

Percutaneous management of iatrogenic biliary injury

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Abstract

Iatrogenic biliary injuries are infrequent complications after hepatobiliary surgery or intervention, but potentially harmful. The injuries are mainly divided into biliary stricture and bile leak. Surgical correction is the definite treatment, but many limitations including inappropriate patient's conditions, difficult surgical approach due to extensive adhesion and the availability of experience hepatobiliary surgeons. Nonoperative (endoscopic or percutaneous) management performs well in such patients. However, endoscopic treatment is sometimes impossible in patients with bilioenteric anastomosis and sometimes does not do well in patients with hilar lesions. Percutaneous management plays an important role in both diagnosis and treatment. There are many common strategies including percutaneous transhepatic cholangiography (PTC), percutaneous transhepatic biliary drainage (PTBD), percutaneous biliary balloon dilation (PBBD), percutaneous biliary stent placement, and percutaneous drainage of fluid collection or biloma. Several standard and advanced techniques, outcomes and complications of these procedures are reviewed in this study. Percutaneous management is an effective procedure for iatrogenic biliary injuries with acceptable complication rates.

Key words: Biliary injury, Percutaneous cholangioplasty, Biliary stent

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Introduction

Iatrogenic biliary injury can occur after cholecystectomy, gastric or hepatic resection with or without bilioenteric anastomoses and after liver transplantation¹. The injuries may appear as biliary stenosis, bile leak or fistula. Laparoscopic cholecystectomy accounts for the largest proportion, approximately 0.5% after procedure².

Biliary injuries that are not recognized may become manifest days, months, or years later. The signs and symptoms of bile duct stricture or bile duct ligation are jaundice, alteration of liver function. Fever, cholangitis or abscess formation may occur later. Serious consequences if left untreated include stone formation, recurrent cholangitis and secondary biliary cirrhosis. The signs and symptoms of bile leak include abdominal fullness and dull right upper quadrant abdominal pain, nausea, vomiting. Rapid bile leak often produces severe abdominal pain due to biliary peritonitis. However, the nonspecific initial symptoms such as abdominal discomfort, malaise, nausea, and anorexia occur more frequent, and may account for the delays in diagnosis².

Imaging is needed for diagnosis, assessment the extent of injury and preprocedural planning. Trans-abdominal ultrasound (US), computed tomography (CT) and magnetic resonance cholangio-pancreatography (MRCP) are the noninvasive imaging modalities for the evaluation of the liver parenchyma and the biliary tree. US can show the biliary dilatation and may demonstrate the level of obstruction, but are limited in obese patients and the common bile duct (CBD) may be obscured by bowel gases. CT helps in the detection of the biliary dilatation, point and cause of obstruction, and associated vascular injuries. MRCP provides excellent delineation of the biliary

anatomy proximal and distal to the level of injury. MRCP permits evaluation of biliary tract without the use of contrast material, and can be used for definite diagnosis of conditions that do not require intervention. Endoscopic retrograde cholangiography (ERC) is a modality for diagnostic and therapeutic options. ERC has a limited capacity to image the biliary tree proximal to the site of obstruction. Also, it cannot be performed if altered anatomy prevents endoscopic access to the ampulla²⁻⁵.

In case of bile leaks and fistulas, cholescintigraphy has high accuracy for the detection of bile leaks, but limited locating the site of injury by poor spatial resolution³. US and CT can detect the collections of bile with no evidence or only mild degree of biliary dilatation. (Figure 1) Dynamic contrast-enhanced MRCP with a hepatocyte-selective contrast agent with biliary excretion allows a functional assessment of the biliary tree for detection and localization of bile leaks. (Figure 2) However, there is limited evaluation in case of poor liver function. CT cholangiogram (CT IVC) may be an alternative option for patients who are contraindicated for MRC. It can detect and localize bile leaks and biloma in patients with serum bilirubin levels less than 3 mL/mL. However, the availability of intravenous cholangiographic contrast medium is limited to a few countries (Japan, Germany, the UK, Austria and Australia)^{4,5}. The best way to prove the site of leaks or fistulous tract is the use of an invasive cholangiogram, either endoscopic or percutaneous, which can demonstrate the origin of leak and delineate the fistulous tract¹. Percutaneous cholangiography (PTC) is superior to ERC for evaluating proximal bile duct injuries, common duct ligation or transection, and transection or ligation of an aberrant right hepatic duct².

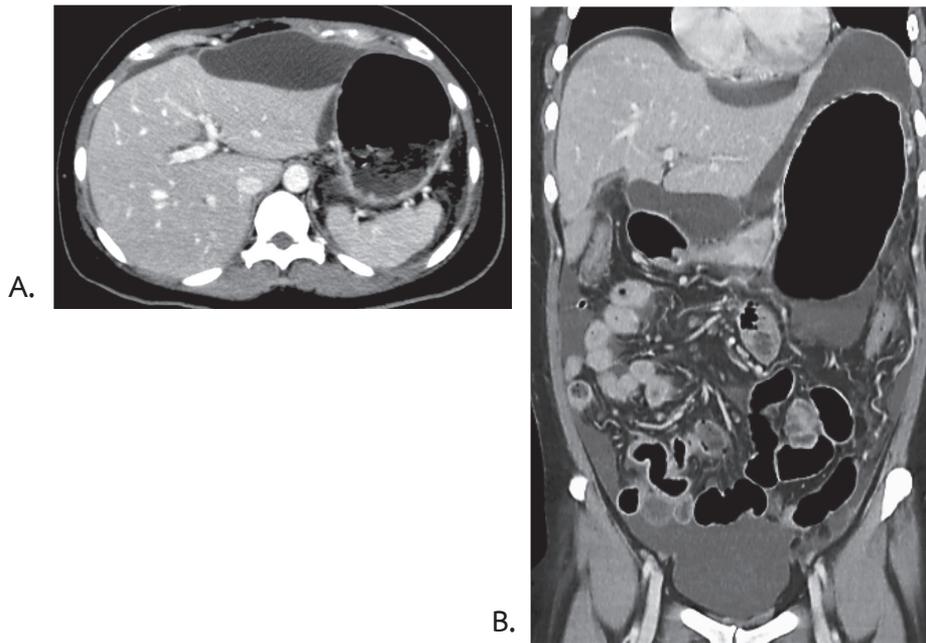


Figure 1 CT scan of a 42-year-old female who underwent laparoscopic cholecystectomy. (A) Axial and (B) coronal views showed large amount of intra-abdominal fluid collection. No bile duct dilatation was observed. The site of leakage cannot be demonstrated.

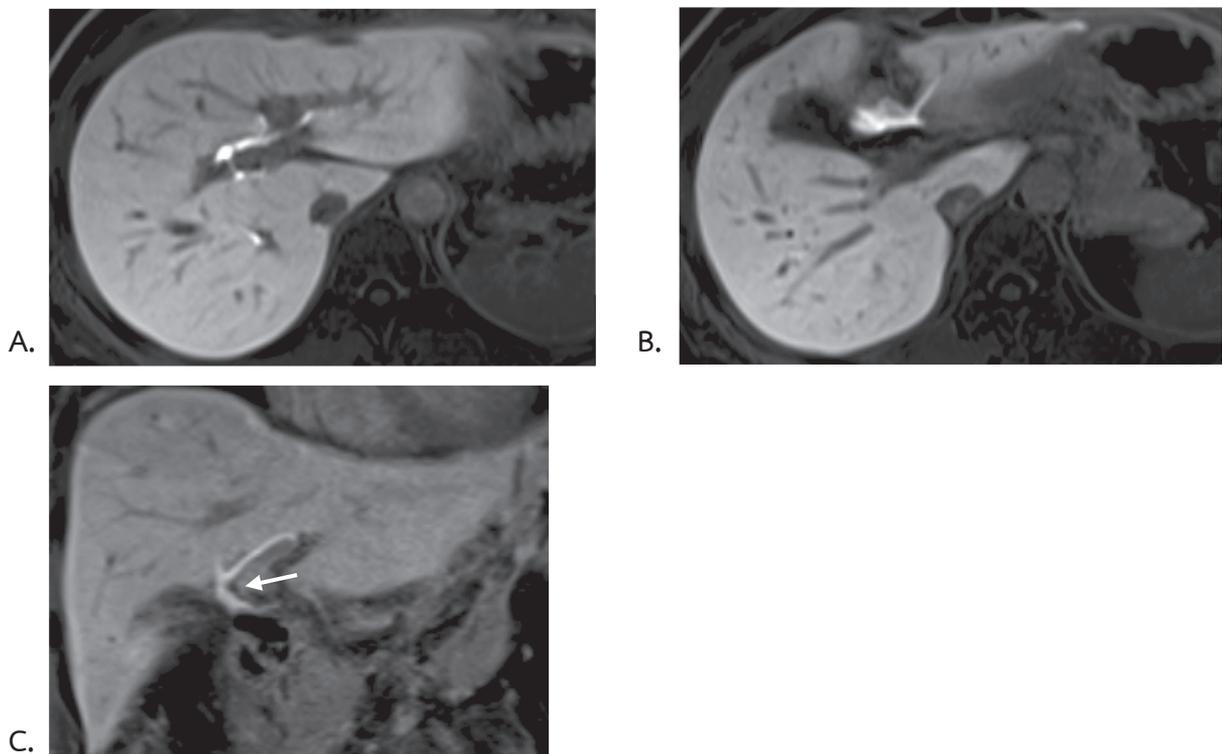


Figure 2 MRI and MRCP of the patient in figure 1 after percutaneous drainage of biloma, obtained 30 minutes after intravenous injection of gadoxetate disodium. (A) There was much decreased intra-abdominal fluid collection. Evidence of contrast excretion within bile ducts was observed. (B, more caudal than A) Contrast accumulation at hilar region was seen. (C) Coronal views showed the region of contrast extravasation adjacent to the common hepatic duct (arrow).

Appropriate management includes endoscopic, percutaneous, and surgical interventions. Bile duct injuries are usually repaired surgically, which are best performed at institutions that specialize in care. In a series by Stewart and Way⁶, repairs by the primary surgeon were successful only 17% of the time for the primary repair, with no successful outcomes for the secondary repair. In contrast, if a tertiary-care biliary surgeon performed the initial repair, the success rate was 94%. Surgical repair typically involves creation of a Roux-en-Y choledochojejunostomy in patients with a healthy common bile duct remnant, or a hepaticojejunostomy by connecting the common hepatic or one of the branch ducts to the jejunum when injuries are located at the liver hilum or involve one of the lobar or segmental ducts.

Bilioenteric strictures occur in 8% to 40% of patients after a bilioenterostomy performed for benign disease⁷. Surgical revision of recurrent benign bilioenteric strictures (BBES) is complex due to extensive scar tissue resulting difficulty in obtaining adequate exposure, and lack of adequate length of healthy bile duct needed to construct a new anastomosis. One study showed 68% and 80% of patients with surgical revision of a bilioenteric stricture developed recurrent stricture at 3 years and 5 years, respectively⁸.

Nonsurgical therapies for postoperative biliary stenosis evolved because surgical revision is difficult, particularly when the remaining bile duct is short, inflammation and adhesion in the porta hepatis is extensive, or the patient has comorbid conditions. Tocchi, et al and Davids, et al.^{9, 10} showed similar patency after hepaticojejunostomy and endoscopic stent placement in the treatment of post cholecystectomy biliary stricture. In general, iatrogenic injuries if not treated surgically, endoscopy is the treatment of choice, by performing progressive balloon dilatation with an increasing number of plastic stents for biliary stricture. For bile leaks, placement of biliary plastic

stents and/or sphincterotomy could successfully treat in 70 - 100% of patients¹¹.

However, endoscopic access to bile duct is not always possible for patients with history of bilioenteric anastomosis, narrowing of the bowel lumen preventing endoscopic passage, or tight stenosis at the level of ampulla of Vater precluding bile duct cannulation. In addition, in the presence of intrahepatic bile duct stones, or obstruction of the hepatic ducts junction or peripheral duct, central drainage via ERCP may be unsuccessful because the transfer of force to overcome the stricture by endoscopic instruments is less effective in comparison with percutaneous access. Furthermore, in case of bile leak, the cannulation of the bile duct above the leak is sometimes difficult, and a technical failure rate of 46% has been reported¹².

Percutaneous transhepatic approach plays the important role in both diagnosis and treatment of patients who cannot be treated by the surgical or endoscopic approach by precisely defining bile duct anatomy via percutaneous transhepatic cholangiography (PTC), performing percutaneous transhepatic biliary drainage (PTBD), and offering therapeutic options including percutaneous treatment of bile duct strictures using catheters, balloons, and stents. Eum, et al.¹³ reported non-surgical treatment of post-surgical bile duct injury. There is no significant difference in the overall success rate according to the initial treatment between endoscopic and percutaneous approach for bile leak only or biliary stricture only. For combined bile leak and biliary stricture, surgical approach is considered as a first treatment of choice.

Contraindications of the percutaneous interventions are unfavorable anatomy (such as large amount of ascites, colon interposition, or liver masses) and uncorrectable severe coagulopathy or thrombocytopenia. Significant ascites should be drained prior to biliary intervention as this increases the risk of hemorrhage and catheter displacement¹⁴.

Percutaneous management

1. Bile duct or bilioenteric anastomotic stricture

1.1 Percutaneous transhepatic cholangiography (PTC) and biliary drainage (PTBD)

PTBD is useful for both biliary decompression and diversion. Prophylactic antibiotics is always required to minimize septic complication¹⁵.

An anterior subxiphoid approach is used for the left duct, whereas a right lateral intercostal approach is used for the right duct. The entry site of right duct should be at the level of inferior portion of right hepatic lobe and along superior margin of the rib to minimize the risks of pleural transgression and intercostals neurovascular bundle injury, respectively. US guidance is preferred because of the real-time visualization of the target bile duct¹⁶.

The suitable duct is punctured with a 21G - 22G needle. Diluted contrast medium is slowly and minimally injected to confirm the needle position.

A 0.018-inch guidewire is advanced into the bile ducts, over which a 6F access system is inserted. This will accept a 0.035-inch guidewire. The tract is then dilated, and a simple drainage catheter can be advanced over the wire, so called Seldinger technique.

In patients with cholangitis, an external drainage should be placed for 2 - 4 days and a course of antibiotics should be administered before attempting the internal drainage. In patients without cholangitis, placement of internal-external drainage catheter may be performed initially.

Injuries of the common duct usually need only one catheter drainage. (Figure 3) If injuries result in loss of communication between right and left ducts, bilateral drainage catheters are required. Overall, percutaneous transhepatic biliary drainage has a success rate of 90%. The complication rate is higher than that for endoscopic drainage¹⁶.



Figure 3 Common bile duct (CBD) injury after opened cholecystectomy. Only one PTBD was needed for biliary drainage.

1.2 Percutaneous biliary balloon dilation (PBBD)

Balloon dilation with long-term internal-external drainage are generally accepted as a treat-

ment of benign biliary stricture. In patient with cholangitis, external PTBD should be performed for biliary diversion firstly and attempt to cross the stricture later after the infection resolves.

The narrowing bilioenteric anastomosis that was created less than 1 month ago may be related to postsurgical edema or a kink. Balloon dilation now may disrupt the anastomosis and result in a leak. Retaining an internal-external PTBD across the stricture for approximately 2 weeks and repeating another cholangiogram are reasonable.

Prophylactic intravenous antibiotics should be routinely administered within 1 hour before the procedure¹⁷. Either right-sided or left-sided transhepatic approach does not preclude dilation.

The minimal 7F sheath or larger (up to 9F sheath) is required. An 8F sheath is ideal for procedures which many tools may have to be passed. A 5F angiographic catheter should be used for guidewire guidance for crossing the stenosis. For strictures that are difficult to cross, a microcatheter and a microwire can be used. If a tear in the bile duct or a false passage is created during cannulation, the procedure should be stopped and an external biliary drain should be placed. Another attempt can be done in 1 - 2 weeks later.

There are several controversies regarding cholangioplasty techniques and protocols, including types of balloons, the optimal inflation time, number of inflations per session, time interval between dilation sessions and the required sessions per treatment. Criteria for the removal of the internal-external catheter across the dilated stricture also varies.

Dilatation of the stricture is usually performed with a conventional angioplasty balloon. The diameter of the balloon should be at least as large as the diameter of the bile duct proximal and distal to the obstruction and can be oversized by 25 - 30%. Strictures in the common hepatic and common bile ducts can be safely dilated to 10 - 14 mm in adult. A 4 - 8 mm balloon may be used for lobar ducts or biliary stricture in children⁴. For hepaticojejunostomy stricture, ballooning from two sides effectively increases overall diameter of the anastomosis. The

balloon is inserted across the stenosis and inflated until the waist disappeared, which is usually no less than 10 atm. A pressure inflator should be used as it allows much more controlled inflation and much higher inflation pressure than hand inflation¹⁴. The balloon is left inflated for at least 1 minute (inflation duration can be up to 30 minutes)¹⁷, and the dilation should be repeated at the stricture site several times. A larger diameter or a high-pressure balloon can be used if the stricture persists.

A cutting balloon is available in diameters of 6 - 8 mm. It can also be used in these cases. The diameter of cutting balloon should be 1 - 2 mm less than the required diameter of a conventional balloon⁴. Some routinely use a cutting balloon followed by a higher pressure conventional balloon. Other only use cutting balloons in strictures refractory to prior conventional balloon dilations, followed by repeat dilation with a larger diameter high pressure balloon^{17, 18}. Amar Mukund, et al.¹⁹ described the used of combined cutting balloon and conventional balloon in cholangioplasty of the resistant biliary-enteric anastomotic strictures in 8 patients. All achieve technical success, no major complications and no re-stenosis during the mean follow up on 14 months. Cutting balloon seems to raise the technical success rate close to 100% with no significant increase in major complications. However, it is unknown whether the increased technical success rate of cutting balloons will improve long-term patency rate²⁰.

Intraprocedural failure is classified into three types. Type I is failure to pass the biliary stricture with a guidewire, catheter, and/or a balloon. Type II is failure to efface a waist while the balloon (oversized to 20 - 25% of the estimated true size of the duct) is fully inflated under maximal recommended pressures exceeding 15 atm. Type III is the complete recoil of the stenotic lesion immediately after deflation of the balloon¹⁷.

Repeated cholangiogram after balloon dilation is performed to evaluate bleeding (new onset filling defects) and biliary rupture (bile leak).

Between sessions of balloon dilation, large drains should be placed across the stricture with side holes above and below the site of obstruction to prevent its relapse. The sizes of the drains vary between 10F - 14F.

The time interval between balloon dilation sessions varies from every 1 - 2 days, 1 - 2 weeks to every 3 months¹⁷. The maximum of three to six sessions for each treatment was reported depending on the institution.

The optimal duration of biliary catheter placement is ascertained. Cholangiographic findings that show the successful treatment include resolution of intrahepatic duct dilatation, spontaneous passage of contrast agent through the previously narrowed segment, and near-complete or complete resolution of bile duct narrowing (less than 20 - 30% residual stenosis). After documentation of bile duct patency, the biliary catheter is externalized and capped for 1 - 2 weeks. If the patient has no signs and symptoms of biliary obstruction and laboratory results appear normal, the catheter can be removed. (Figure 4) Savader, et al.²¹ compared manometric perfusion test with clinical test for assessment of the PBBD treatment. They concluded the same predictive value for long-term patency. They recommended to use the manometric test instead of the clinical test for its simplicity, lower costs and immediate availability of results. In a study of Bonnel and Fingerhut⁷, the criteria for catheter removal was disappearance of the waist on cholangiogram at least two consecutive sessions

at 6-weeks intervals. There is unknown which method is correct. This may be one of the reasons why there is a wide discrepancy between the patency results of balloon dilation studies in the literatures. Those who rely on functional/clinical outcome tend to have a better patency than those that rely on anatomical/cholangiographic outcome^{22, 23}.

Misra, et al.²⁴ showed that a duration of catheter placement of more than 4 months was associated with improved ductal patency. Patients with more complex injuries (Bismuth 3, 4, 5, or isolated right hepatic duct) had significantly more failure rate when stents for a short period of time. Lee, et al.¹⁸ reported patients who were unsuccessfully managed with balloon dilation required significantly more invasive procedures and were left with an indwelling biliary catheter for a significantly longer period (8.8 vs. 2.0 months; $p = 0.02$) than patients whose strictures could be resolved by balloon dilation.

For patients with recalcitrant biliary strictures, inserting increasing numbers of plastic stents can be performed endoscopically. For percutaneous management, there are several approaches including 1. Large-bore biliary drain, using 16F - 18F silastic or silicone PTBD placing across the narrowing segment for several months (typically 6 - 12 months). 2. Double-barrel technique, inserting a 14F internal-external biliary drain through which a second 8.5F PTBD is threaded so that the smaller drain exits from the larger drain peripheral to the site of the stricture. At the level of the stricture, the drains run parallel, yielding a total diameter of 22.5F. (Figure 4) Catheters were exchanged once every 2 months⁴.

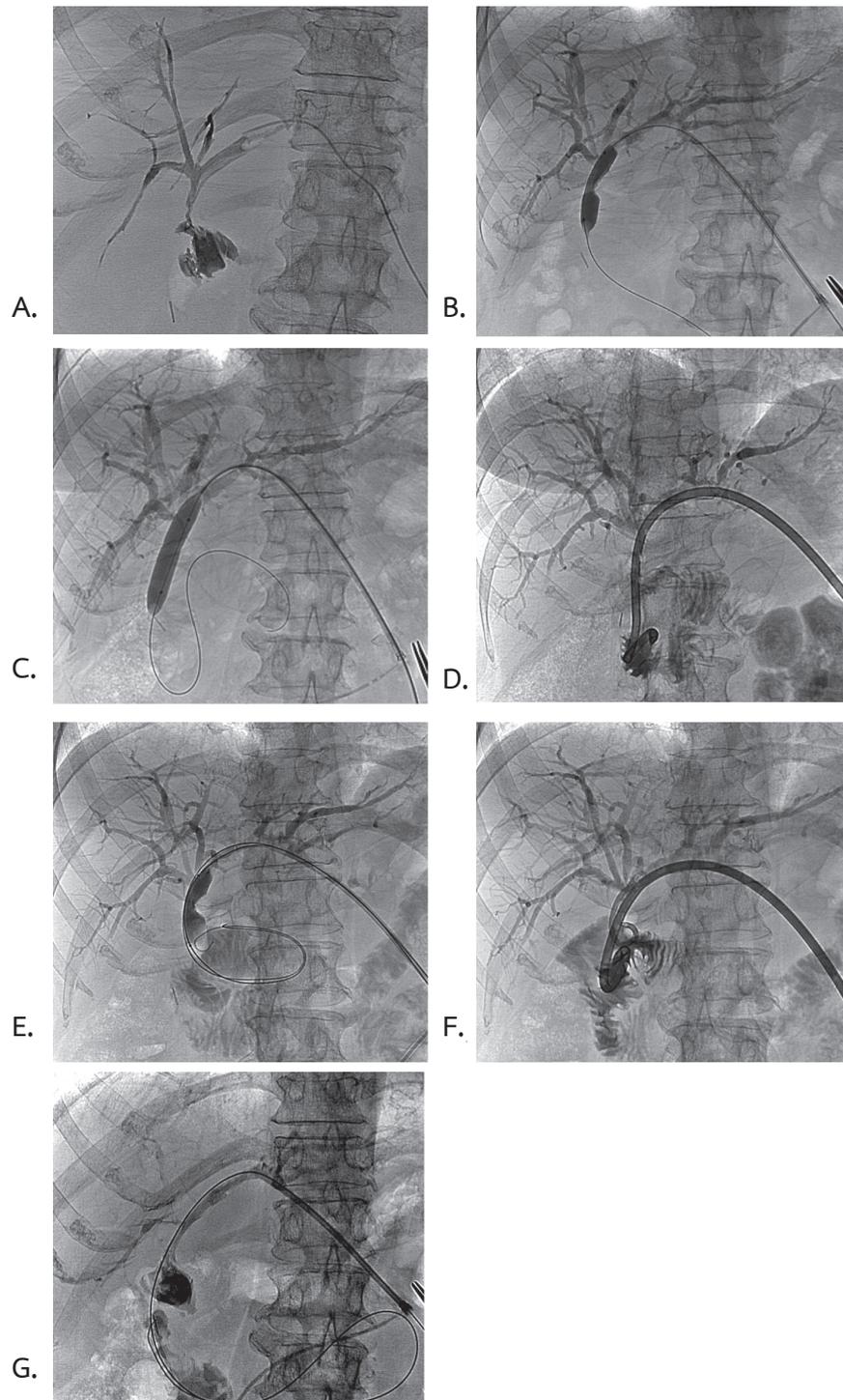


Figure 4 Post laparoscopic cholecystectomy with CBD injury, post hepaticojejunostomy. Patient presented with jaundice. (A) Cholangiogram showed stricture of the hepatic duct confluence just above hepaticojejunostomy anastomotic site. PTBD was done first for improving the symptoms (not shown). (B and C) Balloon cholangioplasty was done, using a 10 x 40 mm balloon catheter. The waist disappeared. (D) A 12F internal-external drainage catheter was installed. The stricture still persisted after cholangioplasty for 3 sessions within the period of 4 months. (E) 4th cholangioplasty was done, using 12 x 40 mm balloon catheter and (F) double-barrel PTBDs was retained across the stricture. (G) Cholangiogram via sheath showed contrast easily passed through the anastomosis without biliary dilatation after a period of 9 months. Then external PTBD was retained and capped for 1 week. The patient had no symptoms of biliary obstruction. PTBD was removed.

Results of cholangioplasty

Definitions of technical success and clinical success vary among literatures. For technical success, some define as the successful balloon dilation and placement of the catheters in the appropriate position^{25, 26}. Other define by fluent passage of contrast through the anastomosis into small bowel and absence of bile duct dilatation^{19, 27}. For clinical success, several definitions are reported, including the disappearance of the patient symptoms, normalization of chemical data or their decrease to less than 1.5 times the normal levels after drainage catheter removal²⁶, or the absence of cholangitis and decreased in serum bilirubin level of more than 20% relative to baseline after 1 month of stent insertion²⁵, or the absence of recurrent biliary obstruction during follow up¹⁵.

Primary patency is the time interval from drainage catheter removal to the detection of recurrent symptoms or the last follow up.

In the study of Martin Köcher, et al.²⁸, percutaneous balloon dilation with internal-external drainage placement in the treatment of the 21 patients with benign biliary stricture showed the 1-year, 2-year and 3-year primary clinical success rates of 94%, 83% and 77%, respectively. No major complication was seen. A study by Lee, et al.¹⁸ showed no significant differences in the number of balloon dilation performed or in the maximum balloon diameter used between patients with successful and unsuccessful balloon cholangioplasty. A study by Cantwell, et al.²⁹

demonstrated no significant difference in clinically significant restenosis after balloon dilatation between anastomotic and nonanastomotic stricture ($p = 0.75$), while some investigators suggested that balloon dilation of anastomotic stenosis may have a better prognosis than nonanastomotic stricture. Pitt, et al.³⁰ did compare surgical repair (choledochojejunostomy or hepaticojejunostomy) with PBBD, with PBBD being performed in patients who were not suitable candidates for surgery. The patency rates were 88% and 55% at 5 years for the surgical reconstruction group and the PBBD group, respectively, with a higher complication rate in the PBBD group and comparable treatment cost and hospitalization periods. However, it is not possible to conclude outcomes comparing primary surgery and percutaneous balloon cholangioplasty for benign postoperative biliary stricture because the series are nonrandomized. The outcomes of balloon cholangioplasty are summarized in table 1.

If the initial treatment fails, secondary therapy, usually with surgical revision, results in successful outcome. However, the decision when to say unsuccessful cholangioplasty and proceed to surgical revision should be based on both interventional radiologist and referring surgeon's preferences.

For the recurrent stricture after cholangioplasty, repeated PTBD with balloon dilation can lead to resolution¹⁸. However, other studies showed that recurrent anastomotic biliary strictures subsequent to balloon dilation was more refractory (up to 2.5-fold) to repeat balloon dilation than first comers^{20, 22 - 23}.

Table 1 Data from the series reported in the literatures

Author	Misra, et al. ²⁴	Köcher, et al. ²⁸	Cantwell, et al. ²⁹	Bonnel and Fingerhut ⁷	Lee, et al. ¹⁸	Gupta, et al. ²⁵
Year	2004	2007	2008	2012	2012	2014
Number of patients	51	21	75	110	32	14
Stricture characteristics	BBES and major bile duct injury post LC	BBES and major bile duct injury post LC	BBES and iatrogenic stenosis of bile duct	BBES	BBES	BBES, major bile duct injury post LC, and chronic pancreatitis with ampullary stricture
Caliber of the balloon	Not detailed	10 - 12 mm	8 - 12 mm	10 mm	6 - 10 mm, some additional 6 - 8 mm cutting balloon	8 - 10 mm
Inflation time	Not detailed	3 min	1-3 min	Not detailed	1 min	2 - 5 min
Number of inflation per session	Not detailed	3	3 to 5	Not detailed	Not detailed	3
Time interval between dilatations	8 to 12 weeks	12 weeks	0.3 to 2.0 weeks	6 weeks	6 weeks	4 to 12 weeks
Caliber of the stenting catheter	Not detailed	12F - 14F	10F - 12F	14F	10.2F	10F - 14F
Criteria for definitive catheter removal	Biliary manometric perfusion study and/ or no signs/ symptoms of biliary obstruction for 2 weeks	no stenosis on cholangiography and no signs/ symptoms of biliary obstruction for 1 week	no stenosis on cholangiography and no signs/ symptoms of biliary obstruction for 1 week	Disappearance of the waist at least 2 consecutive sessions at 6-weeks intervals	less than 30% residual stenosis on cholangiography and no signs/ symptoms of biliary obstruction for 2 weeks	no stenosis on and cholangiography no signs/symptoms of biliary obstruction for 1 week
Immediate technical success	100%	95.2%	100%	99%	100%	100%
Dilatation session, n	Range 1 - 3	Not detailed	Mean, 2	Median, 5 (range, 1 - 4)	1 to 3 (range, 2 - 30)	1 to 2
Duration of stenting, mo	Three subgroups (< 4 , 4 - 9 , > 9)	Mean, 7.5 (range 3 - 11), except one for 5 years	Mean, 1.1 (range 1 - 1.5)	Median, 8.5 (range, 4.5 - 45) 9 patients require long-term stenting (> 12)	2.0+/-1.7 for successful 8.8+/-11.9 for unsuccessful	Median, 6.5 (range 3-9)
Clinical success**	58.80%	94.00%	75%	85%	66%	92.80%
Follow up duration, mo	Median, 77 (range, 23 - 140)	Mean, 62.4 (range, 16 - 132)	Mean, 96 (range, 12 - 324)	Median, 59 (range, 0.5 - 278)	Mean, 157 (range, 23 - 209)	Mean, 34.4 (range 3 - 61)
Recurrence of biliary obstruction	41.20%	19.00%	34% - 44%	15%	5%	Not detailed
Time to recurrence, yr	Mean, 0.7 (range, 0.08 - 3.6)	0.75 - 2	2.5 - 3	Not detailed	5	Not detailed
Complications	Not detailed	None	Hemorrhage 1% Subphrenic abscess 1%	Hemorrhage 3.6% Biloma 6.3% Bile effusion 4.5%	Not detailed	Puncture site hematoma 7.1% Mild bilious ascites 7.1%

* Benign bilioenteric stricture

** Achieving the criteria of catheter removal

2. Bile leakage or fistula

Biliary leaks are an abnormal passage or communication from the biliary system to another location, intra- or extra-hepatic. Definition of bile leak requires 1. the presence of bile discharge from an abdominal wound and/or drain, with a total bilirubin level of > 5 mg/ml or three-times the serum level, or 2. intra-abdominal collections of bile confirmed by percutaneous aspiration, or 3. cholangiographic evidence of contrast leaking from the opacified bile ducts¹.

Bile leaks can be classified by fistulography via the drainage catheter, ERC or PTC as central type (leakage from extrahepatic bile duct, and seen the leaky bile ducts communicate with the biliary tree) and peripheral type (leakage from the cut surface of the remnant liver, which the leaky bile ducts do not communicate with the biliary tree)³¹. Complex leaks are defined as those that are refractory to endoscopic intervention with biliary sphincterotomy or plastic stent placement, bile leak following orthotopic liver transplantation or complicated cholecystectomy with large leaks. Nagano et al. classified types and options of treatment of bile

leaks as following: Type A: minor leaks from small bile radicles on the surface of the liver, which are usually self-limiting, and can close spontaneously with external drainage although sometimes ERCP and sphincterotomy may be required. Type B: leaks from inadequate closures of the major bile duct branches on the liver's surface. Type C: injury to the main duct commonly near the hilum. Type B and C can be managed by ERCP and plastic stent or PTBD combined with percutaneous drainage of the bile collection. Type D: leakage due to a transected duct disconnected from the main duct, requiring surgery and bilioenteric anastomosis or, if the draining segment is small, fibrin glue occlusion or acetic acid ablation. Sometimes operative excision of the excluded segment may be required³².

The incidence of bile leak after liver resection without biliary reconstruction ranges from 3.6% to 12% and after hepaticojejunostomy ranges from 0.4% to 8%³³. Percutaneous management of bile leaks and fistulas include percutaneous drainage of bile collection, PTBD (external or internal-external) for biliary diversion, dilation of concomitant stricture, seal the tract or fistula by embolization or ablation of the leakage, and treatment with a covered stent. (Figure 5)

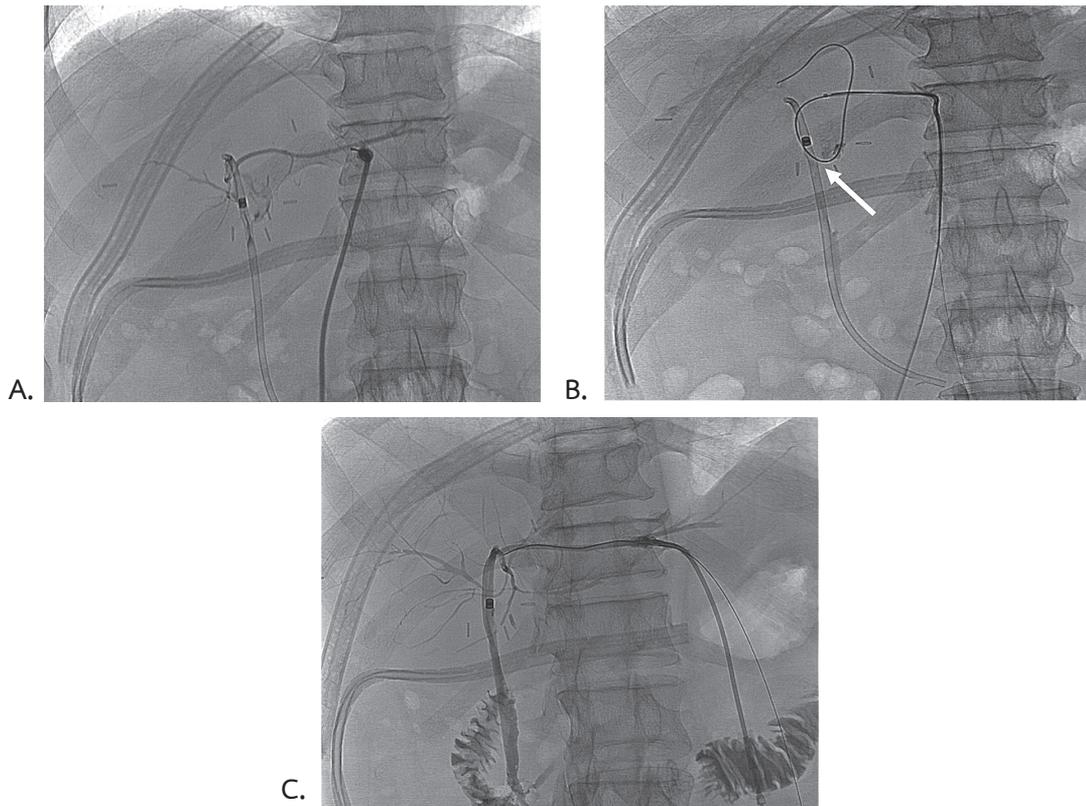


Figure 5 Cholangiocarcinoma post S6, 7 hepatectomy with post operative bile leak. An internal plastic stent was inserted endoscopically. However, fever with jaundice persisted. The patient was sent for PTBD. (A) Cholangiogram showed no evidence of bile duct dilatation. Small amount of contrast leakage at proximal CBD (arrow). (B) Guidewire was out of the path of CBD during the procedure (arrow), likely passing of the guidewire into the leakage site. (C) The contrast leakage was no longer seen after PTBD placement.

Most bile leaks from the intrahepatic biliary tree are transient and usually managed conservatively by drainage alone or diversion of the bile away from the site of bile wall defect. Surgical treatment is reserved for failing conservative treatment. Hoekstra, et al.³⁴ reported the management of 19 patients with post operative bile leak. 15 patients underwent PTBD, 3 patients underwent endoscopic drainage and only one patient was treated surgically. All were successfully treated. Ernst, et al.¹² revealed 16 patients with bile leaks from extrahepatic bile duct or hepaticojejunostomy anastomosis. 13 of 16 patients healed after PTBD with mean duration of 78 days (range, 30 - 150 days). Four of 13 patients had a residual narrowing of the bile duct and were successfully treated with balloon dilation. All remained cured at the mean

follow up of 38 months. Jong, et al.³⁵ measured the clinical outcomes of PTBD in the treatment of postsurgical bile leak divided by the site of leakage. Bile leaks at the biliodigestive anastomosis, at the bile duct and at the plane of resection were resolved in 80.0%, 65.5% and 25.0%, respectively.

3. Biloma

Biloma is the collection of bile outside the biliary tree, whether intrahepatic or extrahepatic, encapsulated or not. Bilomas can either result from bile duct injury with bile leakage or biliary obstruction with a weak biliary ductal wall, causing rupture of the bile duct. Small bilomas can often be conservatively managed with monitoring, whereas larger or symptomatic bilomas require intervention.

Percutaneous drainage can be done using Seldinger technique or trocar technique for larger superficial collection with either under US or CT guidance. CT is suggested for bilomas that are at interloops of bowel or only a narrow safe access route is available.

Drainage alone is often sufficient to manage bilomas. If a biloma does not respond to drainage, other treatments are required, including endoscopic stent placement, PTBD or surgical intervention. In the study of Lo, et al.^{36, 24} cases out of 177 liver resection surgery (13%) had evidence of bile leak. All required external drainage for biloma. 17 of the 24 cases (71%) did not need any other procedure. 6/24 patients (25%) were required for additional PTBD and only one patient (4%) was performed a rendezvous procedure to reanalyze the bile ducts.

Role of stent

PTBD allows biliary drainage and established access for repeat procedures. However, it is inconvenience for the patients who retain the external drainage. Also, there is limitation to achieve a large diameter catheter. Larger diameter stents maintain longer patency. The diameters of self-expanding metal stents (SEMS) are 6 to 10 mm, with the stent length of 4 to 12 cm. The biliary SEMS is released by retracting the sheath from preloaded, with a diameter of 6 to 8.5 Fr³⁷.

Bare (uncovered) metal stents result in reactive tissue hyperplasia growing through the interstices of the stent, which prevents migration, but results in occlusion and irretrievability. They are commonly used for malignant biliary obstruction. Partially covered self-expanding metal stents (PCSEMS) were also limited by in-stent tissue hyperplasia, migration, and difficulty in extraction due to mucosal hyperplasia at the uncovered proximal end. Fully covered self-expandable metal stents (FCSEMS) are coated circumferentially with a material that prevents stent

occlusion and imbedding due to bacterial colonization, tissue hyperplasia, and tumor ingrowth thereby increasing the duration of patency and permitting easier stent retrieval.

FCSEMS for use in benign biliary strictures is actively being studied. In 2014, a large prospective multicenter trial by Devière, et al.³⁸ looked at FCSEMS in 187 patients at 13 centers across 11 countries. Ninety percent had stricture resolution for chronic pancreatitis, 88% for post-liver transplant, and 91% for patients that underwent cholecystectomy. Follow up at the 20 months showed a stricture recurrence of 15%. Successful endoscopic removal was achieved in 75% of patients. Success rates of FCSEMS in benign biliary stricture range from 76 to 90% with mean follow up periods of 12 - 20 months after removal^{38, 39}. Median time to stent removal was range from 2.0 - 4.4 months^{40 - 42}. The only randomized study comparing FCSEMS with multiple plastic stents (MPS) showed no significant stricture resolution and recurrence rates but fewer endoscopic procedures and adverse events were experienced making the FCSEMS strategy more cost-effective⁴³.

Wang, et al.⁴⁴ looked at 13 patients with complex bile leaks undergoing temporary placement of FCSEMS after cholecystectomy or liver transplantation. All patients had resolution of bile leaks. Ten of 11 patients had biliary debris at removal, and two patients developed a stricture below the confluence. In this study, FCSEMS are associated with ulcerations, choledocholithiasis, and strictures. Choi, et al.⁴⁵ collected 11 patients with covered stent placement after postoperative bile leaks. Percutaneous covered stent was planned in case of major bile leak (greater than 500 mL/day) or refractory minor bile leak (less than 500 mL/day, with more than 10 days of PTBD placement). Technical success was 100% although only two patients (18.2%) revealed dilated intrahepatic bile duct. All stents were successfully removed at a mean of 31 days (range 14 - 64 days). Clinical

success was achieved in all patients with no clinical recurrence during the mean follow up of 335 days (range 184 - 699 days). Elevation of serum bilirubin was observed in five patients (45.5%) following stent placement and was caused by intrahepatic bile duct occlusion by the stent. However, the elevation had normalized within four days after stent placement without cholangitis. Success rates of FCSEMS in bile leaks were range 79 - 100% with median time to stent removal of 1.4 - 3.4 months^{46 - 48}. The predictors for success included longer indwelling time (> 90 days) and an absence of migration⁴⁹.

Although there is no consensus on the optimal duration of biliary stenting some advocate for at least 1 month and no longer than 6 months³⁹. Several randomized trials have shown that FCSEMS remained patent for up to a median of 9 months^{50 - 51}.

Two main issues regarding FCSEMS are stent migration and ease of removal. Several studies show significant migration rates up to 40%. Stent migration is observed in many patients but no major complications have been reported⁵². However, the rate of resolution of stricture was lower in patients with stent migration, and proximal stent migration may result in unsuccessful stent removal³⁸. To minimize stent migration, the concept of flared ends and anchoring flap has been introduced. Perri, et al.⁵³ conducted a prospective trial consisting of 17 patients examining FCSEMS in benign biliary strictures. Initial stent placement with unflared ends had a migration rate of 100%, with 43% in stricture resolution. Patients were then given flared-end stents, showing 40% migration with stricture resolution of 90% at 6 months and 80% at 12 months. Mahajan, et al.⁴⁰ showed that only two of 44 FCSEMS with anchoring fins migrated, but increasing incidence of ulceration and bleeding was a consequence of the fins.

In order to facilitate removal, a retrieval lasso for catching with endoscopic forceps is created. Stents designed for percutaneous removal are also available with a circumferential retrieval string at the proximal end. Traction contracts the proximal end, allowing this to be pulled into a transhepatic sheath. Removal as planned, even in expert hands, is achieved in 75 - 95% of cases, thus patients should be informed for the consequences of failed stent removal³⁸.

It should be kept in mind that a fully covered stent can occlude side branches of biliary tree, cystic duct and pancreatic duct. The potential subsegmental occlusion of contralateral intrahepatic ducts may limit the use of FCSEMS in hilar region. This issue may be managed by placing a plastic stent in the contralateral intrahepatic ducts to facilitate bile flow before placing the FCSEMS⁵². SEM results in higher rate of acute pancreatitis when compared to plastic stents (7.3% vs. 1.3%)⁵⁴. The proposed mechanism is that the FCSEMS may have higher chance of causing pancreatic orifice occlusion given its larger diameter. Endoscopic sphincterotomy or transpapillary balloon dilatation may be performed to facilitate pancreatic drainage.

The reported complications associated with placement of FCSEMS included stent migration (12 - 35%), stent clogging (5 - 12%), cholangitis (6 - 14%), pancreatitis (2 - 15%), cholecystitis (3 - 12%), and abdominal pain (2 - 10%)^{11, 38 - 42, 46 - 48}. There was no reports of tissue ingrowth or overgrowth.

In conclusion, many considerations on FCSEMS are needed including their efficacy, risks and also cost-effectiveness. FCSEMS may be a reasonable good alternative treatment option in select conditions only, such as refractory benign biliary stricture, large complex leaks and refractory bile leaks⁵².

Various types of novel SEMs such as magnetic stents, bioabsorbable stents, drug-eluting stents and anti-reflux stents are being studied. All had no significant benefit and need further clinical studies³⁷.

Complications of percutaneous management

Complications are categorized as major or minor. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization (> 48 hours), permanent adverse sequelae, or death. Major complications include sepsis, cholangitis, major venous or arterial hemobilia (arterial pseudoaneurysm or arteriobiliary fistula), hemoperitoneum and subcapsular hematoma, biloma, pleural complications (ie, pneumothorax, hemothorax, bilious effusion), and death. Minor complications result in no sequelae, including pericatheter leakage, catheter dislodgement, minor bleeding, bacteremia, and transient hyperamylasemia¹⁵.

The major and minor complications of PTC are about 2%. The complications rate for PTBD varies with preprocedural patient status and diagnosis. Patients with coagulopathies, cholangitis, stones, malignant obstruction, or proximal obstruction will have higher complication rates. The average major complications for PTBD placement is 2.5%. Complications after balloon dilation occur in 4 to 12% of cases^{15,17}.

The risk of arterial and major venous hemobilia can be minimized by avoiding puncture of the central duct. Hemodynamically unstable patient or patient with pulsatile bleeding from within or around a drainage catheter should be suspected for arterial bleeding. Prompt hepatic arteriography with embolization can treat the arterial source of bleeding. In a hemodynamically stable patient with hemobilia, tractography is performed to evaluate source of bleeding. The catheter is exchanged for a sheath. Contrast media is injected via the sheath during fluoroscopy while slowing withdrawing the sheath over the wire. If a venous source is identified, a large diameter drain may be placed and capped for 1 to 2 days to tamponade the bleeding. If these measures fail or bleeding from a large portal vein, the catheter can be relocated, and coil embolization of the old drainage tract can be performed.

Conclusion

The clinical decision whether to pursue surgical, endoscopic or percutaneous management of biliary injury is based on many clinical factors including clinical presentation, local expertise, the likelihood of longterm outcome and patient preference. Interventional radiologists play a key role in diagnosis and treatment of patients who cannot be managed by the endoscopic or surgical approach. Both symptomatic and curative treatments can be achieved by percutaneous approach.

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บทคัดย่อ

การรักษาภาวะบาดเจ็บของท่อทางเดินน้ำดีผ่านทางผิวหนัง

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ภาวะบาดเจ็บของท่อทางเดินน้ำดีเป็นภาวะแทรกซ้อนที่มักจะพบได้ไม่บ่อยจากการทำหัตถการหรือการผ่าตัดบริเวณตับและทางเดินน้ำดี แต่มีความสำคัญและเป็นอันตรายต่อผู้ป่วย ภาวะท่อทางเดินน้ำดีบาดเจ็บสามารถแบ่งได้เป็น ๒ กลุ่มใหญ่ๆ คือ ท่อน้ำดีตีบตันและท่อน้ำดีรั่ว การรักษาด้วยการผ่าตัดซ่อมแซมทำให้ผู้ป่วยหายได้ แต่การผ่าตัดมักมีข้อจำกัด เช่น ภาวะผู้ป่วยไม่เหมาะสมต่อการผ่าตัด มีผังผืดมากบริเวณที่ผ่าตัด หรือขาดศัลยแพทย์ผู้เชี่ยวชาญด้านการผ่าตัดทางเดินน้ำดี การรักษาโดยไม่ผ่าตัดได้แก่ การทำหัตถการผ่านการส่องกล้องหรือผ่านทางผนังหน้าท้อง สามารถทำได้ในผู้ป่วยเหล่านี้ อย่างไรก็ตามการส่องกล้องบางครั้งก็พบข้อจำกัด เช่น กรณีผู้ป่วยเคยทำการตัดต่อลำไส้กับท่อน้ำดีมาก่อน หรือรอยโรคอยู่บริเวณขั้วตับ การทำหัตถการผ่านทางผนังหน้าท้องจึงมีความสำคัญทั้งในแง่ของการวินิจฉัยและการรักษา หัตถการที่ทำบ่อย ได้แก่ การฉีดสารทึบรังสีเข้าไปในท่อทางเดินน้ำดีเพื่อการวินิจฉัย การใส่สายระบายน้ำดีผ่านทางผนังหน้าท้อง การใช้บอลูนขยายท่อน้ำดีผ่านทางผนังหน้าท้อง การใส่ท่อค้ำยันบริเวณท่อทางเดินน้ำดีที่ตีบหรือรั่ว และการใส่สายระบายน้ำดีที่ซึ่งอยู่ในตับหรือช่องท้อง บทความนี้ได้รวบรวมข้อมูลเกี่ยวกับวิธีการผลลัพธ์ และภาวะแทรกซ้อนของการทำหัตถการต่างๆ ผ่านทางผนังหน้าท้อง ซึ่งพบว่ามีประสิทธิภาพดีในการรักษาผู้ป่วยที่มีภาวะบาดเจ็บของท่อทางเดินน้ำดีและมีภาวะแทรกซ้อนน้อย

คำสำคัญ: ภาวะบาดเจ็บของท่อทางเดินน้ำดี, บอลูนขยายท่อน้ำดี, ท่อค้ำยันบริเวณท่อทางเดินน้ำดี