

Quality Improvement Guidelines for Percutaneous Transhepatic Cholangiography, Biliary Drainage, and Percutaneous Cholecystostomy



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PREAMBLE

THE membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

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Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then a critical review of peer-reviewed articles is performed with regards to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members using a modified Delphi consensus method

(Appendix A). For purposes of these documents consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Subcommittee, and appropriate revisions made to create the finished standards document. Prior to its publication the document is endorsed by the SIR Executive Council.

INTRODUCTION

Percutaneous transhepatic cholangiography is a safe and effective technique for evaluating biliary abnormalities. It reliably demonstrates the level of abnormalities and sometimes can help diagnose their etiologies. Percutaneous transhepatic biliary drainage is an effective method for the primary or palliative treatment of many biliary abnormalities demonstrated with cholangiography. Percutaneous cholecystostomy is an effective method for decompressing the gallbladder for managing cholecystitis either definitively or as a temporizing measure before cholecystectomy.

These guidelines are written to be used in quality improvement programs to assess percutaneous transhe-

patric cholangiography, biliary drainage, and cholecystostomy. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Percutaneous transhepatic cholangiography is a diagnostic procedure that involves the sterile placement of a small-gauge needle into peripheral biliary radicles with use of imaging guidance, followed by contrast material injection to delineate biliary anatomy and potential biliary pathologic processes. The findings are documented on radiographs obtained in multiple projections. Percutaneous transhepatic biliary drainage is a therapeutic procedure that includes the sterile cannulation of a peripheral biliary radicle after percutaneous puncture followed by imaging-guided wire and catheter manipulation. Placement of a tube or stent for external and/or internal drainage completes the procedure. Percutaneous therapy of biliary lesions is often staged, requiring several sessions to achieve the therapeutic goals. Percutaneous cholecystostomy is a therapeutic procedure that involves the sterile placement of a needle into the gallbladder with use of imaging guidance to aspirate bile. This is commonly followed by sterile placement of a tube for external drainage of gallbladder contents, which completes the procedure.

Successful percutaneous transhepatic cholangiography is defined as sufficient needle localization and contrast material opacification to allow image-based diagnosis or planning of treatment. Successful biliary drainage or cholecystostomy is defined as the placement of a tube or stent with use of imaging guidance to provide continuous drainage of bile.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal

Table 1
Percutaneous Transhepatic Cholangiography: Indications (1–6)

Define level of obstruction in patients with dilated bile ducts
Evaluate for presence of suspected bile duct stones
Determine etiology of cholangitis
Evaluate suspected bile duct inflammatory disorders
Demonstrate site of bile duct leak
Determine etiology of transplanted hepatic graft dysfunction

Table 2
Percutaneous Transhepatic Biliary Drainage: Indications (7–10)

Provide adequate biliary drainage
Decompress obstructed biliary tree
Divert bile from and place stent in bile duct defect
Provide a portal of access to the biliary tract for therapeutic purposes that include but are not limited to
Dilate biliary strictures
Remove bile duct stones
Stent malignant lesions
Brachytherapy/phototherapy
Endoluminal tissue sample or foreign body retrieval
Provide a portal of access to the biliary tract for mid- to long-term diagnostic purposes (lower-risk cholangiography*)

*Cholangiography from an indwelling percutaneous biliary drain site is probably a lower-risk cholangiography procedure than repetitive de novo percutaneous transhepatic cholangiography with the use of needles.

therapy or a short hospital stay for observation (generally overnight; see [Appendix B](#)). The complication rates and thresholds described herein refer to major complications unless otherwise specified.

INDICATIONS AND CONTRAINDICATIONS

Indications for percutaneous transhepatic cholangiography, percutaneous transhepatic biliary drainage, and cholecystostomy are listed in [Tables 1–3](#), respectively (1–27). The threshold for these indications is 95%. When fewer

Table 3
Percutaneous Cholecystostomy: Indications (11–27)

Gallbladder access (>95%)*
Management of cholecystitis
Portal for dissolution/removal of stones
Biliary tract access (<5%)*
Decompress obstructed biliary tract
Divert bile from bile duct defect
Provide a portal of access to the biliary tract for therapeutic purposes (see [Table 2](#))

*The thresholds for gallbladder and transcholecystic biliary tract access are 95% and 5%, respectively. When this ratio for these indications is different, the department will review the process of patient selection. The first-line route for percutaneous biliary tract access is the transhepatic route and not the transcholecystic route.

than 95% of procedures are for these indications, the department will review the process of patient selection.

Currently, metal stents are used almost exclusively for malignant disease. However, the committee recognizes that covered metal stent (or stent-graft) placement for benign strictures with the intent of subsequent retrieval is a potentially new indication, although the results of this are still inconclusive.

Gallbladder decompression for the management of cholecystitis can be performed with the intent of definitive therapy in patients at high risk with medical comorbidities or as a temporizing measure augmenting medical treatment and preceding a subsequent, more elective, cholecystectomy. The decision of whether to proceed with cholecystectomy (in a surgical candidate) or consider percutaneous cholecystostomy a definitive measure (in a nonsurgical candidate) is usually multidisciplinary (ie, surgical, anesthesiology, and radiology) and depends on patients' response to therapy.

Coagulopathy is a relative contraindication to percutaneous transhepatic cholangiography, biliary drainage, and percutaneous cholecystostomy. Every effort should be made to correct or improve coagulopathy before the procedure. In patients with persistent coagulopathy, these procedures may still be indicated if they are associated with a

Table 4
Percutaneous Transhepatic Cholangiography: Success Rates (1–4)

Outcome	Threshold (%)
Opacify dilated ducts	95
Opacify nondilated ducts	65

lower expected morbidity rate than alternative methods of diagnosis or treatment.

QUALITY IMPROVEMENT

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. “Procedure thresholds” or “overall thresholds” reference a group of indicators for a procedure (eg, major complications). Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary. For example, if the incidence of sepsis is one measure of the quality of percutaneous transhepatic cholangiography, values in excess of the defined threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to increase or decrease values to meet its own quality improvement program needs.

Participation by the radiologist in patient follow-up is an integral part of percutaneous transhepatic cholangiography, biliary drainage, and cholecystostomy

Table 5
Percutaneous Transhepatic Biliary Drainage: Success Rates (9,28–41)

Outcome	Threshold (%)
Procedural success after opacification by PTC	
Cannulation	
Dilated ducts	95
Nondilated ducts	70
Internal drainage (tube or stent)	90*
Stone removal (9,34)	90
Patency success	
Stricture dilation (benign)	
Sclerosing cholangitis (35–37)	†
Other (35,38–41)	†
Palliative stents for malignant disease (28–33)	50 (at 6 mo)

Note.—PTC = percutaneous transhepatic cholangiography.
*Among successful cannulations.
†Consensus for threshold not reached (see Appendix A).

Table 6
Percutaneous Cholecystostomy: Success Rates (19,42–59)

Outcome	Threshold (%)
Procedural success for aspiration of gallbladder contents (19,42–44)	
Technical success*	
21-gauge needle	80
18-gauge needle	95
Clinical success†	
Single aspiration	50
Multiple (<i>n</i> = 2–3) aspirations	80
Procedural success for cholecystostomy drain placement (45–59)	
Technical success	90
Intent-to-treat clinical success†	65
Cholecystostomy as definitive treatment in the sick (high risk of morbidity)	
With cholecystectomy or repeat cholecystostomy resorted to as needed	75
Cholecystostomy for acalculous cholecystitis	65
Cholecystostomy for calculous cholecystitis	75

*Greater than 95% of failures resulted from thick aspirate and not failure to access gallbladder under image guidance (19,42–44).
†Clinical success based on reduction of pain, fever, white blood cell count, and C-reactive protein (19,42–59).

and will increase the success rate of the procedure. Close follow-up, with monitoring and management of patients who have undergone percutaneous transhepatic cholangiography, biliary drainage, and cholecystostomy, is appropriate for the radiologist.

SUCCESS RATES AND THRESHOLDS

Success rates for percutaneous transhepatic cholangiography, percutaneous transhepatic biliary drainage, and percutaneous cholecystostomy are

listed in **Tables 4–6**, respectively (1–4,9,19,28–59).

Clinical success rate of cholecystostomy in a particular practice depends on patient selection. Patients’ comorbidity, the proportion of patients with cholelithiasis, and whether the preprocedural diagnosis of cholecystitis is correct affect results. Having a low threshold for diagnosing cholecystitis in inpatients potentially increases the rate of false positive cholecystitis, and in turn this reduces the success rate of cholecystostomy. Positive microbial culture of gallbladder aspirate has

been reported in between 40% and 80% of cases (12,14,18,52,54,55,58–61).

COMPLICATION RATES

Percutaneous Transhepatic Cholangiography

When 21-gauge or smaller needles are used, the major and minor complications of percutaneous transhepatic cholangiography should be low. All patients should be treated with appropriate antibiotics before needle puncture (1–4,62,63). Complication rates are listed in **Table 7**.

Percutaneous Transhepatic Biliary Drainage

The complication rate for transhepatic biliary drainage can be substantial, and varies with preprocedure patient status and diagnosis (**Table 8**) (10,28–30,32,33,64–66). Patients with coagulopathies, cholangitis, stones, malignant obstruction, or proximal obstruction will have higher complication rates (9,32,65,67,68). Several authors have suggested that complications related to internal/external tubes as a result of inadequate bile flow and tube dislodgment (sepsis and hemorrhage) can be minimized by placing a self-retaining tube of at least 10 F through the ampulla or anastomosis (8,10,64). All patients should be treated with appropriate antibiotics before initiating the procedures to minimize septic complications (62,63). The duration of antibiotic therapy after the procedures will be determined by the clinical course of individual patients.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Therefore, we recommend that complication-specific thresholds be set at twice the complication-specific rates listed in **Table 8**. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program. The recommended overall proce-

Table 7
Percutaneous Transhepatic Cholangiography: Major Complications

Major Complication	Reported Rate (%)	Suggested Procedure Threshold (%)
Sepsis, cholangitis, bile leak, hemorrhage, or pneumothorax	2	4

Table 8
Percutaneous Transhepatic Biliary Drainage: Major Complications (10,28–30,32–33,64–66)

Major Complication	Reported Rate (%)	Suggested Specific Threshold (%)
Intraprocedural		
Sepsis	2.5	5
Hemorrhage	2.5	5
Inflammatory/infectious (abscess, peritonitis, cholecystitis, pancreatitis)	1.2	5
Pleural	0.5	2
Death	1.7	3
Postprocedural		
Inadvertent catheter discontinuation requiring de novo PTC, death and/or surgery	*	*

Note.—PTC = percutaneous transhepatic cholangiography.

*There is no clear consensus in the literature on the rate of this complication. However, it is a recognized postprocedural complication.

Table 9
Percutaneous Cholecystostomy: Major Complications (11–19,42,46–50,52,54,58–59)

Major Complication	Reported Rate (%)	Suggested Specific Threshold (%)
Intraprocedural		
Sepsis	2.5	5
Hemorrhage	2.2	5
Inflammatory/infectious (abscess, peritonitis)	2.9	6
Transgression of adjacent structures (colon, small bowel, pleura)	1.6	2
Death	2.5	3
Postprocedural		
Inadvertent catheter discontinuation requiring de novo cholecystostomy, death and/or surgery	<1	2

cedure threshold for all major complications of percutaneous transhepatic biliary drainage is 10%.

Percutaneous Cholecystostomy

The complication rate for percutaneous cholecystostomy varies with preprocedure patient status (**Table 9**) (11–19,42,46–50,52,54,58,59). All patients should be treated with appropriate antibiotics, and the duration of antibiotic therapy after the procedure will be determined by the clinical

course of individual patients. Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising tens of patients, which is a volume larger than most individual practitioners are likely to treat. Therefore, we recommend that complication-specific thresholds be set at twice the complication-specific rates listed in **Table 9**. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication

occurs in a small volume of patients (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program. The recommended overall procedure threshold for all major complications of percutaneous cholecystostomy is 5% (sequelae of catheter dislodgment not included). The 30-day postprocedural mortality rate depends on patient selection/referral patterns and has a wide range (8%–36%) depending on the population presented (13,15,18,47,53,54,57). The vast majority of 30-day mortality cases are related to patient comorbidities and not directly a cause of the procedure.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a larger volume than most individual practitioners are likely to treat. Generally the complication-specific thresholds should be set higher than the complication-specific reported rates listed here. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient series (eg, early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program. In **Table 9**, all values are supported by the weight of literature evidence and panel consensus.

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APPENDIX A: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

The Committee was unable to reach consensus on (i) the patency rate or threshold for dilation of strictures caused by sclerosing cholangitis and the (ii) patency rate or threshold for dilation of benign strictures not caused by sclerosing cholangitis. The failure to reach consensus was a result of limited reported data and lack of agreement between reported data and the experiences of the committee members.

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APPENDIX B: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

- A. No therapy, no consequence.
- B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

- C. Require therapy, minor hospitalization (<48 hours).
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
- E. Permanent adverse sequelae.
- F. Death.

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.