



Effective Health Care Program

Comparative Effectiveness of Core-Needle and Open Surgical Biopsy for the Diagnosis of Breast Lesions *Executive Summary*

Background

Breast cancer is the second most common malignancy of women, with over 180,000 new cases diagnosed each year in the United States. Survival rates depend on the stage of disease at diagnosis. Women diagnosed with early stages of breast cancer have a 5-year survival rate near 100 percent. However, early breast cancer is asymptomatic, and the only way to detect it is by population-wide screening programs that include regular mammography and physical examination.

Mammography uses x-rays to examine the breast for calcifications, masses, or other abnormal structures. Currently, most professional organizations recommend that all women 50 years of age and over receive a mammogram every 1 to 2 years. Many professional organizations recommend that routine breast cancer screening begin earlier, at age 40, although x-ray mammography screening is less effective in younger women. Most experts believe that regular x-ray mammographic screening of all women ages 50-70 can reduce mortality from breast cancer.

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

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The American College of Radiology has created a standardized system for reporting the results of mammography, the Breast Imaging Reporting and Data System (BI-RADS®). There are seven categories of assessment and recommendation:

- 0 Need additional imaging evaluation and/or prior mammograms for comparison.
- 1 Negative.
- 2 Benign finding.
- 3 Probably benign finding. Initial short-interval followup suggested.
- 4 Suspicious abnormality. Biopsy should be considered.
- 5 Highly suggestive of malignancy. Appropriate action should be taken.
- 6 Known biopsy-proven malignancy. Appropriate action should be taken.

After identification of an abnormality on screening mammography or physical examination, women typically undergo additional imaging studies (diagnostic mammography, ultrasound, magnetic resonance imaging [MRI]) and a physical examination. If these studies suggest the abnormality may be malignant, a biopsy of the suspicious area may be recommended. Biopsy material may be obtained by fine-needle aspiration, core-needle biopsy, or open surgical procedures.

Open surgical biopsy involves removing a sample of tissue from the suspicious area through a surgical incision. To aid in location of a nonpalpable lesion, it may be marked with a wire, dye, or carbon particles using an imaging method (mammography, ultrasound, MRI) to guide placement of the marker. The procedure may be performed under general anesthesia, sedation plus local anesthesia, or local anesthesia only. The surgeon may attempt to remove the entire lesion during the biopsy procedure (excisional biopsy) if the lesion is fairly small. After the tissue sample is removed, the incision is closed with sutures.

Open surgical biopsy is the “gold standard” or “reference standard” method of evaluating a suspicious breast lesion because it is thought to be very accurate in diagnosing these lesions. While generally considered

safe, it is a surgical procedure that, like all surgeries, places the patient at risk of experiencing morbidities and, in rare cases, mortality. However, only 20 to 30 percent of women who undergo breast biopsy procedures are diagnosed with cancer. Exposing large numbers of women who do not have cancer to invasive surgical procedures may be considered an undesirable medical practice. A less invasive method for evaluation of suspicious breast lesions would be preferable if it were sufficiently accurate.

A core-needle biopsy is a procedure that involves removing small samples of breast tissue through a hollow core needle inserted through the skin. Basic core-needle biopsy uses a special 11-, 14-, or 16-gauge needle (the smaller the gauge, the larger the diameter of the needle). The suspicious lesion may be located by palpation or by imaging (stereotactic mammography, ultrasound, MRI). The procedure is usually performed under local anesthesia. Multiple core-needle samples may be taken from the suspicious area.

A variant on core-needle biopsy is vacuum-assisted biopsy. After locating the suspicious area by stereotactic mammography or ultrasound, the probe of the device is inserted into the suspicious area. The device uses vacuum suction to help remove tissue samples. Multiple samples may be taken from the suspicious area without reinserting the needle.

The primary goal of initial biopsy of any abnormality is to diagnose the abnormality as benign or malignant. Generally, only malignant lesions require invasive followup procedures such as surgical excision or lymph node evaluation. As discussed above, the majority of women who are sent for breast biopsy do not have malignant lesions and do not require followup surgery. Thus an accurate initial core-needle biopsy would in most cases allow women to avoid any open surgical procedure. If the core-needle biopsy suggests the lesion is malignant, lymph node exploration and lesion excision to clear margins could be performed during the follow-on surgical procedure. Women who are diagnosed with malignant lesions by open surgical biopsy are often subject to an additional surgical procedure to ensure the lesion has been completely removed and, in some cases, for lymph node evaluation. Therefore, an accurate method of performing core-needle biopsies may enable many women to avoid

surgery altogether and reduce the number of surgical procedures women with malignancies must undergo.

Medical indications—such as size and location of the lesion, imaging characteristics of the lesion, and likelihood of eventual surgical excision—may direct the preference of one type of breast biopsy procedure over another. However, other factors—such as patient preferences, access, and practice and referral patterns—also influence decisions about which procedure should be performed.

The large number of possible methods of performing breast biopsy can be bewildering to patients and health care providers alike. Which method should one choose? Is a particular method clearly superior, or does the method of choice depend upon individual patient characteristics? We have performed a systematic review intended to evaluate the accuracy of different methods of performing breast biopsy and to explore what factor(s) may impact the accuracy and possible harms of different methods of performing breast biopsy.

Methods

The topic of this systematic review was nominated in a public process. The Key Questions were developed by a technical expert panel assembled by the Scientific Resource Center for the Agency for Healthcare Research and Quality (AHRQ). The medical literature was systematically searched for articles from December 1990 through September 11, 2009, that addressed the Key Questions.

Medical personnel usually want to see the results of at least one randomized controlled trial demonstrating that a medical procedure is safe, effective, and beneficial to patients before adopting the procedure into general clinical practice. However, it is generally acknowledged that early diagnosis and treatment of breast tumors leads to improved survival rates and quality of life. Women found to have benign lesions on biopsy are able to avoid unnecessary treatment and receive reassurance that they do not have breast cancer. Given the currently available alternatives, there is no need to conduct randomized controlled trials of breast biopsy procedures. Establishing that a type of breast biopsy is safer than open surgical biopsy while being as accurate

or almost as accurate as open surgical biopsy is sufficient to justify its routine use.

Studies of diagnostic test performance compare the results of the experimental test to a reference test. The reference test is intended to measure the “true” disease status of each patient. For the diagnosis of breast cancer, the “gold standard” reference test is open surgery and pathological examination of the removed tissue. However, a difficulty with the use of this reference standard in large cohort studies of screening-detected breast abnormalities is that many women with lesions that are probably benign will be subjected to open surgery. The principle of clinical equipoise means that there is genuine uncertainty over whether or not the intervention will be beneficial, and therefore it is acceptable to study the intervention in a clinical research trial. Subjecting women with lesions that are probably benign to open surgery does not meet the principle of clinical equipoise. Therefore we have chosen to include studies that used a combination of followup and open surgical biopsy as the reference standard in our analyses.

Studies of diagnostic test performance were examined to see if they met the inclusion criteria. In brief, the inclusion criteria were: the study directly compared core-needle biopsy to pathological examination of tissue obtained by open surgery and/or patient followup for at least 6 months; the study enrolled 10 or more patients at average risk of primary breast cancer who were referred for breast biopsy after discovery of a possible breast abnormality on screening mammography, routine physical examination, or routine self-examination; the study was a full-length article published in English; and 50 percent or more of the enrolled subjects completed the study.

In our analysis of biopsy accuracy, we focused on measures that evaluate the extent of false-negative errors (cancers falsely diagnosed as benign): sensitivity and negative likelihood ratio. Sensitivity is expressed as a percentage. A biopsy method with a sensitivity close to 100 percent will miss very few cancers. A negative likelihood ratio can be used to calculate an individual woman’s risk of having a malignancy following a “benign” diagnosis on breast biopsy. In general, the smaller the negative likelihood ratio, the more accurate

the diagnostic test is in predicting the absence of disease. However, each individual woman's post-test risk varies by her individual pre-test risk of malignancy.

We also analyzed the "underestimation rate." Lesions diagnosed by core-needle biopsy as ductal carcinoma in situ (DCIS, a noninvasive early stage of breast cancer) that were found to be invasive by the reference standard were counted as DCIS underestimates. Similarly, lesions diagnosed by core-needle biopsy as benign atypical ductal hyperplasia (ADH) that were found instead to be invasive by the reference standard were counted as ADH underestimates. The underestimation rate was then calculated as the number of underestimates per number of DCIS (or ADH) diagnoses. In the primary analysis of sensitivity and negative likelihood ratio, underestimates were not considered to be missed cancers because current clinical practice is to suggest surgical removal of ADH and DCIS lesions, and thus underestimates would not have been "missed."

The quality of the included studies was evaluated using an internal validity rating instrument for diagnostic studies. The studies were rated as low, moderate, or high in quality for the assessment of accuracy outcomes. Data from the included articles were abstracted and analyzed. Where possible, the data were combined using a bivariate mixed-effects binomial regression meta-analysis model. Underestimation rates were combined using a random-effects meta-analysis. The summary likelihood ratios and Bayes theorem were used to compute post-test probabilities of a malignancy.

The strength of evidence supporting each major conclusion was graded as high, moderate, low, or insufficient. The grade was developed after consideration of the quality of the evidence base, the size of the evidence base, the consistency of the findings, and the robustness of the findings to sensitivity analyses.

Conclusions

Key Question 1. In women with a palpable or nonpalpable breast abnormality, what is the accuracy of different types of core-needle breast biopsy compared with open biopsy for diagnosis?

Our literature searches identified 107 studies of 57,088 breast lesions that met the inclusion criteria. All of the studies were diagnostic cohort studies that enrolled a population of women found to have suspicious breast abnormalities on routine screening (mammography and/or physical examination). The women were sent for various types of breast biopsies, and the accuracy of the breast biopsy was determined by comparing the results of the breast biopsy to the results of a combination of open surgery and patient followup. We graded the supporting evidence for these conclusions as low based on the low quality of the evidence base (i.e., greater potential for bias), although we rated the quantity, consistency, and robustness of the evidence base as sufficient. Our conclusions for Key Question 1 are summarized in Table A and Figures A through D. Our key conclusions are stated below.

- Stereotactically guided vacuum-assisted core-needle biopsies have a sensitivity of 99.2 percent (95-percent confidence interval [CI]: 97.9 to 99.7 percent). Strength of evidence: Low.
- Stereotactically guided automated gun core-needle biopsies have a sensitivity of 97.8 percent (95-percent CI: 95.8 to 98.9 percent). Strength of evidence: Low.
- Ultrasound-guided vacuum-assisted core-needle biopsies have a sensitivity of 96.5 percent (95-percent CI: 81.2 to 99.4 percent). Strength of evidence: Low.
- Ultrasound-guided automated gun core-needle biopsies have a sensitivity of 97.7 percent (95-percent CI: 97.2 to 98.2 percent). Strength of evidence: Low.
- Freehand automated gun core-needle biopsies have a sensitivity of 85.8 percent (95-percent CI: 75.8 to 92.1 percent). Strength of evidence: Low.

There was insufficient evidence to estimate the accuracy of MRI-guided core-needle biopsies.

The included studies assumed that open surgical biopsy was 100-percent accurate. We obtained information about the actual accuracy of open surgical biopsy from a review article, and therefore a formal conclusion and strength of evidence rating was not derived for estimates about the accuracy of open surgical biopsy.

Key Question 2. In women with a palpable or nonpalpable breast abnormality, what are the harms associated with different types of core-needle breast biopsy compared with open biopsy for diagnosis?

We recorded the complications and harms reported by the 107 studies that met the inclusion criteria for Key Question 1. Our results are summarized in Table B. Severe complications following core-needle biopsy of any type are very rare, affecting fewer than 1 percent of procedures. Vacuum-assisted procedures may be associated with slightly more severe bleeding events than automated gun core-needle biopsies. The strength of evidence supporting the quantitative estimates of the frequency of complications is low. Information about harms of open surgical biopsy was scanty in the included studies, and we supplemented it with information from recent review articles. Therefore, the strength of the evidence was not rated for conclusions about the safety of open surgical biopsy. However, it is clear that core-needle biopsies have a lower risk of complications than do open surgical procedures.

In Figure E we present a simplified model of what might happen if the same cohort of 1,000 women underwent various types of breast biopsy. The theoretical cohort of women includes 300 women with malignant tumors and 700 women with benign lesions. The model is based on the point estimates of accuracy from our analyses and do not incorporate estimates of uncertainty of the point estimates. Refer to Figures A through D for a visual representation of the degree of uncertainty in the point estimates. The model assumes that all women with nonbenign diagnoses on their first biopsy procedure, including all women who had open surgical biopsy as their first biopsy procedure, will be subject to an open surgical excisional procedure.

We also performed a number of meta-regressions exploring the impact of various factors on the accuracy and harms of core-needle biopsies. Our findings from these meta-regressions are summarized in Table C. Use of image guidance and vacuum assistance improved the accuracy of core-needle biopsy; however, vacuum assistance increased the percentage of procedures complicated by severe bleeding and hematoma formation. Performing biopsies with patients seated upright increased the incidence of vasovagal reactions.

Our meta-regressions did not identify a statistically significant effect of the following factors on the results: needle size, method of verification of biopsy (open surgery, open surgery and at least 6 months' followup, or open surgery and at least 2 years' followup), whether the studies were conducted at a single center or at multiple centers, whether the studies were conducted in general hospitals or dedicated cancer clinics, or the country in which the study was conducted. The studies reported insufficient information about lesion characteristics, patient characteristics, or the training or experience of the persons performing the biopsies to explore the effect of such factors on the accuracy or harms of the biopsies.

Key Question 3. How do open biopsy and various core-needle techniques differ in terms of patient preference, availability, costs, availability of qualified pathologist interpretations, and other factors that may influence choice of a particular technique?

Due to the nature of Key Question 3, we did not use formal inclusion criteria, nor did we come to many formal evidence-based conclusions. We collected information relevant to the topic from many sources, including interviews with experts. There was general agreement that core-needle biopsy costs less than open surgical biopsy, consumes fewer resources, and is preferred by patients. Women were generally satisfied with the cosmetic results of core-needle procedures. Women who underwent a core-needle biopsy as their first invasive test to diagnose a breast cancer had, on average, fewer surgical procedures than women who underwent an open biopsy procedure as their first invasive test. One particularly important finding was that women diagnosed with breast cancer by core-needle biopsy were usually able to have their cancer treated with a single surgical procedure, but women diagnosed with breast cancer by open surgical biopsy often required more than one surgical procedure to treat their cancer (odds ratio 13.7, 95-percent CI: 5.6 to 34.6). Due to the consistency, robustness, and extremely large strength of association between the type of biopsy and the requirement for more than one surgery for treatment, we rated the strength of evidence supporting this conclusion as moderate. There was insufficient information available to evaluate the impact of equipment or pathologist availability.

Discussion

When making decisions about what type of biopsy to use, individual women and their health care providers will need to weigh the pros and cons of each type of biopsy for each individual woman. Open surgical biopsies are highly accurate; however, core-needle biopsies are associated with a much lower incidence of harms and morbidity. In addition, women who are diagnosed with cancer by core-needle biopsy undergo fewer surgeries during treatment than do women who are diagnosed with cancer by open biopsy. The crux of the decision then becomes the question, “Is core-needle biopsy accurate enough?” The answer to this question may vary depending on the individual woman’s estimated prebiopsy chance of having cancer (an estimate derived from mammography results and other prebiopsy examination information) and an individual woman’s desire to avoid risk. For some women, core-needle biopsy will never be accurate enough to satisfy their desire to know, for sure, whether they do or do not have cancer. For others, the greater safety and less invasive nature of core-needle biopsy are worth a small sacrifice in accuracy. During decisionmaking, women and health care providers also need to consider the clinical implications of a cancer missed on core-needle biopsy. In many cases, the cancer will be detected on subsequent mammography. Women with negative core-needle biopsies should have careful diagnostic followup with clinical correlation as appropriate for the individual patient.

The ratings of low strength of evidence apply to the individual estimates of accuracy for each type of core-needle biopsy. Due to the poor reporting and low internal validity of the included studies, we are concerned that the studies may be consistently biased toward finding that core-needle biopsies are more accurate than they actually are. We have performed sensitivity analyses (Table D) of the impact of this possibility on our conclusions. For each biopsy method, we have estimated the post-test probability of a woman actually having cancer after a negative core-needle biopsy result (assuming the woman had a prebiopsy probability of having cancer of 30 percent). We

calculated probabilities using the summary estimate of the negative likelihood ratio from our analysis, and for summary estimates calculated after assuming our analysis had overestimated the sensitivity of the procedure by 1 percent, 5 percent, and 10 percent. We are moderately confident that our analysis has not overestimated the sensitivity by as much as 10 percent, but we present the results of this sensitivity analysis as a “worst case” scenario. For example, for ultrasound (US) guidance vacuum-assisted core-needle biopsy, we estimated the probability of a woman actually having cancer after a negative core-needle biopsy result to be 2 percent. Sensitivity analyses using overestimation of the sensitivity by 5 percent and 10 percent suggest that this probability would increase to 3 percent and 6 percent, respectively.

Remaining Issues

Our systematic review has found that both stereotactically guided vacuum-assisted and US-guided core-needle biopsies are safer than open surgical biopsy and are almost as accurate as open surgical biopsy, justifying their routine use. However, well-reported retrospective chart reviews, retrospective database analyses, or prospective diagnostic accuracy studies are needed to address the as-yet-unanswered questions as to what factors affect the accuracy and harms of core-needle breast biopsy. Answers to such questions are important for both patients and clinicians when faced with the decision of what type of breast biopsy is best for each individual patient. In addition, our conclusions are rated as being supported by a low strength of evidence. The low rating is almost entirely due to the fact that the evidence base, while large, consists of universally poorly reported studies. The studies omitted important details about patients, methods, and sometimes results. The studies presented results in an often confusing and haphazard manner. The poor reporting made it difficult to determine whether or not the studies were likely to be affected by bias, and therefore we rated the evidence base as being of low quality. Publication of better reported diagnostic accuracy studies would permit verification that our

conclusions are accurate and not influenced by biases in the studies included in this assessment. Additional studies of MRI-guided biopsy are necessary in order to evaluate the accuracy and safety of MRI guidance.

Summary

An overall summary of the findings and level of evidence for each biopsy type is presented in Table E. Based on currently available evidence, it appears reasonable to consider choosing certain core-needle biopsy procedures given the comparable sensitivity and lower complication rates for some of the percutaneous methods. Our analyses found the highest sensitivity for methods utilizing stereotactic guidance, particularly in conjunction with vacuum assistance. The appearance of breast lesions on imaging and the location within the breast may affect the type of core needle/imaging combination chosen for any particular woman. In general, women undergoing core needle biopsy are subjected to fewer surgical procedures overall than women who initially are diagnosed by open surgical biopsy, and they express satisfaction with the cosmetic results. However, the available studies suffered from poor reporting of important details that would help to identify patient and lesion characteristics that might impact the validity of this conclusion for individual women. We rated the strength of evidence as low for the accuracy outcomes, in large part because the

absence of these details also compromised our ability to assess the risk of bias in the published studies. We have identified a number of questions that should be answered by future studies in order to improve individualized decisionmaking.

Full Report

This executive summary is part of the following document: Bruening W, Schoelles K, Treadwell J, Launders J, Fontanarosa J, Tipton K. Comparative Effectiveness of Core-Needle and Open Surgical Biopsy for the Diagnosis of Breast Lesions. Comparative Effectiveness Review No. 19. (Prepared by ECRI Institute Evidence-based Practice Center under Contract No. 290-02-0019.) Rockville, MD: Agency for Healthcare Research and Quality. December 2009. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

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Table A. Summary of key accuracy findings (Key Question 1)

Type of biopsy	Number of missed cancers expected for every 1,000 biopsies ¹	Risk of malignancy following a “benign” test result ²	Number of malignancies expected per 1,000 biopsy diagnoses of “high risk” lesion ³	Number of invasive cancers expected per 1,000 biopsy diagnoses of DCIS	Strength of evidence supporting the conclusion
Open surgical ⁴	3 to 6	0 to 1%	0	0	Not rated
Freehand automated gun	24 to 73	3.4 to 10%	Insufficient data to estimate		Low
US guidance automated gun	6 to 9	1 to 2%	234 to 359	271 to 450	Low
Stereotactic guidance automated gun	3 to 13	0.5 to 2%	357 to 517	180 to 321	Low
MRI guidance automated gun	Insufficient data to estimate				Insufficient
US guidance vacuum-assisted	2 to 56	0.3 to 8%	Insufficient data to estimate		Low
Stereotactic guidance vacuum-assisted	1 to 6	0.1 to 1%	177 to 264	111 to 151	Low

¹ For a population of women with a prevalence of malignancy of 30%, assuming a 100% specificity (no false positives).

² For a woman with a BI-RADS[®] 4 score following mammography expected to have an approximate prebiopsy risk of malignancy of 30%. Note that an individual woman’s risk may be different from these estimates, depending on her own individual characteristics.

³ Primarily ADH lesions.

⁴ Estimates based on other literature reviews.

Abbreviations: ADH=atypical ductal hyperplasia; DCIS=ductal carcinoma in situ; MRI=magnetic resonance imaging; US=ultrasound.

Table B. Summary of key harms findings (Key Question 2)

Type of biopsy	Number of deaths expected for every 1,000 biopsies	Number of cases of severe bleeding ¹ expected for every 1,000 biopsies	Number of cases of hematomas requiring treatment expected for every 1,000 biopsies	Number of infections expected for every 1,000 biopsies	Strength of evidence supporting the conclusion
Open surgical ²	0	Insufficient data to estimate	20 to 100	38 to 63	Not rated
Automated gun core needle	0	6	1	1	Low
Vacuum-assisted core needle	0	9	1	1	Low

¹ Although not all studies provided a definition of severe bleeding, those that did included episodes of bleeding necessitating treatment, including hospitalization or surgery.

² Estimates based on other literature reviews.

Table C. Summary of impact of various factors on accuracy and harms

Category	Factor	Impact on accuracy	Impact on harms	Strength of evidence supporting the conclusion
Patient characteristics	Insufficient data for any patient characteristics			Insufficient
Lesion characteristics	Insufficient data for any lesion characteristics			Insufficient
Biopsy methods	Patient position	Insufficient data	Vasovagal reactions occur more often in patients seated upright	Low
	Needle gauge	Does not affect accuracy	Insufficient data	Low
	Insufficient data for any other factor related to biopsy methods			Insufficient
Clinician characteristics	Operator experience	Accuracy improves with experience	Insufficient data	Insufficient
	Insufficient data for any other factor related to clinician characteristics			Inconclusive
Facility type	Type of facility	Does not affect accuracy	Insufficient data	Low
	Geographic location of facility	Does not affect accuracy	Insufficient data	Low

Table D. Sensitivity analysis of impact of low quality evidence on the conclusions

Type of biopsy	Post-biopsy probability of having cancer after a negative core-needle biopsy result ¹			
	Analysis results	Analysis overestimated sensitivity by 1% (e.g., sensitivity 97% rather than 98%)	Analysis overestimated sensitivity by 5% (e.g., sensitivity 93% rather than 98%)	Analysis overestimated sensitivity by 10% (e.g., sensitivity 88% rather than 98%)
Freehand automated gun	6%	6%	8%	9%
Ultrasound guidance automated gun	1%	1%	3%	5%
Stereotactic guidance automated gun	1%	1%	3%	5%
Ultrasound guidance vacuum-assisted	2%	2%	3%	6%
Stereotactic guidance vacuum-assisted	0.4%	0.8%	3%	5%

¹ For a woman with a BI-RADS[®] 4 score following mammography expected to have an approximate prebiopsy risk of malignancy of 30%. Note that an individual woman's risk may be different from these estimates, depending on her own individual characteristics.

Table E. Summary of all findings on comparative effectiveness of core-needle biopsy methods

Accuracy			
Type of guidance	Method of biopsy	Level of evidence	Sensitivity (95% CI)
Any or none	Open surgical	Not rated	98% to 99%
Stereotactic	Automated gun	Low	97.8% (95.8 to 98.9)
	Vacuum-assisted	Low	99.2% (97.9 to 99.7)
Ultrasound	Automated gun	Low	97.7% (97.2 to 98.2)
	Vacuum-assisted	Low	96.5% (81.2 to 99.4)
MRI	Automated gun	Insufficient	83.3% (43.5 to 96.5)
Freehand	Automated gun	Low	85.8% (75.8 to 92.1)
Type of guidance	Method of biopsy	Level of evidence	Negative likelihood ratio (95% CI)
Any or none	Open surgical	Not rated	0.00 to 0.025
Stereotactic	Automated gun	Low	0.022 (0.012 to 0.043)
	Vacuum-assisted	Low	0.0090 (0.003 to 0.023)
Ultrasound	Automated gun	Low	0.030 (0.022 to 0.040)
	Vacuum-assisted	Low	0.036 (0.0060 to 0.21)
MRI	Any	Insufficient	0.23 (0.05 to 0.95)
Freehand	Automated gun	Low	0.14 (0.082 to 0.25)
Type of guidance	Method of biopsy	Level of evidence	DCIS underestimation rate (95% CI)
Any or none	Open surgical	Not rated	0.0%
Stereotactic	Automated gun	Low	24.4% (18.0 to 32.1)
	Vacuum-assisted	Low	13.0% (11.1 to 15.1)
Ultrasound	Automated gun	Low	35.5% (27.1 to 45.0)
	Vacuum-assisted	Insufficient	Not possible to calculate
MRI	Any	Insufficient	Not possible to calculate
Freehand	Automated gun	Insufficient	Not possible to calculate
Type of guidance	Method of biopsy	Level of evidence	ADH underestimation rate (95% CI)
Any or none	Open surgical	Not rated	0.0%
Stereotactic	Automated gun	Low	43.5% (35.7 to 51.7)
	Vacuum-assisted	Low	21.7% (17.7 to 26.4)
Ultrasound	Automated gun	Low	29.2% (23.4 to 35.9)
	Vacuum-assisted	Insufficient	Not possible to calculate
MRI	Any	Insufficient	Not possible to calculate
Freehand	Automated gun	Insufficient	Not possible to calculate

Table E. Summary of all findings on comparative effectiveness of core-needle biopsy methods (continued)

Factors potentially affecting accuracy			
Factor category	Factor	Level of evidence	Conclusion about impact of factor on accuracy
Patient characteristics	Patient age	Insufficient	No conclusion possible
	Breast density	Insufficient	No conclusion possible
	Patient comorbidities	Insufficient	No conclusion possible
Lesion characteristics	Palpable vs. nonpalpable	Insufficient	No conclusion possible
	Microcalcifications vs. masses	Insufficient	No conclusion possible
	Distortions vs. masses	Insufficient	No conclusion possible
	Size of lesion	Insufficient	No conclusion possible
	Location of lesion	Insufficient	No conclusion possible
Biopsy methodology	Number of cores	Insufficient	No conclusion possible
	Patient position	Insufficient	No conclusion possible
	Reference standard	Not rated	The type of reference standard (open surgery, 2 years' of followup, or only 6 months' of followup) had no impact on the data reported by the studies about the accuracy of core-needle biopsy
	Use of vacuum	Low	Vacuum assistance improved accuracy
	Use of image guidance	Low	Use of image guidance improved accuracy; stereotactic guidance was more accurate than US guidance
	Size of needle	Not rated	The size of the needle did not affect the accuracy of the procedure
Clinician and facility factors	Experience of operator	Insufficient	No conclusion possible
	Training of operator	Insufficient	No conclusion possible
	Facility location	Not rated	The location of the facility had no impact on the accuracy of core-needle biopsy
	Facility type	Not rated	The type of facility had no impact on the accuracy of core-needle biopsy

Table E. Summary of all findings on comparative effectiveness of core-needle biopsy methods (continued)

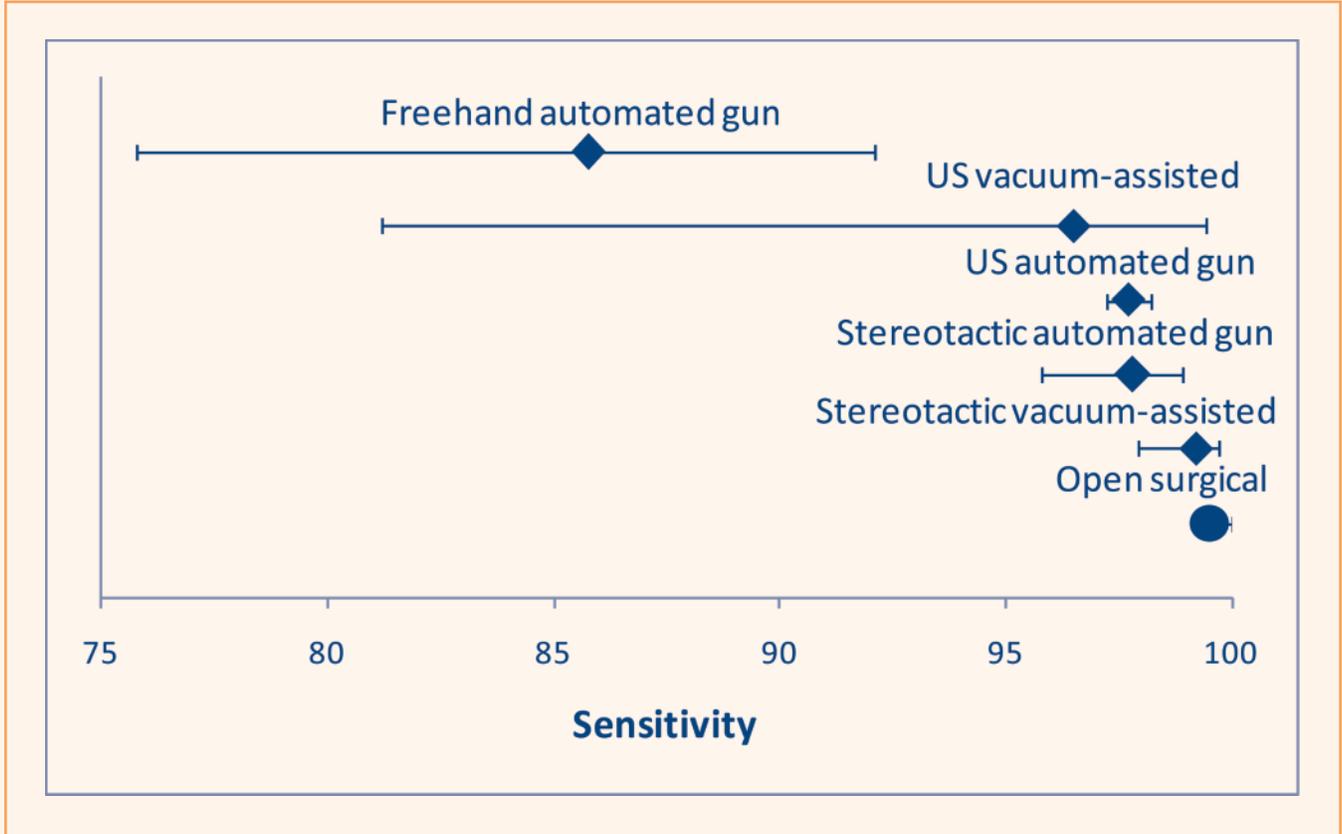
Harms			
Harm category	Harm	Level of evidence	Conclusion
Number of surgeries required	Undergoing surgery	Moderate	Women diagnosed with breast cancer by core-needle biopsies are more likely to be able to be treated with a single surgical procedure than women diagnosed with breast cancer by open surgical biopsies
Complications	Any	High	Core-needle biopsies have a lower risk of complications than open surgical procedures
Severe complications	Any	Low	2 to 10% of open surgical procedures may be affected by severe complications; 0.09 to 0.72% of core-needle biopsy procedures may be affected by severe complications
	Deaths	Low	No deaths were reported in association with any type of breast biopsy procedure
	Bleeding severe enough to require treatment	Low	0.72% of core-needle procedures were affected by severe bleeding
	Hematomas requiring treatment	Low	0.09% of core-needle procedures were affected by hematomas requiring treatment
	Infections	Low	0.15% of core-needle procedures were affected by infections requiring antibiotic treatment
	Severe pain	Low	1.7% of patients reported experiencing severe pain during core-needle procedures
Minor complications	Bruising	Low	Bruising following core-needle procedures was reported to be common
	Vasovagal reactions	Low	1.0% of patients had vasovagal reactions during core-needle procedures
	Pain	Low	3.7% of patients required pain medications following core-needle procedures

Table E. Summary of all findings on comparative effectiveness of core-needle biopsy methods (continued)

Factors potentially affecting harms			
Factor category	Factor	Level of evidence	Conclusion about impact of factor on harms
Patient characteristics	Patient age	Insufficient	No conclusion possible
	Breast density	Insufficient	No conclusion possible
	Patient comorbidities	Insufficient	No conclusion possible
Lesion characteristics	Palpable vs. nonpalpable	Insufficient	No conclusion possible
	Microcalcifications vs. masses	Insufficient	No conclusion possible
	Distortions vs. masses	Insufficient	No conclusion possible
	Size of lesion	Insufficient	No conclusion possible
	Location of lesion	Insufficient	No conclusion possible
Biopsy methodology	Number of cores	Insufficient	No conclusion possible
	Patient position	Low	Vasovagal reactions occur more often in patients seated upright
	Reference standard	Insufficient	No conclusion possible
	Use of vacuum	Low	Use of vacuum increased the percentage of procedures complicated by severe bleeding and hematoma formation
	Use of image guidance	Insufficient	No conclusion possible
	Size of needle	Insufficient	No conclusion possible
Clinician and facility factors	Experience of operator	Insufficient	No conclusion possible
	Training of operator	Insufficient	No conclusion possible
	Facility location	Insufficient	No conclusion possible
	Facility type	Insufficient	No conclusion possible

Abbreviations: ADH=atypical ductal hyperplasia; CI=confidence interval; DCIS=ductal carcinoma in situ; MRI=magnetic resonance imaging; US=ultrasound.

Figure A. Sensitivity of different types of biopsy



Sensitivity = (true positives/ (true positives + false negatives))*100.

Freehand automated gun: 5 studies of 610 biopsies.

US vacuum-assisted: 7 studies of 507 biopsies.

US automated gun: 16 studies of 7,124 biopsies.

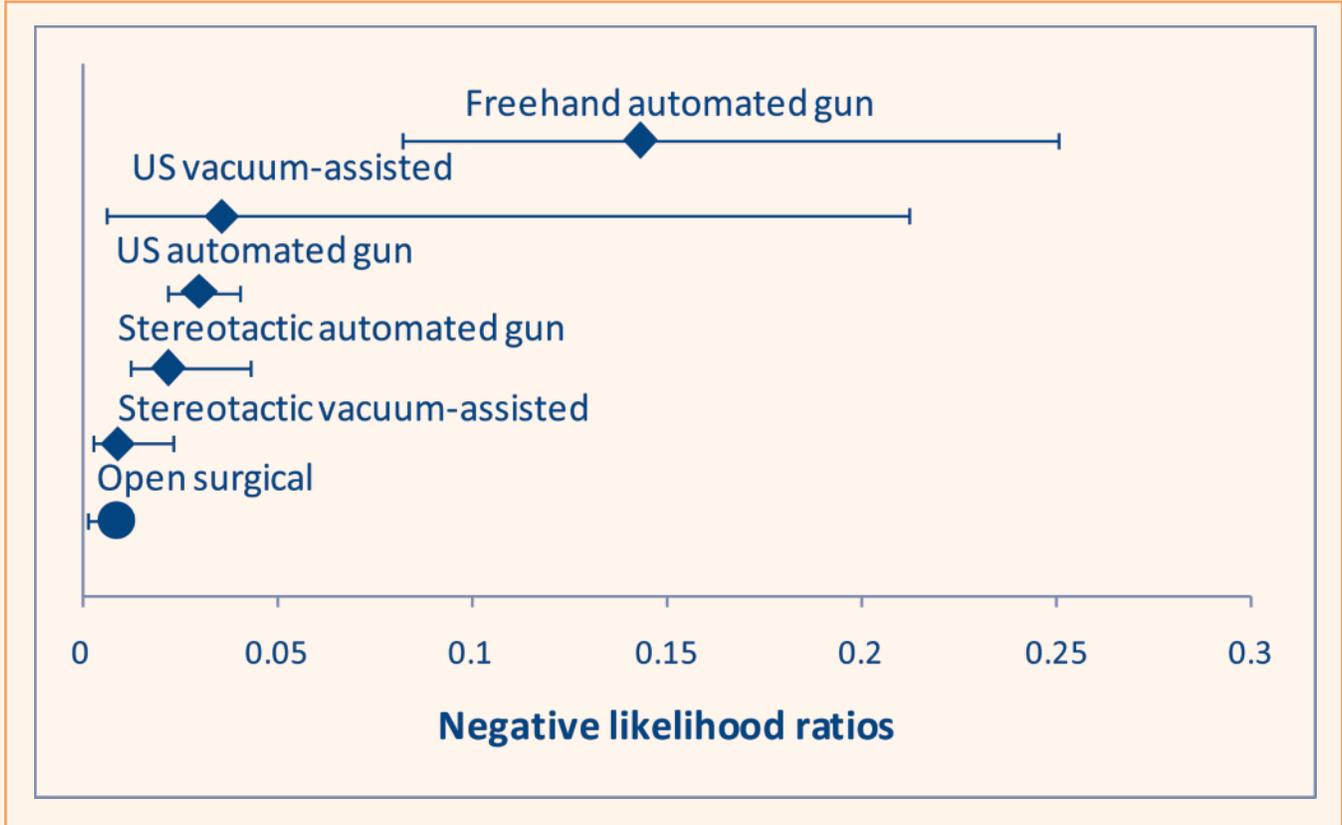
Stereotactic automated gun: 33 studies of 7,135 biopsies.

Stereotactic vacuum-assisted: 22 studies of 7,512 biopsies.

Open surgical estimate based on other literature reviews.

Abbreviation: US=ultrasound.

Figure B. Negative likelihood ratios of different types of biopsy



Negative likelihood ratio = (false negatives/(true positives + false negatives))/(true negatives/false positives + true negatives).

Freehand automated gun: 5 studies of 610 biopsies.

US vacuum-assisted: 7 studies of 507 biopsies.

US automated gun: 16 studies of 7,124 biopsies.

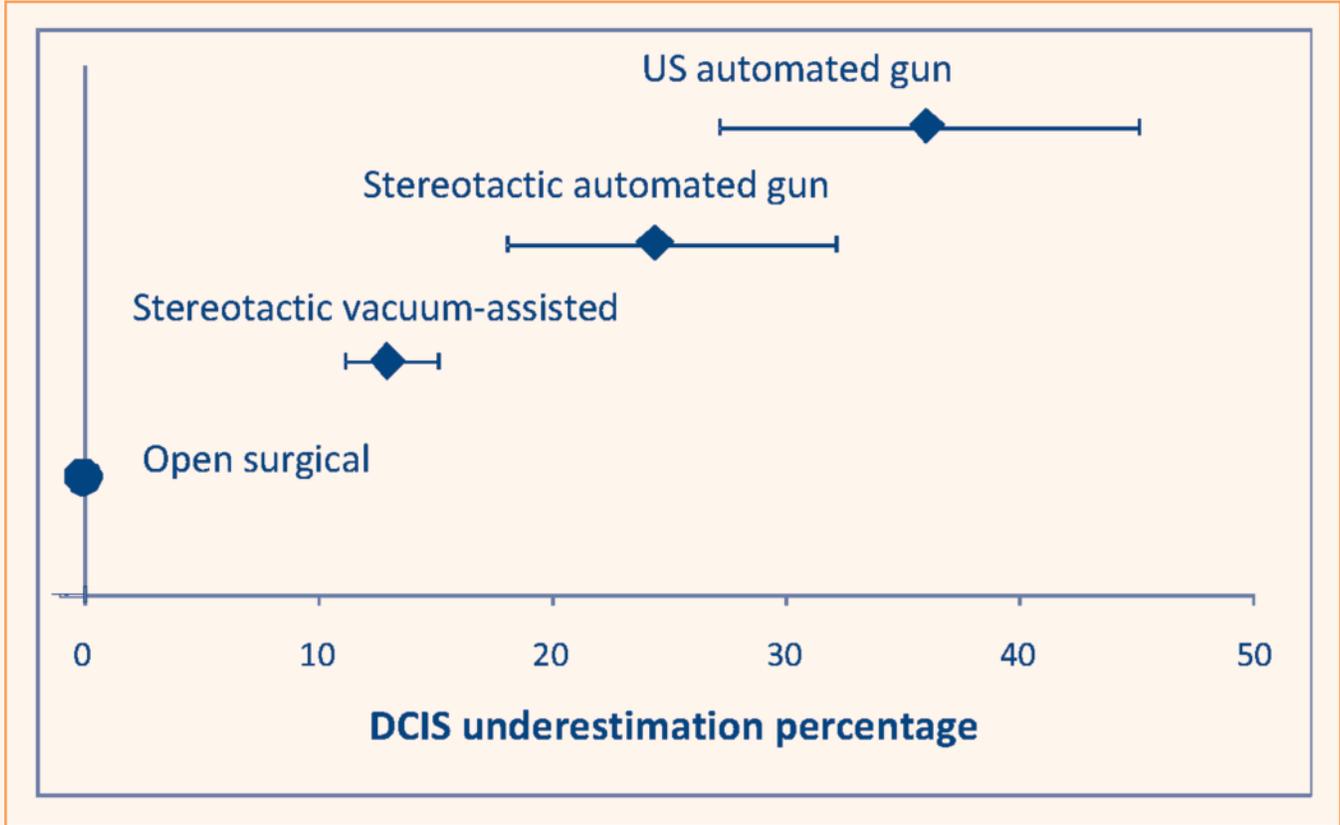
Stereotactic automated gun: 33 studies of 7,135 biopsies.

Stereotactic vacuum-assisted: 22 studies of 7,512 biopsies.

Open surgical estimate based on other literature reviews.

Abbreviation: US=ultrasound.

Figure C. DCIS underestimation rates of different types of biopsy



DCIS underestimation = (number cases diagnosed as DCIS on core-needle biopsy that were found to be invasive cancer by the reference standard)/(total number cases diagnosed as DCIS on core-needle biopsy)*100.

US automated gun: 12 studies of 208 core-needle diagnoses of DCIS.

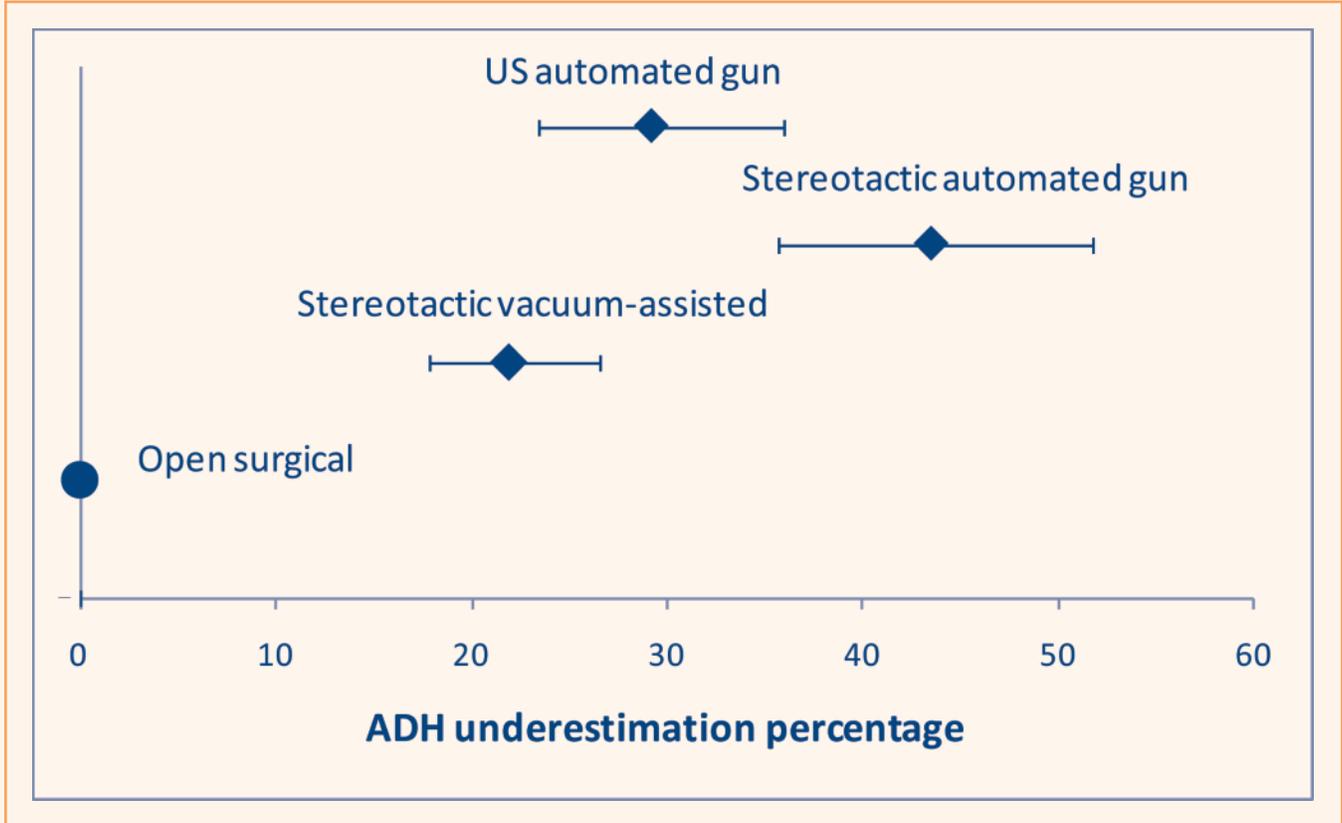
Stereotactic automated gun: 19 studies of 694 core-needle diagnoses of DCIS.

Stereotactic vacuum-assisted: 21 studies of 1,224 core-needle diagnoses of DCIS.

Open surgical estimate based on other literature reviews.

Abbreviations: DCIS=ductal carcinoma in situ; US=ultrasound.

Figure D. ADH underestimation rates of different types of biopsy



ADH underestimation = (number cases diagnosed as ADH on core-needle biopsy that were found to be invasive or in situ cancer by the reference standard)/(total number cases diagnosed as ADH on core-needle biopsy)*100.

US automated gun: 13 studies of 207 core-needle diagnoses of ADH.

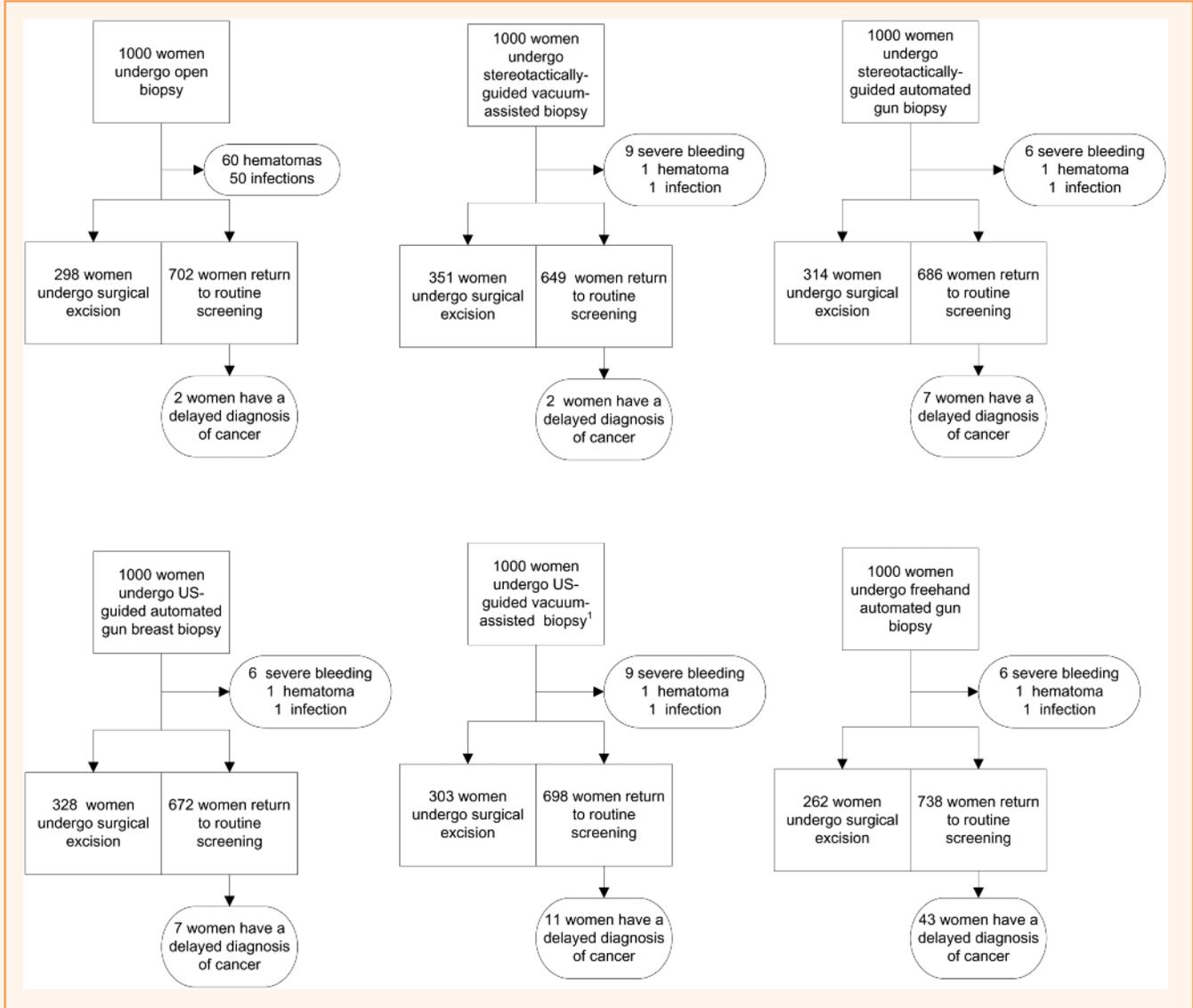
Stereotactic automated gun: 26 studies of 321 core-needle diagnoses of ADH.

Stereotactic vacuum-assisted: 21 studies of 380 core-needle diagnoses of ADH.

Open surgical estimate based on other literature reviews.

Abbreviations: ADH=atypical ductal hyperplasia; US=ultrasound.

Figure E. Models of 1,000 women undergoing breast biopsy



Abbreviation: US=ultrasound.

The numbers may not sum to exactly 1,000 due to rounding.

