Core-Needle Biopsy for Breast Abnormalities

This is a summary of a systematic review update evaluating the current evidence regarding the comparative effectiveness of core-needle biopsy and open surgical biopsy for diagnosing breast lesions. The systematic review summarizes the accuracy and possible harms of various core-needle biopsy methods. It does not discuss fine-needle aspiration. The systematic review included 316 clinical studies published through December 16, 2013. The full report, listing all studies, is available at: *www.effectivehealthcare.ahrq.gov/breast-biopsy*. This summary is provided to assist in informed clinical decisionmaking. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Clinical Issue

About one in eight women in the United States will develop invasive breast cancer during her lifetime. Approximately 290,000 new cases of breast cancer are diagnosed each year in the United States, and more than 230,000 of these cases are invasive breast cancer.

Routine screening with physical examination and mammography is widely used in the United States. Breast abnormalities can also be found through self-examination or when symptoms arise. Suspicious mammographic findings may require a biopsy for diagnosis. More than 1 million women have breast biopsies each year in the United States. About 20 percent of these biopsies yield a diagnosis of breast cancer.

Open surgical biopsy removes suspicious tissue through a surgical incision. This procedure requires either a general or local anesthetic and closure of the incision with sutures.

Core-needle procedures, which remove a small tissue sample through a very small incision, have been widely adopted as a less-invasive biopsy option. Core-needle biopsy uses a hollow-core needle, ranging in size from 11 to 16 gauge, to remove one or more pieces of breast tissue. The operator either aims the needle directly at the area of a palpable lesion (freehand biopsy) or uses an imaging technique to localize the target lesion. The imaging techniques include stereotactic radiography, ultrasound, and magnetic resonance imaging (MRI). Techniques used to extract the biopsy specimen include an automated device and vacuum assistance. No consensus has been reached about which of these techniques is preferable for attaining the highest accuracy and lowest rate of harm with core-needle breast biopsies.

Currently, more than half of all breast biopsies use a core-needle technique. In light of the widespread use of core-needle methods, it is important to understand their accuracy and possible harms when compared with those of open surgical biopsy.

Clinical Bottom Line

- The sensitivity of core-needle biopsies performed using either stereotactic or ultrasound guidance is 97–99 percent. ●●○
- The underestimation probability of invasive cancer in core-needle biopsies read as noninvasive neoplastic lesions (such as ductal carcinoma in situ) or high-risk lesions (such as atypical ductal hyperplasia) ranges from about 10 percent to slightly more than 45 percent, depending on the core-needle method used. ●○○
- The rate of complications (hematoma formation, bleeding, and infection) after core-needle biopsy is less than 1.5 percent (median). ●○○

Strength of Evidence Scale

High:	●●●	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate:	●●○	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
Low:	●○○	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
Insufficient:	○○○	Evidence either is unavailable or does not permit a conclusion.

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Accuracy of Core-Needle Breast Biopsy

Because core-needle biopsy samples only part of the suspicious tissue, a lesion could be misclassified as benign, high risk, or noninvasive when invasive cancer is in fact present in unsampled areas (a false-negative biopsy). Open surgical biopsy samples most or all of the lesion, so it is considered to have a smaller risk of misclassification. However, open procedures may carry a greater risk of complications, such as bleeding or infection, when compared with core-needle biopsy procedures. Therefore, if core-needle biopsy is also highly accurate, it may be preferable to open surgical biopsy.

Sensitivity is an estimate of the proportion of all cases of cancer that are identified by a diagnostic test (in this case, core-needle biopsy). Research studies designed to measure the sensitivity of core-needle biopsy generally use a second biopsy (with the open surgical method) or clinical followup over time to detect cancerous lesions that were missed.

All open surgical biopsy specimens read as invasive breast cancer are considered true-positive readings. Occasionally, a core-needle biopsy removes the entire target lesion, thereby rendering subsequent open surgical biopsies unable to confirm the findings of the original core-needle biopsy. In such cases of core-needle biopsy-diagnosed malignancy, the core-needle biopsy results are considered to be true positive.

The clinical technique used to perform a core-needle breast biopsy was found to influence the sensitivity of the procedure (see Tables 1 and 2). The freehand technique has lower sensitivity than biopsies using either stereotactic radiography or ultrasound for guidance but has similar specificity. Stereotactically guided automated techniques are associated with a lower sensitivity and a higher specificity when compared with stereotactically guided vacuum-assisted methods. Evidence is insufficient to determine the accuracy of MRI-guided core-needle biopsies.

Studies on the accuracy of core-needle breast biopsies were deemed to have moderate to high risk of bias because of characteristics related to their design and conduct, which did not permit strong conclusions. Information on study- or population-level characteristics that could be modifiers of test performance was inadequate. The size, location, or imaging characteristics of a lesion may influence the choice of one breast biopsy technique over another. However, research studies have not included sufficient information about these characteristics to determine their impact on biopsy accuracy.

Table 1: Sensitivity and Specificity of Core-Needle Biopsy Methods in Women at Average Risk of Breast Cancer

Biopsy Method	Sensitivity (95% CrI)	Specificity (95% CrI)	Strength of Evidence
Freehand	0.91 (0.80 to 0.96)	0.98 (0.95 to 1.00)	●○○
Ultrasound, automated	0.99 (0.98 to 0.99)	0.97 (0.95 to 0.98)	●●○
Ultrasound, vacuum-assisted	0.97 (0.92 to 0.99)	0.98 (0.96 to 0.99)	●●○
Stereotactically guided, automated	0.97 (0.95 to 0.98)	0.97 (0.96 to 0.98)	●●○
Stereotactically guided, vacuum-assisted	0.99 (0.98 to 0.99)	0.92 (0.89 to 0.94)	●●○

95% CrI = 95-percent credible interval

Table 2: Comparative Effectiveness of Core-Needle Biopsy Methods in Women at Average Risk of Breast Cancer

Comparison	Finding	Strength of Evidence
Ultrasound, automated vs. vacuum-assisted	No difference in sensitivity or specificity.	●○○
Stereotactically guided, automated vs. vacuum-assisted	Sensitivity of vacuum assistance is better.	●○○
	Specificity of automation is better.	●○○

Misclassification of Biopsy Results

Some biopsies are read as noninvasive neoplastic lesions. These neoplastic lesions include ductal carcinoma in situ and high-risk lesions, such as lobular carcinoma in situ, atypical lobular hyperplasia, and atypical ductal hyperplasia.

There is concern that core-needle breast biopsies may miss areas of invasive cancer in specimens in which the lesion is predominantly noninvasive.

Table 3: Underestimation Rates in Women at Average Risk of Breast Cancer

Biopsy Method	Average Underestimation Probability		Strength of Evidence
	DCIS (95% CrI)	High-Risk Lesion* (95% CrI)	
Ultrasound, automated	0.38 (0.26–0.51)	0.25 (0.16–0.36)	●○○
Ultrasound, vacuum-assisted	0.09 (0.02–0.26)	0.11 (0.02–0.33)	●○○
Stereotactically guided, automated	0.26 (0.19–0.36)	0.47 (0.37–0.58)	●○○
Stereotactically guided, vacuum-assisted	0.11 (0.08–0.14)	0.18 (0.13–0.24)	●○○
Other methods	Insufficient evidence	Insufficient evidence	○○○

95% CrI = 95-percent credible interval; DCIS = ductal carcinoma in situ

* The most common reading of high-risk lesions is atypical ductal hyperplasia.

Complications and Pain

Clinically significant complications occur in a minority of women who undergo open surgical biopsies. The rate of hematomas is 2–10 percent, and the rate of infections is 4–6 percent. The rate of any complication is substantially lower with core-needle biopsies (see Table 4).

Pain was assessed heterogeneously across studies, which did not permit conclusions about pain occurring after biopsy procedures.

- Vasovagal reactions are more common among patients who sit during a biopsy procedure. ●○○
- Vacuum-assisted core-needle breast biopsy procedures are associated with slightly increased rates of bleeding and hematoma formation than biopsies performed with an automated device. ●○○

Table 4: Complications Associated With Core-Needle Breast Biopsy

Outcome	Median % (25th–75th Percentile)	Strength of Evidence
Hematoma	1.44 (0.25–8.57)	●○○
Bleeding	1.21 (0.33–3.97)	●○○
Bleeding requiring treatment	0.00 (0.00–0.14)	●○○
Infection	0.00 (0.00–0.33)	●○○
Vasovagal reaction	1.27 (0.37–3.88)	●○○

Applicability of Findings

The existing evidence base on core-needle biopsy of breast lesions in women at average risk of breast cancer is applicable to clinical practice in the United States. The average age of women in the studies was similar to that of women undergoing breast biopsy in the United States, and the indications were similar to the prevalent indications in clinical practice (i.e., mammographic findings of suspicious lesions). The applicability of findings to women at high risk of breast cancer is uncertain because few studies explicitly reported on groups of patients at high baseline risk of breast cancer and because comparisons of test performance between subgroups of women produced imprecise results.

Resource for Patients

Having a Breast Biopsy: A Review of the Research for Women and Their Families is a companion to this clinician research summary. It can help women talk with their health care professionals about breast biopsy options. It provides information about:

- Core-needle and open surgical biopsies
- Accuracy of breast biopsies
- Discomfort and complications associated with breast biopsies

Ordering Information

Electronic copies of *Having a Breast Biopsy: A Review of the Research for Women and Their Families*, this clinician research summary, and the full systematic review are available at the Effective Health Care Program Web site: *www.effectivehealthcare.ahrq.gov/breast-biopsy.*

Source

The source material for this clinician summary is a systematic review of 316 research studies. The review, *Core Needle and Open Surgical Biopsy for Diagnosis of Breast Lesions: An Update to the 2009 Report* (2014), was prepared by the Brown Evidence-based Practice Center. It is an update of the 2009 review *Comparative Effectiveness of Core Needle and Open Surgical Biopsy for the Diagnosis of Breast Lesions,* by the ECRI Institute Evidence-based Practice Center. The Agency for Healthcare Research and Quality (AHRQ) funded the systematic review update and this summary. The full systematic review update is available at: *www.effectivehealthcare.ahrq.gov/breast-biopsy.*

AHRQ created the John M. Eisenberg Center for Clinical Decisions and Communications Science to make research useful for decisionmakers. The clinician summary based on the 2009 review was prepared by the Eisenberg Center when located at Oregon Health & Science University, Portland, OR, and clinicians reviewed preliminary drafts of the summary. Based on the 2014 review, the summary was updated by the Eisenberg Center located at Baylor College of Medicine, Houston, TX.

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