required to be dealt with during the surgery. However, there is no consensus on the treatment of the leaks identified immediately post-operative. ERCP plays a definitive role in establishing diagnosis, defining site, severity of leak, and acts as a therapeutic method.

We report our experience of endoscopic management

of post-operative biliary injuries from a tertiary care hospital.

Patients and Methods

The prospective, non-randomised cross-sectional study was conducted at the endoscopic suite of Surgical Unit-IV of Civil Hospital, Karachi, over a period of three years from January 23, 2007 to December 1, 2009.

A total of 97 patients referred to the unit with post-operative bile leak from wound, drains, intra abdominal collection, obstructive jaundice and sepsis were included in the study. Patients having T-tube in situ, hepaticoenteric anastomosis or gastric bypass were excluded from the study. A pro-forma was filled for each patient at the time of presentation which included details of previous surgery, symptoms at presentation, time interval between surgery and symptoms and details of pre-operative workup (biochemical and haematological testing, ultrasound, MRCP). Approval was taken from the hospital's Ethics Committee.

After taking informed consent, the ERCP was performed by a single experienced endoscopist, under conscious sedation. Prerequisite investigation included liver function tests, ultrasound abdomen, complete blood count and prothrombin time. Endoscopic sphincterotomy was carried out in all patients. In cases of difficulty in cannulation, precut sphincterotomy was done.

Bile duct injuries on ERCP were divided broadly into three groups.⁴ Bile leaks with or without stones, biliary strictures, and complete cutoff of the biliary system. In case of bile leaks with stones, the extraction was carried out with balloon or basket. In cases of high-grade biliary leaks, plastic stents were placed with the advice for removal of stent after 3 months, and for low-grade leaks, only sphincterotomy was carried out. In patients presenting with biliary strictures, plastic stents were placed. In patients with persistent strictures at 3 months, stent exchange with placement of two or three stents was attempted. In patients where cholangitis or jaundice developed due to stent blockage in less than 3 months, stent exchange was done.

Post-procedure patients were followed up for resolution of symptoms, cessation of bile leak and response to stenting in term of relief of jaundice for patients presenting with stricture. Drains and tubes were removed when the drainage was less than 30ml in 24 hours and inadequate biliary drainage was taken as a biliary output of more than 200ml/24 hours for 5 consecutive days.

Average followup of patients in our study was for 3 months by clinical evaluation, liver function tests and ultrasound abdomen. Patients with complete biliary cutoff or transection on ERCP were advised MRCP and if some biliary continuity was demonstrated, then repeat ERCP was done. The rest of the patients were sent for surgical reconstruction.

Bile duct strictures were considered resolved if there was no persistent narrowing on cholangiogram after the removal of stent and normal liver function tests. Data was analysed by using SPSS Version 11.0. Level of significance was taken as $p \leq 0.05$. Mann Whitney U test was applied for non-parametric data.

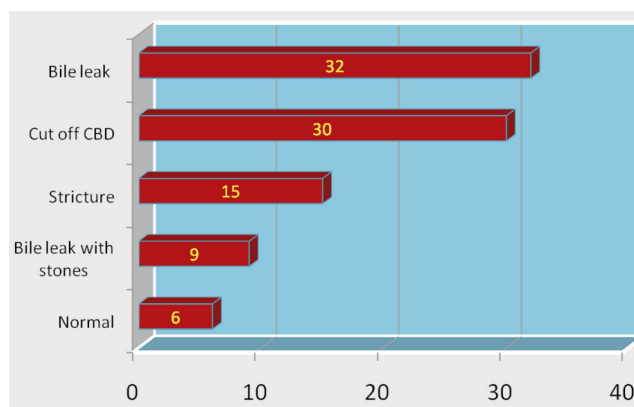
Results

A total of 97 patients presenting with post-operative bile leakage or obstructive jaundice were included in the study. Age of the study population ranged from 20-70 years with a mean age of 40.80 ± 13.45 years. Male-to-female ratio was 1:3 (Table). Majority of referrals were from private hospitals of Karachi and Hyderabad.

Of the total, 82 (84.5%) presented with post-operative bile leakage and 15 (15.5%) patients with obstructive jaundice. Mean bilirubin level in bile leakage patients was 2.58 ± 2.72 and alkaline phosphatase of 484.76 ± 478.05 as

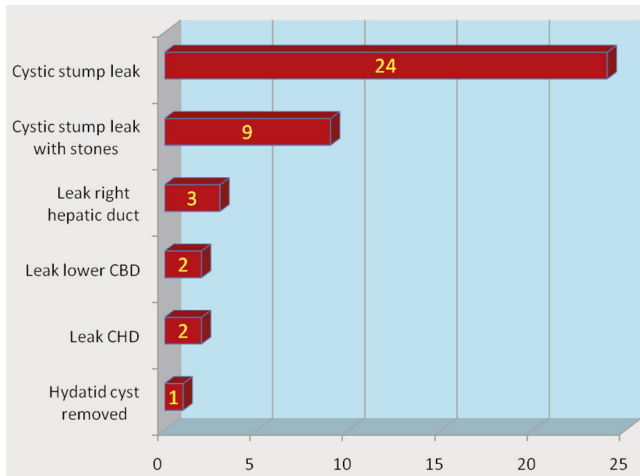
Table: Patient's characteristics.

Characteristics	Value	p
Total patients (n)	97	
Male / Female (Ratio)	24 / 73 (1:3)	
Age range (median) & mean years.	20-70 (40) & (40.86±13.45)	
Presentation (n)		
Bile leak	82	
Obstructive Jaundice	15	
Surgery to procedure		
Bile leak	24.77±24.77 days	0.03
Obstructive Jaundice	40.87±37.46 days	
Bilirubin levels		
Bile leak	2.58±2.72 mg/dl	0.0001
Obstructive Jaundice	13.42±8.03 mg/dl	
Alkaline Phosphatase levels		
Bile leak	484.76±478.05 IU	0.004
Obstructive Jaundice	673.80±357.21 IU	



ERCP: Endoscopic Retragrade Cholaugio-Pancreatography. CBD: Common Bile Duct.

Figure-1: ERCP findings of patients with postoperative biliary injury.



ERCP: Endoscopic Retrograde Cholangio-Pancreatography.
CBD: Common Bile Duct.
CHD: Common Hepatic Duct.

Figure-2: Pattern of bile leak on ERCP.

compared to patients with obstructive jaundice where mean bilirubin was 13.42 ± 8.03 and alkaline phosphatase of 673.80 ± 357.21 .

Findings on imaging post-surgery included normal ultrasound examination in 27 (27.8%) patients, subhepatic/intraabdominal bile collection in 51 (52.6%) patients, dilated intrahepatic ducts in 14 (14.4%) patients and retained stones in 5 (5.2%) patients. Fourteen (14.4%) patients had bile injuries after laparoscopic cholecystectomy, 78 (80.4%) had open cholecystectomy, 3 (3.1%) had laparoscopic cholecystectomy converted to open cholecystectomy, 1 (1%) patient had laparotomy for abdominal trauma and 1(1%) had bile leakage after surgery for hydatid cyst of liver.

Mean number of ERCPs done in each patient were 1.38 ± 0.62 . Fourteen (14.4%) patients had second surgery in the form of exploratory laparotomy prior to being referred for ERCP. Time taken from surgery to ERCP was 2-210 days with a mean of 27.26 days ± 29.73 . Mean presentation time in patients with bile leakage was 24.77 days ± 27.65 and in patients with obstructive jaundice it was 40.87 days ± 37.46 ($p=0.03$).

ERCP findings in our study included 41 (42.26%) patients with bile leakage out of which 9 (9.3%) patients had CBD stones. Out of 32 patients with bile leak without stones, stenting was done in 27 patients with high-grade leakage, while 5 patients with low-grade leakage had sphincterotomy. Besides, 39 (40.2%) patients had complete cutoff of CBD. There were 15 patients with strictures and 6 with normal ERCP (Figure-1). The pattern of bile leak was also noted (Figure-2).

Of the 41 patients with bile leakage, 36 (87.8%) were managed successfully by endoscopic stenting, stone removal or simple sphincterotomy. The remaining 5 (12.2%) patients developed biliary stricture on subsequent ERCP.

Complete cutoff of CBD was seen in 39 patients on initial ERCP. Of the 15 patients that returned with MRCP, 9 demonstrated some biliary continuity. Stents were passed in these patients on subsequent ERCP and were included in the stricture group. The remaining 6 patients were referred to surgery. In a total of 15 patients with strictures, only 1 could not be stented.

Biliary cannulation failed in 5 patients. Six (40%) patients with complete cutoff of CBD on ERCP and MRCP were referred for surgery.

Discussion

Post-operative bile duct injuries can have a crippling effect on the life of the patient as well as the physician. Only 30% are recognised at the time of surgery and in expert hands have a reasonably good prognosis.⁴ Management depends on the timing of the recognition of injury, type of injury, patient's condition and available facilities.

Broadly, bile duct injuries present with either biliary leakage/fistula or with obstructive biliary symptoms. There may be an overlap between these groups.^{5,6} Among our patients, 15.5% presented with obstructive jaundice and 84.5% with bile leakage, but there was considerable overlap seen. Quite a few patients had jaundice with leakage and intra-abdominal collection at presentation.

Patients with obstructive jaundice have a delayed presentation as compared to bile leakage patients. Mean presentation time was 40.87 days as compared to 24.7 days for bile leak patients. These were the patients in whom CBD is either ligated or clipped or there is some damage to the vascularity of CBD resulting in the development of stricture. Delayed presentation up to median 2 months is reported in international studies.⁷ Most strictures are induced by the use of diathermy for control of moderate bleeding in Calot's triangle. So it is necessary to avoid liberal use of diathermy in that zone to prevent this post-operative complication.

Transabdominal ultrasound is often the first investigation carried out to evaluate the patient with post-surgical biliary injuries. Ultrasound is useful for screening for bilioma or ascities or to rule out CBD injury or retained stones, but several studies have shown that early ultrasound for bile leak is inaccurate. Other modalities to be used in diagnosis include cholescintigraphy, CT abdomen, MRCP. The sensitivity of these modalities in detecting bile leakage is 100%, 95% and 95% respectively.⁸

Majority of our patients (53%) presented with intra

abdominal collection, but more than a quarter of the patients (28%) had normal imaging despite having biliary injuries. Hence, normal imaging should not defer further evaluation by ERCP/MRCP.

Bile duct injury during conventional cholecystectomy is within the range of 0.2 - 0.5% but with the advent of laproscopic cholecystectomy this has risen to about 0.5-2.7%.⁹ This trend was not confirmed in our study as 81% of the study population had presented after open cholecystectomy and only 15% after laproscopic cholecystectomy. This could be because being a tertiary care hospital, most referrals were from remote parts as well as private-sector hospitals of Karachi and Hyderabad, where laproscopic cholecystectomy is still not very commonly performed as compared to open cholecystectomy.

Bile duct injuries should be properly evaluated before any surgical intervention is undertaken. This requires a multidisciplinary team effort and a structured stepwise approach to the management of these potentially serious complications of surgery.¹⁰ Of our patients, 13.4% had undergone surgery in the form of exploratory laparotomy before ERCP. All that was achieved during these surgeries was intraperitoneal lavage and insertion of intra-abdominal drains which could be achieved percutaneously as well. Surgery does play an important role in the management of these injuries, but only after proper classification and evaluation of injuries have been done.

ERCP is the current standard of care in the management of post-operative bile duct injuries. In a retrospective analysis of 100 patients with post-cholecystectomy bile leak, ERCP demonstrated a leak in 83% with 60% of them being from cystic duct stump.¹¹ ERCP stenting with sphincterotomy reduces the transpapillary pressure gradient maintained by sphincter of Oddi, thus diverting the bile away from leak into the duodenum as well as removing underlying biliary obstruction which may perpetrate or worsen the ductal defect. The true incidence of post-operative bile duct leakage is not really known since many leaks heal spontaneously.¹² We had 6 patients who on ERCP were not found to have any leakage/obstruction in the biliary system.

Biliary leaks can be from anywhere in the extrahepatic ductal system, commonest being the cystic stump leakage. In our study, 24 patients had cystic duct stump leakage and in 9 patients the leak was associated with stones. There are numerous theories regarding the etiology of cystic duct stump leak, amongst these is displacement of cystic duct stump clip which can be because of faulty technique or abnormal cystic duct morphological features.^{13,14} Necrosis of cystic duct stump proximal to applied clips has also been reported to cause cystic duct stump leak along with ischaemic necrosis caused by devascularisation of cystic duct and

stricturing of common bile duct caused by clipping or suturing close to common bile duct.

The gold standard in the treatment of patients with bile leakage has not yet been established. Endoscopic sphincterotomy reduces the distal bile duct pressure and facilitates closure of leaking cystic ducts. Similarly putting plastic stents reduces sphincter resistance and intraductal pressure gradient, but also cures the leaking point and allows it to heal. These techniques are effective in preventing an unnecessary exploratory laparotomy for finding and closing the leaks, thus resulting in shift in the indication for surgery in patients with post-operative bile leakage.¹⁵

Sandha¹⁶ classified bile leaks as being high- or low-grade depending upon whether leakage of the contrast happened before or after opacification of intrahepatic biliary ductal system respectively. The low-grade leaks are due to small defects requiring increased intraductal pressure to demonstrate the leak. We used this classification in our study for the evaluation of the severity of disease. High-grade leaks were seen in 27/32 (84.3%) patients with bile leaks without stones and 4/9 (44.4%) patients with stones. We used endoscopic sphincterotomy alone for patients with low-grade bile leakage and endoscopic stenting with sphincterotomy for patients with high-grade bile leakage. There are many studies proving the effectiveness of endoscopic sphincterotomy alone in the management of post-operative low-grade bile leaks.^{11,17,18}

There is an ongoing controversy regarding the use of endoscopic sphincterotomy, biliary stenting or any other modality in the management of bile leaks.^{17,19} There are no randomised prospective studies comparing endoscopic sphincterotomy with or without stenting for biliary leakage, but in a large series conducted by Kaffes et al,¹¹ it was shown that stent alone or with endoscopic sphincterotomy (EST) was superior to EST alone. This fact was reinforced by the results of our study where all patients with high-grade bile leak were managed successfully with endoscopic sphincterotomy with stents and leaks stopped over a period of 48-72 hours.

One of the established complications of post-operative bile duct injury is biliary stricture formation. Among our patients, 15.46% were found to have developed strictures and these were managed with stricture dilatation and stenting.

The category of bile duct injury which is least amenable to endoscopic management is biliary cutoffs where the bile duct is either completely transected or tied off at the time of initial surgery. Here the only role of ERCP is in diagnosing or delineating the level of cutoff or complete transection. These are the patients where surgery has to play a definite role in reconstructing the biliary tract. We had 39 patients in our study who were shown to have complete cutoff on ERCP and were advised MRCP for the evaluation of

proximal ductal system. Only 15 patients came back with MRCP and of those 9(60%) had some biliary continuity with proximal system on MRCP. These patients were successfully stented on subsequent ERCP. So it is necessary to have complete proper evaluation of proximal and distal biliary tract before proceeding for surgery and in cases where some biliary continuity is demonstrated on MRCP, repeat ERCP should be attempted.

Hepaticojejunostomy before the advent of advanced endoscopy was considered to be the best treatment for benign biliary strictures.^{20,21} Though having excellent results, the high morbidity and mortality associated with this modality mars the picture. Stricture recurrence rate also remains high (17-25%) in this group.²² The success of endoscopic treatment of benign post-operative biliary strictures is confirmed by several studies, having a success rate of up to 69%.²³ We had 15 patients with strictures out of which 14 were stented successfully. Five patients with biliary leakage on subsequent followup had developed stricture which were managed successfully with dilatation and stenting. One drawback of our study was limited followup of 3 months only. Long-term success of stenting in stricture group could not, thus, be evaluated.

Stent placement in patients with strictures is associated with complications like stent blockage, cholangitis etc., that may limit the role of endoscopic therapy. These can be prevented by placing more than one stent and these can be changed every 3 months till the obliteration of stricture. Several published studies have proven the role of sequential placement of increasing number of biliary stents in the treatment of patients with distal biliary strictures with a success rate of up to 90% after a year.^{24,25} In this study, a maximum of three stents were attempted in all patients with strictures. Only 5/15 patients could be double stented and only one could be triple-stented. The rest of them had only one stent placed.

One local study²⁶ has addressed the issue of endoscopic management of post-surgical bile leaks. It differs from this study on the basis of the number of patients and that this study has included patients with strictures who presented late. Another aspect that was highlighted in this study was the importance of MRCP in patients with bile duct cutoff on ERCP.

The sample size of our study was a serious limitation. Due to the lack of national data, we were not able to calculate the adequate sample size based on population figures. For the purpose, we depended on some previous international studies and gathered data of our 97 patients over three years. One may well consider it as a hypothesis generating study.

Conclusion

Patients with post-operative biliary leaks fare much

better than those with complete cutoff or strictures as 93% of patients with post-operative biliary leak were managed successfully. MRCP should be done in all patients before surgery and in case of continuity with proximal system, repeat ERCP should be done. Besides, re-exploration should be deferred till all other non-invasive modalities have been tried out.

References

- Russell JC, Walsh SJ, Mattie AS, Lynch JT. Bile duct injuries, 1989-1993. A statewide experience. Connecticut Laparoscopic Cholecystectomy Registry. *Arch Surg* 1996; 131: 382-8.
- Flum DR, Cheadle A, Prael C, Dellinger EP, Chan L. Bile duct injury during cholecystectomy and survival in medicare beneficiaries. *JAMA* 2003; 290: 2168-73.
- Davids PH, Rauws EA, Tytgat GN, Huijbregt K. Postoperative bile leakage: endoscopic management. *Gut* 1992; 33: 1118-22.
- Lau WY, Lai EC. Classification of iatrogenic bile duct injury. *Hepatobiliary Pancreat Dis Int* 2007; 6: 459-63.
- Kaman L, Sanyal S, Behera A, Singh R, Katariya RN. Comparison of major bile duct injuries following laparoscopic cholecystectomy and open cholecystectomy. *ANZ J Surg* 2006; 76: 788-91.
- Rossi RL, Schirmer WJ, Braasch JW, Sanders LB, Munson JL. Laparoscopic bile duct injuries. Risk factors, recognition, and repair. *Arch Surg* 1992; 127: 596-601.
- Elhamel A, Nagmuish S, Elfaidi S, Ben Dalal H. Handling of biliary complications following laparoscopic cholecystectomy in the setting of Tripoli Central Hospital. *HPB (Oxford)* 2002; 4: 105-10.
- Eisenstein S, Greenstein AJ, Kim U, Divino CM. Cystic duct stump leaks: after the learning curve. *Arch Surg* 2008; 143: 1178-83.
- Pinkas H, Brady PG. Biliary leaks after laparoscopic cholecystectomy: time to stent or time to drain. *Hepatobiliary Pancreat Dis Int* 2008; 7: 628-32.
- Pitt HA, Miyamoto T, Parapatis SK, Tompkins RK, Longmire WP Jr. Factors influencing outcome in patients with postoperative biliary strictures. *Am J Surg* 1982; 144: 14-21.
- Kaffes AJ, Hourigan L, De Luca N, Byth K, Williams SJ, Bourke MJ. Impact of endoscopic intervention in 100 patients with suspected postcholecystectomy bile leak. *Gastrointest Endosc* 2005; 61: 269-75.
- Coté AG, Ansstas M, Shah S, Keswani NR, Alkade S, Jonnalagadda SS, et al. Findings at endoscopic retrograde cholangiopancreatography after endoscopic treatment of postcholecystectomy bile leaks. *Surg Endosc* 2010; 24: 1752-6.
- Hanazaki K, Igarashi J, Sodeyama H, Matsuda Y. Bile leakage resulting from clip displacement of the cystic duct stump: a potential pitfall of laparoscopic cholecystectomy. *Surg Endosc* 1999; 13: 168-71.
- Li JH, Liu HT. Diagnosis and management of cystic duct leakage after laparoscopic cholecystectomy: report of 3 cases. *Hepatobiliary Pancreat Dis Int* 2005; 4: 147-51.
- Ahmad F, Saunders RN, Lloyd GM, Lloyd DM, Robertson GS. An algorithm for the management of bile leak following laparoscopic cholecystectomy. *Ann R Coll Surg Engl* 2007; 89: 51-6.
- Sandha GS, Bourke MJ, Haber GB, Kortan PP. Endoscopic therapy for bile leak based on a new classification: results in 207 patients. *Gastrointest Endosc* 2004; 60: 567-74.
- Agarwal N, Sharma BC, Garg S, Kumar R, Sarin SK. Endoscopic management of postoperative bile leaks. *Hepatobiliary Pancreat Dis Int* 2006; 5: 273-7.
- Yamaner S, Bilsel Y, Bulut T, Bugra D, Buyukuncu Y, Akyuz A, et al. Endoscopic diagnosis and management of complications following surgery for gallstones. *Surg Endosc* 2002; 16: 1685-90.
- Costamagna G, Shah SK, Tringali A. Current management of postoperative complications and benign biliary strictures. *Gastrointest Endosc Clin N Am* 2003; 13: 635-48.
- Nealon WH, Urrutia F. Long-term follow-up after bilioenteric anastomosis for benign bile duct stricture. *Ann Surg* 1996; 223: 639-45.
- Raute M, Podlech P, Jaschke W, Manegold BC, Trede M, Chir B. Management of bile duct injuries and strictures following cholecystectomy. *World J Surg*

- 1993; 17: 553-62.
22. Johnson SR, Koehler A, Pennington LK, Hanto DW. Long-term results of surgical repair of bile duct injuries following laparoscopic cholecystectomy. *Surgery* 2000; 128: 668-77.
 23. Weber A, Feussner H, Winkelmann F, Siewert JR, Schmid MR, Prinz C. Long-term outcome of endoscopic therapy in patients with bile duct injury after cholecystectomy. *J Gastroenterol Hepatol* 2009; 24: 762-9.
 24. Pozsár J, Sahin P, László F, Topa L. Endoscopic treatment of sphincterotomy-associated distal common bile duct strictures by using sequential insertion of multiple plastic stents. *Gastroint Endosc* 2005; 62: 85-91.
 25. Judah JR, Draganov PV. Endoscopic therapy of benign biliary strictures. *World J Gastroenterol* 2007; 13: 3531-9.
 26. Salih M, Hamid S, Shah HA, Abbas Z, Jafri W. Endoscopic management of Biliary leaks after open and laparoscopic cholecystectomy. *J Pak Med Assoc* 2007; 57: 117-9.
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