

Original Article

Successful Endoscopic Management of Bile Leak: A Single-Center Experience

Vinay Pawar, Nikhil Sonthalia, Sunil Pawar, Ravindra Surude, Qais Contractor, Pravin Rathi

Department of
Gastroenterology, Topiwala
National Medical College,
B Y L CH Hospital, Mumbai,
Maharashtra, India

ABSTRACT **Background and Aims:** Bile leak is a rarely encountered complication most commonly occurring in the setting of biliary tract surgery. Site of leak may be from the gallbladder bed, the cystic duct, or rarely from injury to a major bile duct. Management has evolved with from radical surgery prevalent in earlier days to recent increased expertise in biliary endoscopy. This study aims to determine the impact of endoscopic management in treating symptomatic bile leak and discusses the role of surgery. **Patients and Methods:** In this retrospective study, patients with symptomatic bile leak admitted between 2012 and 2015 to the Department of Gastroenterology of a tertiary care center in Western India were analyzed. Site and extent of bile leak was evaluated using contrast enhanced computed tomography or magnetic resonance cholangiopancreatography. Endoscopic retrograde cholangiopancreatography (ERCP) was mainly used as a therapeutic tool rather than a diagnostic tool. ERCP was used as a primary mode of treatment wherever feasible. Percutaneous biliary drainage was used in technically difficult cases. **Results:** Twenty-seven patients with symptomatic bile leak were identified in aforesaid period. Bile leak in 21 (77.88%) patients was due to postlaparoscopic cholecystectomy injury, while in 6 (22.22%) patients, it was associated with liver abscess. Major bile duct injury was seen in 10 patients with postcholecystectomy status and in 5 patients with liver abscess. Out of 27 cases, 25 (92.59%) were treated with ERCP and 2 (7.40%) with percutaneous drainage. Surgery was not required in any of the patients. Sphincterotomy with stent placement for 6 weeks was effective in 23 (92%) patients, and only sphincterotomy was effective in 2 (8%) patients undergoing ERCP. There was no mortality due to bile leak. **Conclusion:** Most patients presenting with bile leak including major bile duct injury without complete bile duct transection can be successfully treated by endoscopic therapy without the need for surgery.

KEYWORDS: Bile leak, laparoscopic cholecystectomy, therapeutic endoscopic retrograde cholangiopancreatography

INTRODUCTION

Bile leak can be defined as persistent leakage of bile from the biliary tree. Management of gallstone disease has dramatically changed with the introduction of laparoscopic cholecystectomy with associated higher incidence of biliary complications as compared to open cholecystectomy.^[1-3] Bile leak after laparoscopic cholecystectomy is reported in 0.3%–2.7% of patients.^[4-6] This can arise from

the common bile duct (CBD) or hepatic duct (major bile duct injury), but majority arise from the cystic duct stump or a subvesical duct of Luschka.^[6]

Address for correspondence: Dr. Vinay Pawar, Department of Gastroenterology, Topiwala National Medical College, B Y L CH Hospital, Dr. A. L. Nair Road, Mumbai - 400 008, Maharashtra, India. E-mail: docvinu@gmail.com

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Pawar V, Sonthalia N, Pawar S, Surude R, Contractor Q, Rathi P. Successful endoscopic management of bile leak: A single-center experience. *J Dig Endosc* 2017;8:170-5.

Access this article online

Quick Response Code:



Website: www.jdeonline.in

DOI: 10.4103/jde.JDE_57_17

The morbidity and mortality of bile leak is significant if not treated promptly.^[7] The formation of a communication between a liver abscess and bile duct is an uncommon cause of bile leak. Surgical management of a biliary fistula is associated with high morbidity and mortality.^[8]

In the early 1990s, bile leaks were being managed conservatively; with no improvement, a laparotomy was often performed. With the recent advancement in therapeutic endoscopic retrograde cholangiopancreatography (ERCP), requirement of surgery has been tremendously reduced in the setting of bile leak.^[9-11] However, because of rarity of the condition and lack of uniform approach, there is paucity of data in the literature regarding the outcomes of endoscopic approaches in bile leak. There has been no study from India previously published in the literature describing the efficacy of endoscopic management in bile leak. The aim of this study was to analyze the efficacy of endoscopic management of bile leak in a resource-limited setup like India.

PATIENTS AND METHODS

Study design

This was a hospital-based interventional study in which retrospective analysis of prospectively maintained database of patients of symptomatic bile leak was evaluated.

Patient selection

Database of patients referred to the Department of Gastroenterology of a tertiary care hospital in Western India between January 2012 and December 2016 was retrospectively analyzed.

Inclusion criteria: Patients diagnosed as symptomatic bile leak based on history, physical examination, ultrasonography of abdomen, and contrast-enhanced computed tomography (CECT) of abdomen or magnetic resonance cholangiopancreatography (MRCP) who required intervention for management of bile leak were included. Interventions included ERCP-guided biliary drainage or percutaneous biliary drainage (PTBD) or surgical intervention.

Exclusion criteria

Patients who were managed conservatively without any intervention were excluded from the analysis.

Treatment protocol

Once the diagnosis of bile leak was made, patients' standard medical care which included antibiotics, intravenous fluid, pigtail drainage of localized collection, and nutritional support was given to all the patients. Based on the anatomical roadmap obtained by CECT

and/or MRCP, biliary drainage was planned for all symptomatic patients irrespective of their serum bilirubin levels. ERCP with sphincterotomy with or without plastic CBD stenting was the first-line treatment adopted for all the patients. PTBD was considered when ERCP was not technically feasible. Reason for doing PTBD instead of ERCP in two of our patients included the presence of ascites and poor general condition not permitting ERCP. All the patients underwent ERCP to delineate the biliary tree, diagnose the leak and had a therapeutic procedure. Patients with postcholecystectomy bile duct injury were classified according to Strasberg classification and into major and minor bile duct injury according to the extent of involvement. Major bile duct injury included complete transection or partial laceration of the CBD, common hepatic duct, or major segmental ducts at the porta hepatis. Minor bile duct injury includes leaks from the cystic duct, subvesical duct of Luschka, or gallbladder fossa. Decision to do only sphincterotomy or to proceed with CBD stenting was decided during cholangiography at ERCP. Only sphincterotomy was deemed appropriate for minor bile duct injury where it was not possible to negotiate CBD plastic stent across the leak site. For all other cases, sphincterotomy with CBD stenting was done. Wilson Cook CBD plastic stent was used in our patients (7–12 Fr diameter, 10–12 cm length). Repeat liver function test (LFT), CECT abdomen, and/or MRCP were done after 6 weeks of index procedure. Stent removal was deemed appropriate when patient was asymptomatic, LFT normalized, and there was no evidence of leak at cholangiography requiring repeat ERCP done for stent removal. If these criteria were not met, then stent exchange was done, and patient was re-evaluated after 3 months.

Surgery was planned in patients who had major bile duct injury with concomitant vascular injury and large peritoneal collection that required cleaning and drainage. Fortunately, none of our patients of bile leak required surgery.

Outcome measures

Primary outcome measure of our study was complete symptomatic resolution, complete normalization of LFT, and absence of demonstration of contrast leak during the second ERCP.

Secondary outcome measures were in-hospital mortality and requirement of repeat CBD stent exchange after 6 weeks.

Statistical analysis

Categorical variables are presented as frequencies (percentages) and continuous variables as median with range. All statistical analyses were performed using SPSS statistical package, version 22.0 statistical software (IBM, Armonk, NY, USA).

RESULTS

Out of 27 patients of symptomatic bile leak included in our study, 21 had a history of cholecystectomy. The median time of presentation was 4 days (range: 1–14) after surgery. Rest 6 cases of bile leak were diagnosed as a complication of liver abscess. Twenty-five patients underwent ERCP for definitive management and 2 required PTBD. None required surgical intervention.

Baseline patient's demographics, clinical characteristics, and treatment outcomes of patients undergoing ERCP ($n = 25$) are demonstrated in Table 1.

There were 15 (60%) males and 10 (40%) females among all bile leak patients. All the liver abscess patients were males. Presentations of postcholecystectomy bile leaks included biloma formation in 4, bile ascites in 5, cholangitis with biliary obstruction in 10, and bilio-cutaneous fistula in 2. Ten patients had peroperative subhepatic drain placed in postcholecystectomy group due to intraoperative identification of bile duct injury. In patients with biloma ($n = 4$), percutaneous catheter drain was placed before ERCP.

All the 6 patients with liver abscess had bilious percutaneous drainage effluent positive for bile salt and bile pigments. The amount of daily drain output was <150 in 2 patients and more than 150 ml in 4 patients.

CBD cannulation was successful in 25 (92.59%) patients with bile leak. Major bile duct injury was seen in 10 (52.63%) of our patients with postcholecystectomy status and in 5/6 patients with liver abscess. Cystic duct stump leak was the most common site seen in 6 (24%) patients followed by right anterior hepatic duct leak in 5 (20%) patients [Figure 1a]. Of the 6 patients with liver abscess having bile leak, the most common site was right hepatic duct seen in 3 (50%) patients. None of our patients had complete transection of the CBD. One patient with normal MRCP had bile leak in the left hepatic duct on ERCP. No leak could be identified in 3 patients with suspected postcholecystectomy bile leak and in 1 patient with liver abscess at ERCP. Injection of inadequate dye could be an explanation since we injected minimum dye as 2 of these had CBD stricture and 1 had papillary stenosis. Of this, 1 patient had distal CBD stricture who underwent dilatation of the stricture with stent placement, 1 patient had distal CBD stricture with choledocholithiasis in which stone removal was done following stricture dilatation and CBD stenting, and 1 patient had papillary stenosis in which only sphincterotomy was performed. Both the patients with distal CBD stricture had negative brush cytology and tumor markers.

Twelve of our patients had Strasberg Class A injury and 4 had Class D injury [Figure 1b].^[12] None of our patients

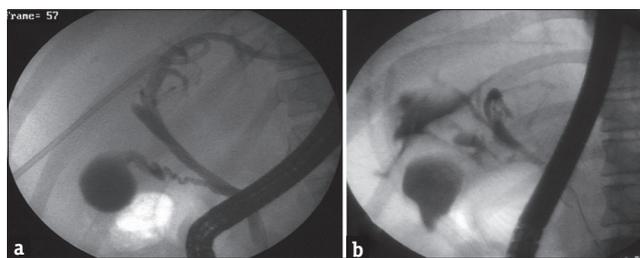


Figure 1: (a) Cholangiogram showing bile leak at the level of the right hepatic duct in a patient with liver abscess. (b) Cholangiogram showing bile leak at the level of duct of Luschka in postlaparoscopic cholecystectomy patient

had complete transection of bile duct which necessitates percutaneous drainage and surgical approach.

All 25 patients received successful endoscopic treatment. Primary outcome of successful resolution of symptoms and absence of leak at 6-week ERCP was achieved in 18 (94.73%) patients in postcholecystectomy group and in 5 (83.33%) patients in liver abscess group. Repeat stent exchange at 6 weeks was required in 2 patients in view of distal CBD stricture, and persistence of leak demonstrated at ERCP. Complications during ERCP included postsphincterotomy bleed in 3 patients which was managed with balloon tamponade and postERCP pancreatitis in 1 patients treated conservatively. One patient had early stent block in 3 weeks requiring early stent exchange. No patients required laparotomy or relaparoscopy. There was no bile leak-related mortality in our patients.

DISCUSSION

Endoscopic therapy was successful in treating both major and minor bile duct injuries in all our patients. None of our patients had complete transection of the CBD or common hepatic duct. Sphincterotomy with and without CBD stent placement was successful in all our patients in treating bile leak with no need of surgery in any of our patients. Complications of ERCP was minor in majority of patients. There was no bile leak-related death.

Laparoscopic cholecystectomy is currently the standard of care for symptomatic gallstones. It has evolved to a daycare procedure over the last 30 years. Similarly, the management of bile leak has changed from conservative to minimally invasive approach. Cystic duct stump and small peripheral right hepatic ducts within the liver bed account for most of the injuries.^[13] Those originating in liver bed often are asymptomatic;^[14] when they become symptomatic, they present with abdominal pain, distension, vomiting, and jaundice or bile leakage in a surgical drain. Retained CBD stones or CBD stricture can increase pressure in the CBD and promote bile leak as seen in two of our patients.^[11]

Table 1: Baseline demographic data, clinical features, and treatment outcome of patients undergoing endoscopic retrograde cholangiopancreatography

Etiology	Postcholecystectomy (n=19)	Liver abscess (n=6)
Median age of presentation, years (range)	38 (19-60)	44 (28-55)
Gender		
Male	9	6
Female	10	0
Clinical features		
Increased drain output/bile in percutaneous drain	14	6
Abdominal pain, fever, vomiting	6	0
Jaundice	11	0
ERCP findings		
Site of bile leak		
Cystic duct stump	6	0
Right anterior biliary system	5	0
Right posterior biliary system	1	0
Right hepatic duct	0	3
Left hepatic duct	1	0
Common hepatic duct	1	1
Proximal common bile duct	1	0
Mid common bile duct	1	1
No leak	3	1
Additional findings		
Distal CBD stricture	1	0
Distal CBD stricture with choledocholithiasis	1	0
Papillary stenosis	1	0
Strasberg classification		
Class A	12	NA
Class B	0	NA
Class C	0	NA
Class D	4	NA
Class E	0	NA
Type of bile duct injury/involvement		
Minor	9	5
Major	10	1
Procedure		
Sphincterotomy alone	1	1
Sphincterotomy with CBD stent placement	18	5
Primary outcome achieved (%)	18 (94.73)	5 (83.33)
Repeat CBD stenting required (%)	3 (15.78)	1 (16.66)
In-hospital mortality	0	0

CBD=Common bile duct, ERCP=Endoscopic retrograde cholangiopancreatography, NA=Not available

The presence of a biliary fistula in liver abscess is suspected by jaundice and/or by the appearance of bile in percutaneous drainage effluent from a liver abscess with most common site being right intrahepatic bile ductal system.

Endoscopic sphincterotomy is used to reduce distal CBD pressure and facilitate closure of leaking cystic ducts.^[15,16] In a previous study from one of the coauthors, bile leak was managed with the help of sphincterotomy alone in 12 out of 13 cases while stent was placed in only one patient.^[17] Stent placement reduces the CBD pressure and covers the leaking point and allows it to heal. Insertion

of a stent not only adequately seals the bile leakage but also allows for prevention or treatment of secondary ductal stenosis which can develop at the site of bile leak.

Nasobiliary tube placement avoids the need for the second ERCP but at the cost of risk of accidental tube removal and patient discomfort and hence is not used frequently.^[18]

In our series, ERCP established the diagnosis and provided the definitive management. Although the use of ERCP has been a major advance, it does have well-established complications. Moreover, the plastic stent which is placed requires a second ERCP

for retrieval. Although there were no ERCP related complications in our study, these are always a concern.

In patients with major bile duct injury with complete transection, clip on the CBD or hepatic duct, especially

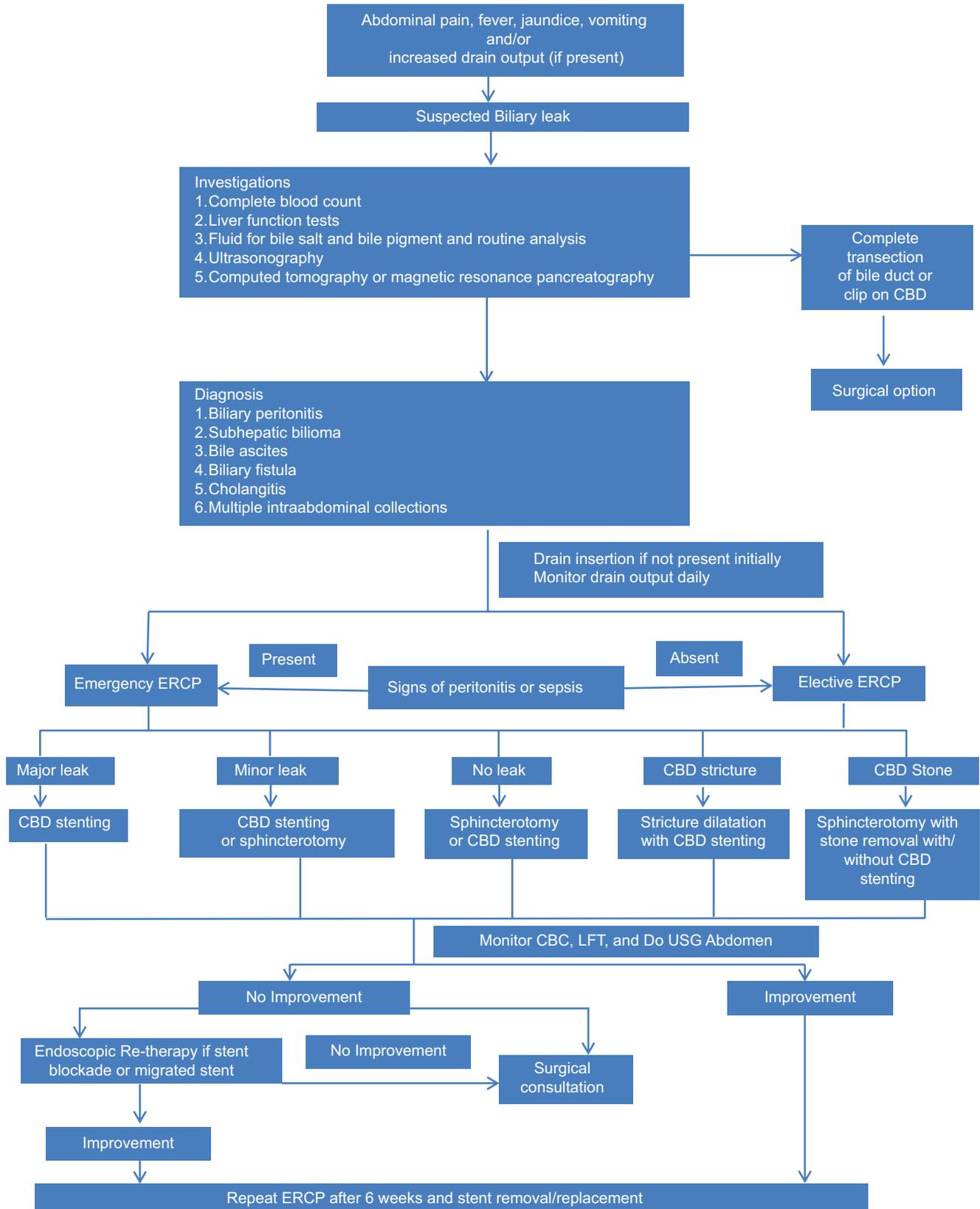


Figure 2: Algorithm for conservative management of bile leak

when they present late with septicemia and peritonitis, needs a team approach. Experienced hepatobiliary surgeons, endoscopists, and interventional radiologists contribute to successful management of such patients at specialized centres.^[19]

None of our patients had complete transection or clip on CBD which will require surgical exploration. We provide an algorithm for conservative management of bile leak [Figure 2].

CONCLUSION

Endoscopic treatment of symptomatic bile leaks including major bile duct injury without complete transection is safe and effective and obviates the need for surgery. It should be the cornerstone in the management of these cases. This study highlights the importance of early recognition of bile leak and its complications, the endoscopic treatment of which will avoid the surgical interventions needed when patient presents late in the course.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Cuschieri A, Dubois F, Mouiel J, Mouret P, Becker H, Buess G, *et al.* The European experience with laparoscopic cholecystectomy. *Am J Surg* 1991;161:385-7.
- Bailey RW, Zucker KA, Flowers JL, Scovill WA, Graham SM, Imbembo AL, *et al.* Laparoscopic cholecystectomy. Experience with 375 consecutive patients. *Ann Surg* 1991;214:531-40.
- Woods MS, Traverso LW, Kozarek RA, Tsao J, Rossi RL, Gough D, *et al.* Characteristics of biliary tract complications during laparoscopic cholecystectomy: A multi-institutional study. *Am J Surg* 1994;167:27-33.
- Vecchio R, MacFadyen BV, Latteri S. Laparoscopic cholecystectomy: An analysis on 114,005 cases of United States series. *Int Surg* 1998;83:215-9.
- Merrie AE, Booth MW, Shah A, Pettigrew RA, McCall JL. Bile duct imaging and injury: A regional audit of laparoscopic cholecystectomy. *Aust N Z J Surg* 1997;67:706-11.
- McMahon AJ, Fullarton G, Baxter JN, O'Dwyer PJ. Bile duct injury and bile leakage in laparoscopic cholecystectomy. *Br J Surg* 1995;82:307-13.
- Buanes T, Waage A, Mjåland O, Solheim K. Bile leak after cholecystectomy significance and treatment: Results from the National Norwegian Cholecystectomy Registry. *Int Surg* 1996;81:276-9.
- Griffin J, Jennings C, Owens A. Hepatic amoebic abscess communicating with the biliary tree. *Br J Radiol* 1983;56:887-90.
- De Palma GD, Galloro G, Iuliano G, Puzziello A, Persico F, Masone S, *et al.* Leaks from laparoscopic cholecystectomy. *Hepatogastroenterology* 2002;49:924-5.
- Mergener K, Strobel JC, Suhocki P, Jowell PS, Enns RA, Branch MS, *et al.* The role of ERCP in diagnosis and management of accessory bile duct leaks after cholecystectomy. *Gastrointest Endosc* 1999;50:527-31.
- Ryan ME, Geenen JE, Lehman GA, Aliperti G, Freeman ML, Silverman WB, *et al.* Endoscopic intervention for biliary leaks after laparoscopic cholecystectomy: A multicenter review. *Gastrointest Endosc* 1998;47:261-6.
- Chun K. Recent classifications of the common bile duct injury. *Korean J Hepatobiliary Pancreat Surg* 2014;18:69-72.
- Neidich R, Soper N, Edmundowicz S, Chokshi H, Aliperti G. Endoscopic management of bile duct leaks after attempted Minimally invasive management of bile leak after laparoscopic cholecystectomy laparoscopic cholecystectomy. *Surg Laparoendosc Endosc* 1996;5:348-54.
- Azurin DJ, Go LS, Maslack M, Kirkland ML. Bile leak following laparoscopic cholecystectomy. *J Laparoendosc Surg* 1995;5:233-6.
- Ponchon T, Gallez JF, Valette PJ, Chavaillon A, Bory R. Endoscopic treatment of biliary tract fistulas. *Gastrointest Endosc* 1989;35:490-8.
- Liguory C, Vitale GC, Lefebvre JF, Bonnel D, Cornud F. Endoscopic treatment of postoperative biliary fistulae. *Surgery* 1991;110:779-83.
- Contractor QQ, Dubian MK, Boujemla M, Contractor TQ. Endoscopic therapy after laparoscopic cholecystectomy. *J Clin Gastroenterol* 2001;33:218-21.
- Chow S, Bosco JJ, Heiss FW, Shea JA, Qaseem T, Howell D, *et al.* Successful treatment of post-cholecystectomy bile leaks using nasobiliary tube drainage and sphincterotomy. *Am J Gastroenterol* 1997;92:1839-43.
- Sicklick JK, Camp MS, Lillemoie KD, Melton GB, Yeo CJ, Campbell KA, *et al.* Surgical management of bile duct injuries sustained during laparoscopic cholecystectomy: Perioperative results in 200 patients. *Ann Surg* 2005;241:786-92.