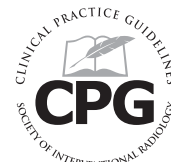


Quality Improvement Guidelines for Percutaneous Needle Biopsy



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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-

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