

Quality Improvement Guidelines for Percutaneous Transhepatic Cholangiography and Biliary Drainage

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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.

Participation by the radiologist in patient follow-up is an integral part of percutaneous transhepatic biliary drainage and will increase the effectiveness of the procedure. Close follow-up, with monitoring and management of the patients' drainage-related problems, is appropriate for the interventional radiologist.

These guidelines are written to be used in quality improvement programs to assess percutaneous biliary procedures. The most important processes of care are (a) patient selection, (b) performing the procedure, and (c)

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. 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 or internal drainage completes the procedure. Percutaneous therapy of biliary lesions is often staged, requiring several sessions to achieve the therapeutic goals. 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 is defined as the placement of a tube or stent with use of imaging guidance to provide continuous drainage of bile.

While 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. Therefore, in addition to quality improvement case reviews customarily conducted after individual procedural failures or complications, indicator thresholds should 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, when reached or crossed, should prompt a review of departmental policies and procedures. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure (eg, major complications for biliary drainage). Individual complications may also be associated with complication-specific thresholds (eg, fever or hemorrhage). When indicators such as success rates or indications fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a departmental review should be performed to determine causes and to implement changes, if necessary. 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. Therefore, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed

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

1. Define level of obstruction in patients with dilated bile ducts
2. Evaluate for presence of suspected bile duct stones
3. Determine etiology of cholangitis
4. Evaluate suspected bile duct inflammatory disorders
5. Demonstrate site of bile duct leak

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

1. Decompress obstructed biliary tree
2. Dilate biliary strictures
3. Remove bile duct stones
4. Divert bile from and stent bile duct defect

Table 3
Percutaneous Transhepatic Cholangiography: Success Rates (1–4)

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

to higher or lower values, to meet its own quality improvement program needs.

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 therapy or a short hospital stay for observation (generally overnight) (Appendix A). The complication rates and thresholds, described subsequently, refer to *major* complications, unless otherwise noted.

INDICATIONS

Indications for percutaneous transhepatic cholangiography and percutaneous transhepatic biliary drainage are

Table 4
Percutaneous Transhepatic Biliary Drainage: Success Rates (10–16)

	Threshold
Procedural success after opacification by PTC	
Cannulation	
Dilated ducts	95%
Nondilated ducts	70%
Internal drainage (tube or stent)	90% of successful cannulations
Stone removal (9,17)	90%
Patency success	
Stricture dilatation (benign)	
Sclerosing cholangitis (18–20)	*
Other (18,21–24)	*
Palliative stents for malignant disease (11–16)	50% @ 6 mo

* Consensus for threshold not reached. See Appendix B.

Table 5
Percutaneous Transhepatic Cholangiography: Major Complications

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

Table 6
Percutaneous Transhepatic Biliary Drainage: Major Complications

Major Complications (procedure related)	Reported Rates (%)	Suggested Specific Thresholds (%)
Sepsis	2.5	5
Hemorrhage	2.5	5
Localized inflammatory/infectious (abscess, peritonitis, cholecystitis, pancreatitis)	1.2	5
Pleural	0.5	2
Death	1.7	3

listed in **Tables 1 and 2**, respectively. Currently, metal stents are used almost exclusively for malignant disease. The threshold for these indications is 95%. When fewer than 95% of procedures are for these indications, the department will review the process of patient selection.

Coagulopathy is a relative contraindication to percutaneous transhepatic cholangiography and biliary drainage. 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 have lower expected morbidity than alternative methods of diagnosis or treatment.

SUCCESS RATES

Success rates for percutaneous transhepatic cholangiography and percutaneous transhepatic biliary drainage are listed in **Tables 3 and 4**, respectively.

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 (1–4,25,26). Complication rates are listed in **Table 5**.

Percutaneous Transhepatic Biliary Drainage

The complication rate for transhepatic biliary drainage can be substantial, and varies with preprocedure patient status and diagnosis (10–13,15,16,27–29) (**Table 6**). Patients with coagulopathies, cholangitis, stones, malignant obstruction, or proximal obstruction will have higher complication rates (9,15,28,30,31). Complications related to internal/external tubes due to 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 (8,10,27). All patients should be treated with appropriate antibiotics before initiating the procedures to minimize septic complications (25,26). 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 6**. 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 transhepatic biliary drainage is 10%.

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APPENDIX A

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.

APPENDIX B

Consensus Methodology

Consensus on statements in this document was obtained utilizing a modified Delphi technique (32,33).

The Committee was unable to reach consensus on the following:

- Patency rate or threshold for dilation of strictures caused by sclerosing cholangitis.
- Patency rate or threshold for dilation of benign strictures not caused by sclerosing cholangitis.

The failure to reach consensus was due to limited reported data and lack of agreement between reported data and the experiences of the committee members.

ADDENDUM

Dr. Dana R. Burke authored the first draft of this document and served as topic leader during subsequent revisions of the first draft. Dr. Curtis A. Lewis is Chairman of the Standards of Practice Committee for the purpose of this document. Dr. Curt Bakal is Councilor of the Standards Division. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are: Timothy E. Allen, MD, John E. Aruny, MD, Raymond E. Bertino, MD, Paramjit S. Chopra, MD, Patricia E. Cole, MD, PhD, Philip S. Cook, MD, Martin Crain, MD, Donald F. Denny, Jr, MD, Elizabeth A. Drucker, MD, JD, Neil J. Freeman, MD, Gregg M. Gaylord, MD, Murray J. Gordon, MD, Patrick Malloy, MD, Patrick C. Malloy, MD, Louis G. Martin, MD, M. Victoria Marx, MD, Terence A. S. Matalon, MD, Steven G. Meranze, MD, Calvin D. Neithamer, Jr, MD, Albert A. Nemcek, Jr, MD, Kenneth S. Rholl, MD, Anne C. Roberts, MD, Orestes Sanchez, MD, Eric J. Stein, MD, Patricia E. Thorpe, MD, Anthony C. Venbrux, MD, Daniel J. Wunder, MD, and Robert Vogelzang, MD.

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 toward 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.