



Standards for Biliary Interventions

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The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

I. INTRODUCTION

Percutaneous transhepatic cholangiography (PTC) is a safe and effective technique for evaluating biliary abnormalities. It reliably demonstrates the level of abnormalities and may help diagnose the etiology.

Percutaneous transhepatic biliary drainage (PTBD) 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.

II. RADIOLOGIST QUALIFICATION

Physicians involved in the performance, supervision and interpretation of Biliary Intervention should be Diagnostic Radiologists and should have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training should meet with pertinent provincial/regional regulations. Continuing professional development should meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

Image-based diagnosis and treatment planning requires integrating the preprocedural imaging findings within the context of the patient's history and physical findings. Therefore, the radiologist should be clinically informed and understand the specific questions to be answered, and the goals to be achieved, by Biliary Intervention, prior to the procedure in order to plan and perform it safely and effectively. It is also expected that the radiologist involved will have some knowledge of alternative procedures (such as ERCP) and be able to discuss these alternatives with the patient, or provide guidance about who to discuss alternative therapy with.

The physician performing Biliary Intervention should fully appreciate the benefits, alternatives, and risks of the procedure. He/she should have a thorough understanding of imaging anatomy (including congenital and developmental variants), fluoroscopic and ultrasound equipment, radiation safety considerations, and physiologic monitoring equipment and have access to adequate supplies and personnel to safely perform the procedure.

Physicians should perform a sufficient number of Biliary Interventions to maintain their skills with acceptable success and complication rates as laid out in this standard. Continued competence should depend on participation in a quality improvement program that monitors these rates. Appropriate attendance at postgraduate courses that provide continuing education on diagnostic advances, newer techniques, and equipment is recommended.

III. TECHNOLOGIST CREDENTIALS/NURSING SERVICES

The Medical Radiation Technologist should have Canadian Association Medical Radiation Technologist certification or be certified by an equivalent licensing body recognized by the CAMRT.

Under the overall supervision of the Radiologist, the Technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, for image technical evaluation and quality, and applicable quality assurance. The training of Technologists specifically engaged in Interventional Radiology shall meet with applicable and valid National and Provincial Specialty qualifications.

Nursing services may be required before, during, and after the procedure for patient care, sedation and monitoring. If a qualified nurse is not available an appropriately trained Technologist may perform some of these functions under the direction of the Radiologist. Adequate numbers of properly trained staff should be available to assist the Radiologist, particularly in the event of an emergency.

IV. INDICATIONS AND CONTRAINDICATIONS

A. Indications

The indications for Biliary Intervention include, but are not limited to:

1. Investigation of obstructive jaundice.
2. Investigation of biliary sepsis/cholangitis.
3. Choledochal calculi.
4. Post-traumatic or iatrogenic common bile duct obstruction or leak.
5. Suspected cholecystitis or hydrops in the nonsurgical (high risk) patient.
6. Symptomatic gallstones in the patient who refuses surgery.
7. Failed endoscopic biliary tract imaging.
8. Decompression of the biliary tree.
9. Dilate biliary stricture.
10. Stent or drain placement.

B. Contraindications

The relative contraindications for Biliary Intervention include:

1. Known coagulopathy, which cannot be adequately corrected;
2. Inability of the patient to cooperate with, or to be positioned for, the procedure;
3. Known adverse reaction to contrast media when contrast media administration is critical to the safe performance of the procedure;
4. Hemodynamic instability;
5. Lack of a safe pathway to the vessel.
6. Lack of informed consent.

Patient management should address these relative contraindications prior to the procedure. Every effort should be made to correct or control these clinical situations before the procedure, if feasible.

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risk to the fetus and clinical benefits of the procedure should be considered before proceeding with the study.

V. EXAMINATION TECHNIQUE, PERFORMANCE AND RELATED MATTERS

These procedures are usually performed with fluoroscopy. Ultrasound (US) may be used as an ancillary imaging modality for Biliary Intervention. The initial needle puncture can be guided with fluoroscopy, or less often US, in the angiography suite, which permits fluoroscopic guidance for subsequent guidewire and catheter manipulation.

A. Imaging Equipment and Facilities

1. The minimum requirements for facilities in which Biliary Intervention is performed include:

a. A high-resolution imaging chain with adequate shielding and collimation is desirable for fluoroscopic guidance. Ability to perform complex angle i.e. AP, lateral, or oblique views is often necessary during fluoroscopically guided procedures to ensure proper needle placement. Image and written documentation of needle or drainage catheter tip location are essential. Overhead fluoroscopic tube suites are less desirable because of increased radiation exposure to personnel during this procedure.

b. When appropriate, availability of US may be helpful. Proper transducer frequency is required to direct and monitor needle placement.

c. Locating the optimal access route to avoid, when possible, transgressing vital structures.

d. The facility should provide an area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, in a short- stay unit, or on a routine nursing unit. There should be immediate access to emergency resuscitation equipment.

e. Laboratory facilities should be available with expertise in cytopathology, microbiology, and chemistry.

2. Performance standards

When using fluoroscopy for Biliary Intervention, a facility should meet or exceed the following imaging practices:

a. Fluoroscopic time should be kept to a minimum. The operator will use only as much fluoroscopy as is necessary to achieve PTC and/or catheter drainage, consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines.

b. Tight collimation and, when appropriate, shielding (e. g., thyroid, gonadal, etc.).

B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities utilizing conscious sedation, a pulse oximeter should be available.

2. There should be ready access to equipment and drugs for emergency resuscitation. The equipment should include an emergency defibrillator with paper recorder and quick-view capability, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag- apparatus, and central venous line sets. Drugs mask-valve for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available.

C. Surgical Support

Although complications of Biliary Intervention only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly. Ideally, this would be a facility with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a free- standing center, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

D. Patient Care

1. Preprocedure care

a. The physician performing the procedure should have knowledge of the following:

i. Clinically significant history including indications for the procedure.

ii. Clinically significant physical examination including an awareness of clinical or medical conditions that may necessitate specific care.

iii. Possible alternative methods, such as surgery, to obtain the desired diagnostic information or therapeutic result.

b. Informed consent is required.

c. Appropriate antibiotic coverage should have been initiated.

2. Procedural care

a. Nursing personnel, technologists, and those directly involved in the patient care during Biliary Intervention should have protocols for use in standardizing care. These should include, but are not limited to, the following:

i. Equipment needed for the procedure.

ii. Patient monitoring.

iii. Patient sedation and analgesia.

Protocols should be reviewed and updated periodically.

3. Postprocedure care

a. Orders for postprocedure patient care should include frequency of monitoring of vital signs, drainage catheter care, discharge instructions, antibiotics, etc.

b. Specific anatomic considerations

Postprocedure imaging and follow-up may involve injection of contrast material to confirm appropriate catheter placement within the biliary tree.

c. Clinical and imaging follow-up

i. Periodic imaging follow-up may be appropriate. Catheter exchange may be routinely scheduled to ensure continued patency, and/or may be required if the indwelling catheter is dislodged/functions poorly.

E. Specifics of the Procedure

1. All invasive image-guided percutaneous procedures involving Biliary Intervention are performed for specific indications, and the examination/procedure should therefore be tailored accordingly.

2. The physician performing Biliary Intervention should understand catheter maintenance and postprocedure care.

VI. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (e. g., 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" refer to a group of indicators for a procedure (e.g., 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 abscess drainage, then values in excess of the defined threshold (in this case 4%) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of 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 higher or lower values to meet its own quality-improvement program needs.

A. Success Rates

PTC %

Opacify dilated ducts 90

Opacify non-dilated ducts 60

PTBD, after opacification of ducts during PTC

Dilated ducts 90

Non-dilated ducts 70

Internal Drain placement

(tube or stent) 70%

B. Complication Rates/Threshold

Percutaneous Transhepatic Cholangiography: Major Complications

Reported Rate(%) Suggested Procedure Threshold (%)

Sepsis, cholangitis, bile leak, hemorrhage or pneumothorax 2 4

Percutaneous Transhepatic Biliary Drainage: 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 2.5

Pleural effusion 0.5 2

Complications of biliary drainage can be divided into acute and delayed. The overall threshold rate recommended for major complications is 10%.

1. Acute complications (5 to 10% of the procedures)

The most common acute complications are related to hemobilia and sepsis. Hemobilia after percutaneous transhepatic biliary drainage has been reported as having an incidence ranging from 3.7 to 13.8%. Acute septic shock has been reported as occurring in 3 to 5% of patients. These major acute complications can result in a death rate ranging from 0.5 to 5.6%. Less common acute complications would include pneumothorax, bilothorax, pancreatitis, subphrenic abscess and peritonitis.

2. Delayed complications

Delayed complications are more common, occurring in 40 to 50% of cases, depending upon the length of time the catheter is left in place. These include:

- a. Cholangitis
- b. Bile leakage
- c. Dislodgement of catheter
- d. Wound infection

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.

VII. REFERENCES

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