

## **Evidence-Based Clinical Practice Guidelines on Bile Duct Stones**

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This information, based on the Philippine Society of General Surgeons Inc. (PSGS) Clinical Practice Guidelines, is intended to assist surgeons and patients in the management of bile duct stones. A distinct panel of experts together with the Committee on Research and Guidelines Development of the PSGS, Inc (Technical Working Group) developed the PSGS Clinical Practice Guidelines. These guidelines are given by the PSGS based on the current scientific evidence and its views concerning accepted approaches to treatment of bile duct stones.

These guidelines are not proposed to change, but to assist the expertise and clinical judgment of general surgeons on the management of patients with bile duct stones. Each patient's condition must be evaluated individually. It is important to discuss the guidelines and all information regarding treatment options with the patient. The choice of a well-informed patient plays a great role in the decision-making of the surgical procedure.

### **Executive Summary**

The Philippine Society of General Surgeons Inc. (PSGS) together with the Philippine College of Surgeons (PCS) will make public this Evidence-based Clinical Practice Guidelines (EBCPG) on the management of bile duct stones. It has been noted that numerous high quality clinical trials have been published on different general surgical problems. These publications have resulted in modifications in other clinical practice guidelines, like those in the United States and Europe. With this in mind, the PSGS working with the PCS set up the organization of this guideline.

In the Philippines, bile duct stones procedures are declining notwithstanding the high prevalence of this problem among Orientals. In all probability, this is because of endoscopic retrograde cholangio-pancreatography being the more acceptable and less invasive option in the management. As a consequence, a surgeon has a reduced amount of practice on these problems and these guidelines will possibly enhance or increase the general surgeons understanding on these problems.

The TWG put in order the clinical questions, search method, levels of evidence and categories of recommendations. The TWG has been regularly monitoring the major sources of publications, namely, the Pubmed (Medline) of the U.S. National Library of Medicine and the Cochrane Library.

## Categories of Recommendation

Category A	At least 75 % consensus by expert panel present
Category B	Recommendation somewhat controversial and did not meet consensus
Category C	Recommendation caused real disagreements among panel

The members of the Committee on Research and Guidelines Development of the PSGS, Inc. prepared the evidence-based report based on the articles retrieved and appraised. After a thorough evaluation and validity appraisal, 13 articles were used to answer the clinical questions out of 69 retrieved articles. The committee members then held several meetings to discuss each question with corresponding evidences and recommendations. The first draft was discussed and modified by a Panel of Experts called together by the PSGS and PCS on November 13, 2004 at the PMA Auditorium. A second draft was completed by the TWG and this was discussed in a Public Forum on December 5, 2004 during the 61<sup>st</sup> Clinical Congress of the PCS held at the Palawan III EDSA Shangri-la Hotel. The PSGS Board of Directors then accepted the guidelines on February 11, 2005.

## LEVELS OF EVIDENCE

### Oxford Centre for Evidence-Based Medicine May 2001

Level	Therapy	Diagnosis
1A	SR** with homogeneity of RCT's	SR with homogeneity of Level 1 diagnostic studies from different clinical centers
1B	Individual RCT	One clinical center
1C	All or none*	High sensitivity and specificity
2A	SR with homogeneity of cohort studies	SR with homogeneity of Level 2 diagnostic studies
2B	Individual cohort study	Cohort study
2C	Outcomes research	
3A	SR with homogeneity of case-control studies	SR with homogeneity of 3 b and better studies
3B	Individual case-control study	Non-consecutive study, or without consistently applied reference standards
4	Case-series (and poor quality cohort and case-control studies)	Case-control study, poor or non-independent reference standard
5	Expert opinion	Expert opinion

\*\* SR systematic reviews

\* Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.

## Recommendations

### *Common Bile Duct Stones*

1. Magnetic resonance cholangiography (MRC) is the procedure of choice for patients with suspected common bile duct stones to confirm the diagnosis. (Level 1A, 1B, and 5, Category C)

The Expert Panel recommends that the patients with suspected stones may proceed with surgery with intra-operative cholangiography in the light of the high-cost and non-availability of MRCP in most local institutions.

2. The recommended treatment for patient with common bile duct stones without cholangitis is surgery. (Level 1A, Category A)
3. Among the different treatment options for common bile duct stones, choledochoduodenostomy has the least recurrence. (Level 4, Category A)
4. The recommended treatment for patients with gall bladder stones after endoscopic common bile duct clearance is surgery, to be performed within 24 to 48 hours after clearance. (Level 1B, Category A)

### *Intrahepatic Stones (Hepatolithiasis)*

5. Magnetic resonance cholangiography is the recommended diagnostic tool to confirm the presence of intrahepatic stones. (Level 2, Category A)
6. The recommended treatment includes surgical management (hepatic resection) and cholangioscopic techniques, whether through a T-tube tract, a percutaneous transhepatic approach (PTBD/PTCS) or a transpapillary approach, singly or in combination. Ancillary techniques include tract or stricture dilatation, stenting and various methods of lithotripsy and stone extraction. (Level 1B, 2, 3, 5, Category A)

In the absence of adequate controlled clinical trials, the Expert Panel recognizes various treatment options, both surgical and endoscopic, and stresses the need for stone clearance in whichever method employed.

### *Cholangitis*

7. The recommended antibiotics for the treatment of cholangitis are:  
Ciprofloxacin 200mgs IV BID or Ceftazidime 1gm IV BID + Ampicillin 500mgs IV QID + Metronidazole 500mgs IV TID (Level 1B, Category B)

Alternative antibiotics would include: Piperacillin + an Aminoglycoside + Metronidazole or Piperacillin-Tazobactam or Ampicillin-Sulbactam or Ticarcillin-Clavulanic acid (Level 5, Category B)

However, if the patient's pre-treatment bilirubin level is greater than 5mg/dl, aminoglycosides should be avoided. (Level 2, Category B)

The expert panel cannot recommend the choices of antibiotics due to the limited comparative studies that were available. Likewise, the panel also stated that the

alternative antibiotic regimen that was recommended (triple therapy) may be too expensive and compliance might be a problem.

8. The recommended treatment for patients with severe cholangitis is non-operative biliary drainage (endoscopic). (Level 1B, Category A)  
If endoscopic drainage is not available or is not successful, percutaneous transhepatic biliary drainage (PTBD) or surgical decompression are the recommended alternatives. (Level 5, Category A)

#### *Retained Common Bile Duct Stones*

9. For patients who have had prior cholecystectomy and have a high probability of common bile duct stones, ERCP and sphincterotomy with Dormia basket extraction is the preferred initial approach. (Level 2B, Category A)

#### *Technical Working Group*

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### **Acknowledgment/Disclosure**

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### **Methods**

A search of publications was carried out using a sensitive search strategy combining MESH and free text searches of databases. This strategy included an extensive search of the following databases:

1. Medline
2. Cochrane Library
3. Philippine Journal of Surgical Specialties and hand searches

From the search results, there were abstracts retrieved and relevant articles were selected for full-text retrieval by the Nominal Group Technique. Retrieved studies were then assessed for eligibility according to the criteria set by the guideline developers.

The pertinent results of the selected 19 articles based on the clinical questions were summarized and compared. For diagnostic articles – sensitivity, specificity, predictive values and likelihood ratios; for articles on therapy – relative risk/absolute risk, risk differences and number-needed-to-treat (NNT) were computed and compared when appropriate.

### *Operational Definitions*

1. Patients with suspected common bile duct stones (CBD)
  - They refer to patients with acute pancreatitis and a suspected choledocholithiasis; acute pancreatitis of unknown cause; acute cholecystitis with dilatation of the common duct and cholestasis; cholangitis; cholestasis with or without painful abdomen or fever; and suspected choledocholithiasis after cholecystectomy
2. Intrahepatic stones
  - Primary intrahepatic stones are formed within the intrahepatic ducts, proximal to the confluence of the right and left hepatic ducts. They are usually noted as multiple stones and accompany morphological ductal changes such as strictures, dilatations and angulations. In practical terms, primary intrahepatic stones can be differentiated from secondary intrahepatic stones by the presence of intrahepatic strictures at a site distal to the stone.
  - Secondary intrahepatic stones are formed initially within the extrahepatic ducts but have migrated into the intrahepatic ducts.
3. Patients suspected with intrahepatic stones
  - These patients present with upper abdominal pain, occasional fever, and/or jaundice although a large proportion of patients may remain asymptomatic

#### 4. Cholangitis

- An infection of an obstructed biliary, most commonly due to CBD stones, ranging from mild ascending cholangitis (in which bacteria colonize the biliary tree but gross purulence is not present) to acute suppurative cholangitis (characterized by the presence of pus under pressure in the obstructed biliary tree)

### Results

#### *Common Bile Duct Stones*

1. What is the recommended ancillary procedure in a patient with suspected common duct stone to confirm its diagnosis?

Magnetic resonance cholangiopancreatography is the recommended procedure for patients with suspected common bile duct stones to confirm the diagnosis. (Level 1A, 1B and 5, Category C).

The expert panel recommends that in patients with suspected stones, one may proceed with surgery and intra-operative cholangiography in the light of the high-cost and non-availability of MRCP in most local institutions.

Romagnuolo, et al.<sup>6</sup> in October 2003 published in the *Annals of Internal Medicine* a meta-analysis of test performance in suspected biliary disease using Magnetic Resonance Cholangiopancreatography (MRCP). It was shown in his study that MRCP, a noninvasive imaging test has excellent overall sensitivity and specificity for demonstrating the level and presence of biliary obstruction, but it is less accurate at differentiating malignant from benign causes of obstruction. It is accurate for choledocholithiasis; however, its ability to diagnose small stones in nondilated ducts may be limited.

#### Overall sensitivity and specificity and their spread for each imaging end point

Imaging End Point	Sensitivity (1.96 SD)	Specificity (1.96 SD)	Likelihood Ratios of Positive Test Result (95% CI)
Presence of obstruction	97 (91-99)	98 (91-99)	49 (25-62)
Level of obstruction	98 (94-99)	98 (94-100)	49 (25-135)
Stone detection	92 (80-97)	97 (90-99)	29 (23-49)
Malignancy detection	88 (97-96)	95 (82-99)	16 (10-30)
Overall	95 (97.5-99)	97 (86-99)	32 (13-84)

Nyree, et al.<sup>3</sup> in 2003 published in the *European Journal of Gastroenterology and Hepatology* a comparative study between magnetic resonance cholangiography versus endoscopic retrograde cholangiopancreatography in the diagnosis of choledocholithiasis. It was shown that MRCP has high sensitivity and specificity for stones greater than 5 mm in diameter and should be performed in preference to ERCP as the first line investigation in patients with gallstones and abnormal liver function tests in the elective setting.

In May 2002, the National Institute of Health (NIH)<sup>12</sup> consensus conference panel recommended that noninvasive imaging studies of the bile duct should be performed when there is low index of clinical suspicion for choledocholithiasis, specifically MRCP and

endoscopic ultrasound (EUS). Endoscopic retrograde cholangiopancreatography should be reserved for patients in whom choledocholithiasis (e.g. clinical cholangitis) is highly suspected or used when other imaging modalities suggest choledocholithiasis.

2. What is the recommended treatment for patients with common bile duct (CBD) stones without cholangitis?

The recommended treatment for patient with CBD stones without cholangitis is surgery. (Level 1A, Category A)

The rate of second anesthesia for additional procedures and, consequently, the additional risks and costs are such that endoscopic management (EM) alone is insufficient and not warranted in patients with symptomatic choledocholithiasis who have not had cholecystectomy<sup>4</sup>.

The only indication for initial EM would be the case of a patient with a previous cholecystectomy because in that case, the risks related to leaving the gallbladder in place are eliminated. Surgical treatment is more advantageous than EM because the gallbladder can be removed (thus eliminating the risk of subsequent acute cholecystitis) and the CBD visualized directly by choledochoscopy.

Routine combined endoscopic and surgical treatment cannot be the choice for CBD and gallbladder stones nowadays because of the increased risks and costs associated with more than 1 anesthesia and additional procedures.

3. Among the different treatment options for common bile duct stones, which procedure has the least recurrence?

Among the different treatment options for common bile duct stones, choledochoduodenostomy has the least recurrence. (Level 4, Category A)

Uchiyama in 2003<sup>4</sup> reviewed 213 cases of CBD stones managed differently, results showed that there was no recurrence with choledochoduodenostomy (CD) while the recurrence rates for T-tube (TT) drainage and endoscopic sphincterotomy (EST) were 10.3% and 9.8%, respectively,  $p$  value < 0.05.

4. What is the recommended treatment for patients with gall bladder stones after endoscopic common bile duct clearance?

Recurrence rate by type of treatment for choledocholithiasis.

	TT	EST	CD	p value
No. of patients	87	82	44	
No. of patients w/ recurrence	9	8	0	
Recurrence rate	10.3%	9.8%	0	< 0.05

The recommended treatment for patients with gall bladder stones after endoscopic common bile duct clearance is surgery, to be performed within 24 to 48 hours after clearance. (Level 1B, Category A)

In a multi-center randomized trial by Boerma and Rauws<sup>5</sup>, 120 patients (age 18-80 years) underwent endoscopic sphincterotomy and stone extraction, with proven gallbladder stones. Patients were randomly allocated to wait and see (n=64) or laparoscopic cholecystectomy (n=56). Primary outcome was recurrence of at least one biliary event during 2-year follow-up, and secondary outcomes were complications of cholecystectomy and quality of life. Analysis was by intention to treat. Sixty-four patients were assigned to wait and see policy after ERCP with 5-drop outs (n=59). The 56 who had outright laparoscopic cholecystectomy after ERCP had 7 drop-outs (n=49). Of 59 patients allocated to wait and see 27 (47%) had recurrent biliary symptoms compared with one of 49 (2%) patients after laparoscopic cholecystectomy (relative risk 22.42, 95% CI 3.16-159.14, p<0.0001). A wait and see policy for gall bladder stones cannot be recommended as standard of treatment due to very high recurrence of biliary symptoms and high conversion rate during laparoscopic cholecystectomy.

Comparisons of wait and see policy and outright laparoscopic cholecystectomy and occurrence of biliary symptoms.

	(+) Biliary Symptoms	(-) Biliary Symptoms	
Wait and see	27	32	59
Outright lap cholecystectomy	1	48	49
	28	80	TOTAL

RR=22.42 95% CI (3.16-159.14)

### *Intrahepatic Stones (Hepatoolithiasis)*

1. What is the recommended diagnostic tool to confirm the presence of intrahepatic stones with or without strictures?

Magnetic resonance cholangiography is the recommended diagnostic tool to confirm the presence of intrahepatic stones. (Level 2, Category A)

Seo<sup>7</sup> in 1999 reviewed intrahepatic stones, several imaging modalities are available: ultrasonography, abdominal CT scan, MRCP, ERCP and percutaneous transhepatic cholangiography. For screening purposes in patients with suspected intrahepatic stones, ultrasonography may be the procedure of first choice, however, its diagnostic accuracy for hepatoolithiasis is not very satisfactory and its success rate is operator-dependent.

An abdominal CT scan gives considerable objective information about intrahepatic stones and the deformity of intrahepatic ducts. However, if the stones are composed mainly of cholesterol with a minimal amount of calcium, the stones might not be noted on CT.

ERCP can be used to delineate the extrahepatic and intrahepatic ducts and detect stones; however, the main obstacle to stone detection is the frequent association of intrahepatic duct strictures and the development of cholangitis after the procedure.



Using PTC as the reference standard, the overall sensitivity, specificity and accuracy rates of MRCP for diagnosing hepatolithiasis were 97%, 99% and 98%, respectively. The overall sensitivity, specificity and accuracy rates of MRCP for detecting intrahepatic bile duct strictures were 93%, 97% and 97%, respectively.

## 2. What is the recommended treatment for intrahepatic stones with or without strictures?

The recommended treatments include surgical management (hepatic resection) and cholangioscopic techniques, whether through a T-tube tract, a percutaneous transhepatic approach (PTBD/PTCS) or a transpapillary approach, singly or in combination. Ancillary techniques include tract or stricture dilatation, stenting and various methods of lithotripsy and stone extraction. (Level 1B, 2, 3 and 5, Category A)

In the absence of adequate controlled clinical trials, the expert panel recognizes various treatment options, both surgical and endoscopic, and stresses the need for stone clearance in whichever method employed.

For patients with intrahepatic stones with mild bile duct strictures and normal segmental bile duct drainage, choledochoscopic treatment is indicated. Takada, et al.<sup>8</sup> in 1996 reported 86 cases of intrahepatic stones wherein successful stone removal was achieved in the absence of bile duct stricture (98%) and mild bile duct stricture (63%); and 80 percent in cases with no drainage variation of the posterior segmental bile duct. In this study “No stricture” meant the successful passage of a 5 mm choledochoscope, “mild stricture” meant drainage and stones were evident but access to the stones was impossible without dilatation and “severe stricture” is when the stones and the lumen of the ducts were not choledochoscopically identifiable.

Dong Wan Seo<sup>7</sup> in 1999 reviewed two major treatment modalities, operative management and percutaneous approach. Operative treatment should aim at complete removal of intrahepatic stones and control factors possibly responsible for their recurrence namely; bile duct strictures, dilatations and angulations of intrahepatic ducts, bile stasis and superimposed bacterial infections. As such, operative treatment should aim for the complete removal of both stones and strictures, and should provide adequate drainage of bile to minimize bile stasis and bacterial infections.

When stones are located only in the left intrahepatic ducts and the affected left hepatic lobe shows atrophic changes, left lateral hepatic segmentectomy or left hepatic lobectomy may be indicated.

When the stones are located exclusively in the right intrahepatic ducts, right anterior or posterior segmentectomy may be considered. Right hepatic lobectomy is technically possible but not usually performed because of surgical risks, and the cholangioscopic approach may be more appropriate. Cholangioscopic techniques and instrumentation could be accomplished through various routes: following PTBD and tract through a postoperative T-tube tract, through the gallbladder after cholecystostomy and tract dilatation using a baby scope, and through a transpapillary approach with the aid of a mother scope. Electrohydraulic or laser lithotripsy may be applied and fragmented stones removed by basket. Strictures could be dilated using balloon catheters or by bougienage.

## *Cholangitis*

### 1. What is the antibiotic of choice for patients with cholangitis?

The recommended antibiotics for the treatment of cholangitis are: Ciprofloxacin 200mgs IV BID or Ceftazidime 1gm IV BID + Ampicillin 500mgs IV QID + Metronidazole 500mgs IV TID (Level 1B, Category B)

Alternative antibiotics would include: Piperacillin + an Aminoglycoside + Metronidazole or Piperacillin-Tazobactam or Ampicillin-Sulbactam or Ticarcillin-Clavulanic acid (Level 5, Category B)

However, if the patient's pre-treatment bilirubin level is greater than 5mg/dl, Aminoglycosides should be avoided. (Level 2, Category B)

The expert panel cannot recommend the choices of antibiotics due to the limited comparative studies that are available. The expert panel also stated that the alternative antibiotic regimen that was recommended (triple therapy) may be too expensive and compliance might be a problem.

The spectrum of bacteria in cholangitis varies between institutions and is influenced by the underlying cause and practice profile. In patients with choledocholithiasis, the most frequent organisms are gram-negative (*Escherichia coli*, *Klebsiella*, *Proteus*, *Pseudomonas aeruginosa*) while anaerobes (*Bacteroides* and *Clostridium sp.*) are less common (Bornman<sup>13</sup> 2003, Scott-Conner<sup>14</sup> 1993, Hanau<sup>15</sup> 2000). Although different antibiotics have different biliary penetration, it is still unclear whether the antimicrobial chosen has to achieve high levels in bile.

In a prospective randomized clinical trial by Sung<sup>16</sup> (1995) involving 100 patients, Ciprofloxacin at a dose of 200mgs IV BID was compared to a combination of Ceftazidime (1gm IV BID), Ampicillin (500mgs IV QID) and Metronidazole (500mgs IV TID) for acute suppurative cholangitis. The response to therapy, recurrence and mortality rates and the need to do endoscopy or surgery for uncontrolled infection was similar for both groups. The results suggest that Ciprofloxacin alone is adequate empirical treatment for patients with cholangitis.

### 2. What is the recommended treatment for patients with severe cholangitis?

The recommended treatment for patients with severe cholangitis is non-operative biliary drainage (endoscopic). (Level 1B, Category A)

If endoscopic drainage is not available or is not successful, percutaneous transhepatic biliary drainage (PTBD) or surgical decompression are the recommended alternatives. (Level 5, Category A)

In a prospective randomized trial involving 82 patients (Lai 1992)<sup>17</sup>, endoscopic biliary drainage was compared to surgery in the emergency management of severe cholangitis. Complications related to biliary tract decompression and subsequent definitive treatment developed in 14 patients treated with endoscopic biliary drainage and 27 treated with surgery (34% vs. 66%,  $p > 0.05$ ). The hospital mortality rate was significantly lower for the patients who underwent endoscopy (4 deaths) than for those treated surgically (13

deaths) (10% vs. 32%,  $p < 0.03$ ). With the RRR for endoscopic drainage in severe cholangitis noted to be 69 percent, an ARR of 22 percent and an NNT of 5, this study showed a significant reduction in mortality after endoscopic drainage.

### *Retained Common Bile Duct Stones*

#### 1. What is the recommended treatment for retained common bile duct stones?

For patients who have had prior cholecystectomy and have a high probability of common bile duct stones, ERCP and sphincterotomy with Dormia basket extraction is the preferred initial approach. (Level 2B, Category A)

NIH Consensus Statement in January 2002<sup>18</sup>, ERCP clears the CBD of stones in up to 85 percent of cases. With the aid of mechanical lithotripsy, 90 percent of all bile duct stones could be endoscopically removed. It is for the remaining problematic bile duct stones where many therapeutic approaches are available, including ESWL, contact dissolution, electrohydraulic and laser lithotripsy, and stenting.

A prospective comparative study (Adamek, 1996)<sup>19</sup> involving 125 patients over a 43-month period was done to compare extracorporeal piezoelectric lithotripsy (ESWL,  $n = 79$ ) and intracorporeal electrohydraulic lithotripsy (EHL,  $n = 46$ ) as complementary modalities for treating difficult bile duct stones. The patients were selected if their stones were not accessible to endoscopic extraction and if at least one attempt at mechanical lithotripsy had failed. The main reasons that conventional endoscopy failed were the large size of the stones (41 patients), impacted stones (48 patients), the presence of a biliary stricture (24 patients), or anatomic reasons like a Billroth II operation (12 patients). Fifty-nine patients (47%) had previously undergone cholecystectomy.

In the ESWL group, visualization of stones by ultrasound and ensuing treatment were possible in 71 out of 79 patients (90 %); stones could be fragmented in 68 patients. The biliary tree could then be completely freed of calculi in 78.5 percent of cases. In the EHL group, stones were successfully fragmented in 38 of 46 patients and 74 percent eventually became stone free. Thirty-day mortality was zero in both groups. Combined treatment was successful in 118 patients (94%). The authors concluded that endoscopic management in combination with lithotripsy techniques could be recommended as the method of choice for treating difficult common bile duct stones.

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