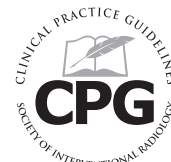


Quality Improvement Guidelines for Percutaneous Needle Biopsy



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Abbreviations: ACR = American College of Radiology, PNB = percutaneous needle biopsy

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

This guideline was revised by the American College of Radiology (ACR) in collaboration with SIR. The guidelines in this document have been revised from the previous quality improvement document (1) taking into account more recent literature, and are intended to update and replace the previously published guidelines.

This guideline was adapted from the ACR practice guideline for the performance of image-guided percutaneous needle biopsy (PNB) in adults as a collaborative document between SIR and ACR. Image-guided PNB is an established, safe, and effective procedure for selected patients with suspected pathologic processes. Extensive experience documents the safety and efficacy of this procedure. As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians (1–3). This guideline outlines the principles

for performing PNB, excluding breast biopsy. The later intervention is addressed by an ACR practice guideline for stereotactic and ultrasound-guided breast interventional procedures.

Successful PNB has been applied in most organ systems with excellent results and few complications (4–16). The key to these procedures has been the use of imaging guidance, which allows for the safe passage of a needle into an organ or mass, to obtain tissue for cytologic or histologic examinations. Image-guided percutaneous biopsy is less invasive than open or excisional biopsy and is associated with lower morbidity and mortality and thus considered the initial approach for diagnosis. Postprocedure monitoring and patient management in addition to outcomes tracking is necessary to continue to improve the safety and efficacy of this procedure.

These guidelines are written to be used in quality improvement programs to assess PNB procedures. 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

PNB is defined as placement of a needle(s) into a suspected abnormal lesion or organ for the purpose of obtaining tissue or cells for diagnosis. PNB includes two basic techniques for sample acquisition, fine needle aspiration biopsy and core biopsy. Fine needle aspiration biopsy is the use of a thin, hollow needle (22 gauge and smaller) inserted into a region of interest to extract cells for cytologic evaluation. Core biopsy is the use of a hollow needle (20 gauge and larger) specially adapted with a cutting mechanism that is inserted into an organ or region of interest to extract a piece of tissue for histologic evaluation.

For purposes of this guideline, successful image-guided PNB is defined as the procurement of sufficient material to establish a pathologic diagnosis or guide appropriate patient management.

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; see Appendix B). The complication rates and thresholds below refer to major complications unless otherwise specified.

Indications and Contraindications

The indications for PNB include, but are not limited to:

1. To establish the benign or malignant nature of a lesion.
2. To obtain material for microbiologic analysis in patients with known or suspected infections.
3. To stage patients with known or suspected malignancy when local spread or distant metastasis is suspected.
4. To determine the nature and extent of certain diffuse parenchymal diseases (eg, hepatic cirrhosis, renal transplant rejection, glomerulonephritis).

The threshold for these indications is 95%. Departmental review with regards to patient selection should occur when the indications for PNB fall below this threshold.

There are no absolute contraindications for PNB but relative contraindications which should be considered and addressed, when feasible, before the initiation of the procedure. Relative contraindications for PNB may include:

1. Significant coagulopathy that cannot be adequately corrected.
2. Severely compromised cardiopulmonary function or hemodynamic instability.
3. Lack of a safe pathway to the lesion.
4. Inability of the patient to cooperate with, or to be positioned for, the procedure.
5. Pregnancy in cases when imaging guidance involves ionizing radiation.
 - a. All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients before the performance of any examination involving ionizing radiation. If the patient is known to be pregnant, the potential risk to the fetus and clinical benefits of the procedure

should be considered before proceeding with this study, per ACR Resolution 1a (established in 1995, revised in 2005).

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 bleeding is one measure of the quality of image-guided PNB, then 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 higher or lower values to meet its own quality improvement program needs.

Participation by the radiologist in patient follow-up is an integral part of PNB and will increase the success rate of the procedure. Close follow-up, with monitoring and management of patients undergoing PNB, is appropriate for the radiologist.

Success Rates and Thresholds

Many variables will affect the eventual success of a PNB procedure. These include the number of samples obtained, the size of the target abnormal-

ity, the organ system in which biopsy is performed, the benign or malignant nature of the lesion, the availability of an on-site cytopathologist, the experience of the institution's pathology staff, the imaging equipment available, and the skill of the operating physician. **Table 1** (17-39) lists the success rates and suggested thresholds for PNB. Thresholds will vary depending on the mix of organ systems, the size and location of lesions, and the relative proportion of benign versus malignant lesions that are sampled, and should be adjusted accordingly.

Complication Rates and Thresholds

The complications of percutaneous biopsies are divided into two types: generic and organ-specific. Generic refers to complications that are common to all biopsies. The major generic complications include bleeding, infection, perforation, and unintended organ injury (40). Clinically significant bleeding is infrequent, although relative bleeding risks increase with increasing needle size, use of cutting needles, and vascularity of the organ/lesion in which biopsy is performed (ie, renal and liver biopsies, hypervascular lesions) (18,41). Infection as a result of biopsy is also rare. Injury may occur to the target organ or to a nearby organ that is traversed by the needle. Injuries of this type require further interventions in fewer than 2% of patients.

Organ-specific complications are those that are associated solely or most commonly with biopsy of a specific organ. For example, pneumothorax is most commonly associated with lung biopsy but can occur during vertebral, rib, liver, spleen, adrenal, kidney, and breast biopsies or aspirations. Other complications may occur but rarely require therapy. These include hematuria after renal or prostate biopsy and hemoptysis after lung biopsy. Perforation may be considered organ-specific.

The reported rates of given complications and suggested thresholds that should prompt a review when exceeded are mentioned in **Table 2** (12,36,42-83). In addition, there are certain complications that are almost always associated with a single organ (42). Very rare complications, such as hypertensive crisis after adrenal biopsy, air embolism after lung biopsy, infection, peritonitis, and pancreatitis

Table 1
Success Rates of PNB (17-39)

PNB Site	Reported Range of Success (%)	Pooled Mean Success (%)	Suggested QI Threshold (%)*
Thoracic/pulmonary (17-25)	77-96	89	75
Musculoskeletal (26-33)	76-93	82	70
Other Sites (34-39)	70-90	89	75
Overall	70-90	85	75

Note.—QI = quality improvement.

* Thresholds will vary depending on the mix of organ systems, the size and location of lesions, and the relative proportion of benign versus malignant lesions that are sampled, and should be adjusted accordingly.

Table 2
Complication Rates and Suggested Thresholds for Nonthoracic PNB (12,36,42-83)

Major Complication	Complication Rate (%)	Suggested QI Threshold (%)
Bleeding requiring transfusion or intervention		
Solid organ*		
Kidney (12,45-59)		
Large caliber (>18 gauge)	2.7-6.6	10
Small caliber (≤18 gauge)	0.5-2.8	5
Liver (42,49,60-68)	0.3-3.3	5
Spleen (69-73)	0-8.3	10
Other (36,74)	0.1-3	6
Tract seeding (43,44,74-83)†	0-3.4	5
Pneumothorax requiring chest tube for nonpulmonary/mediastinal biopsy	0.5	1

Note.—QI = quality improvement.

* Data based on studies involving at least 200 patients.

† Most of the literature is related to needle tract seeding after percutaneous biopsy of hepatocellular carcinoma. Data based on studies involving at least 100 patients.

(44,84), are not given thresholds. Each major incident should be investigated as appropriate.

Nontransthoracic Biopsy Complications

Transthoracic (pulmonary and mediastinal) biopsy is a special consideration with regard to classifying pneumothorax and thoracostomy tube placement as major or minor complications (**Table 3**) (8,18,19,85-98). The presence of a pneumothorax requiring thoracostomy tube placement itself is considered a minor complication (15,19,85,86,99,100) if it only requires a brief overnight hospital stay as part of routine management process. In this setting it is considered a major complication if hospitalization lasts more than 48 hours for management of a persistent air leak. If chest tubes for lung biopsy are routinely managed on an outpatient basis, it is considered a minor complication if the catheter

is removed within approximately 3 days of insertion. In this setting it is considered a major complication if it results in an unexpected admission. Thoracostomy tube placement is also considered as a major complication when it results in delay of chest tube removal beyond 3 days or requires catheter change or upsizing during the course of management, or requires pleurodesis.

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 pro-

Table 3
Complication Rates and Suggested Thresholds for Transthoracic PNB (8,18,19,85–98)

Complication	Complication Rate (%)	Suggested QI Threshold (%)*
Major		
Hemoptysis requiring hospitalization or specific therapy transthoracic biopsy (8,86)	0.5	2
Thoracostomy tube placement requiring prolonged admission, catheter exchange, or pleurodesis (90,91)	1–2	3
Air embolism (86,92)	0.06–0.07	<0.1
Minor		
Pneumothorax (18,19,85,87–89,93–98)	12–45	45
Thoracostomy tube placement (18,19,85,87,88,90,93–98)	2–15	20

Note.—QI = quality improvement.

* 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. The suggested QI threshold should be used to 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.

gram). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program (Table 4). In this table, the threshold value is supported by the weight of literature evidence and panel consensus.

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APPENDIX A: 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.

Table 4
Overall Complication Threshold

Overall Procedure	Suggested QI Threshold (%)*
All major complications resulting from image-guided PNB*	2

* The threshold for overall major complications should be used when the individual practice performs a broad spectrum of biopsies and no particular biopsy site or type dominates the experience. This threshold is based on the premise that uncomplicated thoracostomy tube placement for management of pneumothorax is considered a minor complication.

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

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).

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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.