

Accuracy and Usefulness of FNA vs. Core Needle

Biopsy in Breast Diagnosis

Britt-Marie Ljung, MD

Professor of Pathology

University of California at San Francisco

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Presentation Bullet Points

- Accuracy of both FNAB and CORE are variable and dependent on proficiency of operators, number of specimens collected, type of lesion, method of guidance and for core needle, size of needle.
- Under defined conditions the accuracy of FNAB and CNB is high and similar for both methods.
- FNAB and CNB should be used in the context of the Triple test (clinical and/or imaging findings).
- FNAB was relatively successful in the 1980s with limited numbers of better trained operators. Lower accuracy in the 1990s as more operators without training joined in.
- FNAB is faster, less costly and better tolerated by patients than CNB and similar procedures.

In recent years automated core needle biopsy, and various suction assisted devices of increasing core diameter, with mounting numbers of tissue pieces collected from each lesion, have replaced Fine Needle Aspiration Biopsy (FNAB) as the first line diagnostic method in many settings.

This review will explore some of the consequences of this trend and also examine the accuracy and usefulness of both FNAB and Core Needle Biopsy (CNB) in various settings and conditions.

PAIN

It is generally agreed that one of the advantages of FNAB over CNB and other diagnostic breast procedures is its minimal morbidity, primarily in terms of pain level. As the core needle diameters have increased in size and the number of tissue cores collected for each lesion has mounted, in attempting to increase the accuracy of the test, the patient's discomfort associated with the test appears to have increased. I have chosen to illustrate this by two examples from the last 2 months of 2006. The first one is from the Dec 11 Issue of Newsweek. The headline reads: "Targeting Needless Breast Biopsies".

Following are selected pertinent quotes from the text: "Think mammograms are unpleasant? Breast biopsies are much worse ...1.4 million breast biopsies per year...80 percent benign...Isn't there a better way?" The writer had attended a radiology meeting and listened to a presentation of a new ultrasound technique that would potentially make biopsies of the breast unnecessary. The second example is from a study, conducted at

Harvard Medical School and presented at the same radiology meeting by Lang et al¹ describing the benefits of hypnosis in coping with breast biopsy in 236 women. The authors concluded that, with hypnosis, there was “significant decrease in pain...anxiety during the procedure”.

COST

Although billing and reimbursement rates vary widely, generally FNAB is less costly than CNB and other biopsy systems. The cost of using suction-assisted, large bore (7-11 gauge) devices is similar to the cost of an open, surgical biopsy.

SPEED

Using FNAB, a preliminary diagnosis can often be rendered at the time of the procedure or shortly thereafter, Giard and Hermans². On the other hand, a CNB needs to be processed and a diagnosis takes longer, often days longer.

FNAB ACCURACY IN PALPABLE BREAST MASSES.

Giard and Hermans³, found in a meta-analysis that the accuracy of FNAB varies widely, with sensitivity ranging from 65-98 percent and specificity from 82-100 percent. They concluded that FNAB is an operator-dependent test and suggested that local test characteristics should be established before relying on the test. Most observers agree that training and experience in the interpretation of the specimens is important for accuracy and at least one study has shown that, in addition to knowledge of histology of breast lesions, it is important to have training in the interpretation of cytologic material from

breast lesions, Cohen et al.⁴ Less attention has been paid to the importance of proficiency in the collection of the specimen. At least one study by Lee et al⁵ has shown that operators who perform FNAB sampling more often, collect fewer non-diagnostic specimens. In a study of 1049 consecutive breast FNABs, Ljung et al⁶, we found that training in sampling technique had a profound impact on the sensitivity of FNAB. Operators with formal training in sampling technique produced samples resulting in 98 percent sensitivity for breast cancer while operators without formal training produced samples resulting in only 75 percent sensitivity. Although the operators with formal training did perform the test more often than operators without formal training, among the operators without formal training, there was no evidence that performing more procedures resulted in improved sampling or accuracy. In this study, where all specimens were reviewed without knowledge of the original diagnosis and follow-up was available on all patients, training in sampling technique was the only parameter that had an impact on accuracy of the test. The finding that deliberate practice with expert feedback rather than volume leads to excellence in the performance of procedures is supported in a recent article, Reznick R and MacRae H, in the New Eng J. of Med⁷.

In the US, most operators using FNAB have little or no training in how to perform the procedure. Typically reading a brief description in a text or observing a colleague (who may or may not be proficient), collecting a few samples, may be the full extent of training. Residency review boards for medical specialties requiring training in FNAB sampling typically suggest that 10-15 cases in training is sufficient (personal communication). Our experience is that operators become proficient enough to achieve at

least 95 percent diagnostic samples, from palpable targets, after initial bench practice followed by performing between 100-150 FNABs in training. Not all training FNABs however, need to be from breast lesions. In our experience, operators require this amount of training in order to be exposed to sufficiently challenging cases to develop their skills to an acceptable level.

FNAB or any other biopsy modality of the breast, with a false negative rate of about 5 percent, should be used in the context of the “Triple Test” which includes clinical presentation and any imaging findings. When all indicators are consistent with a benign process, the lesion may be safely observed clinically. If the indicators are not concordant, further investigation is indicated, Lau S. et al⁹.

ACCURACY OF CNB IN BREAST DIAGNOSIS

Like FNAB the accuracy of CNB in diagnosing breast cancer also varies in the literature.

Dillon M. et al¹⁰, based on a meta-analysis, reports false negative ranges as follows:

Palpation guided CNB	0-13 percent
Ultrasound guided CNB	0-12 percent
Stereotactic CNB	0.2-8.9 percent

Because of the low sensitivity for cancer, when collecting a single or a small number of cores, Brenner et al.¹¹, the current recommendation is to collect between 5-15 cores (some reports say up to 22 cores) depending on the type of lesion seen on imaging (mass lesion vs. micro-calcifications vs. architectural distortions etc) and type of imaging used

to guide the needle. Three European studies Sauer G, et al.¹², Leifland K et al.¹³, Vega Bolivar A, et al.¹⁴ recommend that 3 cores be collected when sampling mass lesions using image guidance. There is also a trend toward using larger bore needles (typically 14-7 gauge) Silverstein MJ et al.¹⁵ However, even larger bore instruments, 7 mm, have also been advocated, Russin L¹⁶. By using larger bore needles and collecting a large number of cores (5-15), a sensitivity rate for cancer of 98 percent was reported by Reynolds H, et al.¹⁷

COMPARISON OF ACCURACY OF FNAB AND CNB IN PALPABLE LESIONS.

Two reports investigate this issue. The first by Ballo M and Sniege N¹⁸ was prospective and compared three FNAB samples of a given mass with up to four CNB samples of the same mass during a single visit in the clinic. The number of CNB samples was driven by immediate examination of touch preparations from the cores for evidence of adequate sampling. The second report by Antley et al¹⁹, was retrospective and reported 3 years of FNAB and CNB experience. The number of samples collected by FNAB and CNB for each lesion was not described. The lesions sampled by FNAB and CNB were not the same. In both studies the sampling was carried out by operators with formal training in FNAB sampling technique. Both studies found very high sensitivity for FNAB, exceeding that of CNB, as follows:

	Sensitivity	Specificity	Reports
FNAB	97.5%	100%	Ballo M and Sniege N
CNB	90%	100%	Ballo M and Sniege N
FNAB	99%	99.5%	Antley et al.
CNB	85%	100%	Antley et al.

COMPARISON OF ACCURACY OF FNAB AND CNB OF NON-PALPABLE LESIONS WITH IMAGE GUIDANCE.

The best known prospective study collecting data, from 18 institutions on 442 women who underwent FNAB with image guidance was undertaken by the Radiologic Diagnostic Oncology Group V and published by Pisano et al²⁰. The findings varied significantly from one institution to another but overall the results show low sensitivity for breast cancer. FNAB, in this study, worked better for mass lesions than for micro-calcifications and also better with ultrasound guidance than with stereotactic guidance. No training or experience in FNAB sampling was required for individual radiologists participating in the study. Although there was a requirement that at least 50 FNABs had been collected at each participating institution.

A second study by Symmans F et al²¹ examined 495 breast lesions using stereotactically guided FNAB in a single private practice setting. Two hundred fifty-two of the same patients also underwent stereotactic CNB. In each case at least 5 FNABs were collected and when CNB was utilized at least 5 cores were taken. In a subset of cases, additional sampling, using FNAB and/or CNB, was conducted based on evaluation of the material

collected, by microscopy or presence of micro-calcifications. All radiologists participating in the study had training in FNAB sampling technique. In cases of cancer found on FNAB, a core biopsy was added in order to assess invasion.

	PPV	NPV	Sensitivity	Specificity	Insufficient	Study
FNAB (insufficient samples included and considered positive)	34%	95%	85-88% institutional variability	56-91% institutional variability	35%	Pisano et al
FNAB (insufficient samples excluded and atypical classified as pos)	74%	95%	85%	91%	35%	Pisano et al
FNAB	100%	99%			2%	Symmans et al
CNB	100%	95%			8%	Symmans et al

In the Symmans study 2 out of the 3 cancers missed by FNAB were also missed by CNB.

ACCURACY OF FNAB WITH TRIAGE TO CNB IN A SMALL SUBSET (6%) OF CASES.

A recent study at UCSF (manuscript in preparation) comparing consecutive ultrasound guided FNAB with subsequent histology of any kind over a 6 year period was analyzed. A total of 1356 FNABs with ultrasound guidance of almost exclusively non-palpable lesions were done during this period. Three hundred (22%) of these cases had histologic follow-up at the same institution. One hundred seventy three cancers were found among these 300 cases. There were no known cancers among the lesions without histologic follow-up however, matching of all 1356 with a population-based cancer registry is planned in order to get near complete follow-up. Ninety four percent of all 1356 cases were diagnosed by FNAB alone. An average of 2 FNAB samples were collected from each lesion. All radiologists collecting samples were trained in the procedure and cytopathologists attended and performed immediate interpretations of the samples. Sixty two (5%) of all 1356 cases were converted to CNB at the time of initial FNAB sampling based either on insufficient sample or immediate interpretation of the FNAB sample discordant with the imaging findings. Fourteen (23%) percent of these 62 cases were cancers. An additional 18 cases (1%), had FNAB samples determined to be insufficient at FNAB sign-out, and as a result had subsequent histology for diagnostic purposes. Nine (50%) of these 18 cases were cancers. Three cancers (1.7% of all 173 cancers found) were not triaged to CNB at the time of sampling or FNAB sign-out and were false negative by FNAB report. All 3 were grade I cancers, 1.1 cm in size or smaller. There

were no delays in treatment. All three cases had discordant imaging findings and were triaged to excisional biopsy, soon after cytology sign-out.

Accuracy of FNAB with triage to histology, mostly CNB, in 6% of cases:

Sensitivity	Specificity
98.3%	100%

In summary the literature sets forth wide variability of results of both FNAB and CNB. Factors influencing the accuracy of both tests include: proficiency of operators, number of specimens collected, type of lesion (mass, micro-calcifications, etc.) and method of guidance (palpation, ultrasound and stereotactic).

Clearly, FNAB works less well in settings where operators are not trained adequately in how to collect the specimen. Studies reporting high rates of accuracy were conducted with operators well versed in FNAB sampling and usually with immediate evaluation of the specimen at bedside. For CNB, poor results have been found when using relatively thin (18 gauge) needles and/or collecting limited numbers of cores. Thus, there has been a strong trend in recent years to increase the size of the needles usually to between 14-11 gauge and to recommend increasing the numbers of cores collected to between 5- 15 depending on type of lesion and mode of guidance. Some authors have advocated still larger bore instruments and higher numbers of cores. It is not clear from the literature

how specific training in the use of CNB may influence the diagnostic rates of individual or groups of operators. Perhaps improved training in CNB could reduce the need for large numbers of specimens from big needles.

Although increased numbers of core samples currently collected with larger needles have improved the accuracy of CNBs, this increased accuracy has come at a price, both financial and in the form of increased morbidity.

Based on our experience and published studies, clearly FNAB can deliver highly accurate results comparable to CNB. Further FNAB is faster, less costly and causes less pain and bleeding.

In a world where information is becoming increasingly available to patients, insurers and buyers of insurance, it is likely that at least three factors will be important for future success. These factors are cost, quality and patient satisfaction. FNAB, when practiced by well trained operators, compares well in all three categories to CNB and similar methods. Thomas Friedman's book "THE WORLD IS FLAT" provides an interesting perspective on the impact of information technology in many fields, including medicine. I expect that individual institutions will, in the not too distant future, be asked to report accuracy data for procedures such as breast biopsies, as part of quality assurance and improvement.

These data then can be used to decide what method is the best choice in a particular setting. In settings with the required expertise, FNAB sampling, with triage to CNB when

indicated in a small subset of cases, optimizes patient satisfaction and cost, and delivers accuracy comparable to CNB.

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Why Bother?



Newsweek article

Health for Life

Targeting Needless Breast Biopsies

A promising new technology could help to separate benign lumps from malignant ones.

BY ANNE UNDERWOOD

THINK MAMMOGRAMS ARE unpleasant? Breast biopsies are much worse. Any woman who's had one to determine whether a lump is benign or malignant will attest to that. Even with minimally invasive techniques, the doctor has to guide a needle to the spot to localize the lump before inserting small blades to sample the tissue. "You definitely feel it," says Donna Feo, 42, of Columbiana, Ohio, who had the procedure in February. "You have bandages on your breast for a week or so." Then there's the tense wait for the results.

For Feo, that meant four days during which she agonized over the prospect that her small children would be left without a mother. Some 1.4 million women undergo breast biopsies in this country every year. And after all that grief, 80 percent of the lumps turn out to be benign ... like Feo's. Isn't there a better way?

Soon there may be. Last week at the Radiological Society of North America, Dr. Richard G. Barr, director of ultrasound breast imaging at Southwoods X-Ray and Open MRI in Boardman, Ohio, presented a study on a new ultrasound technique called elasticity imaging. The procedure exploits a simple characteristic of malignant tumors: they're harder than benign ones. "The body attempts to wall them off, so it builds up a fibrous area around the lesion," says Barr. The new technique, which handily separates the stiff from the soft lumps, is so painless and unobtrusive that patients can't tell the difference between that and a regular ultrasound scan. And the results are available immediately.

To perform the scan, the radiologist

moves the ultrasound handpiece over the affected area. The special system continuously records two images—the standard ultrasound picture and the elastogram—which the adjoining monitor displays side by side. Softer tissue that moves with gentle pressure is shown as white on the elastogram, while stiffer tissue is black. As a



Targeting Needles Breast Biopsies

“Think mammograms are unpleasant? Breast biopsies are much worse.”

“...tense wait for results. ...four days during which she agonized over the prospect of...small children...left without a mother.”

“...1.4 million breast biopsies per year ... 80 percent benign.”

“Isn't there a better way?”



Newsweek

December 11, 2006

Hypnosis Helps Women Cope with Breast Biopsy: Study 236 women

Conclusion:

“ significant decrease in pain.... anxiety during the procedure.”

Lang E.V. et al
Harvard Med School
Presented at
Radiological Society
North America
Nov. 2006



Cost

Surgical bx and
Assorted devices

CNB

FNAB



SPEED

- FNAB – typically preliminary dx at time of procedure- final 24-48 h
- CNB – typically 2 days+



Hidden Reality – Missed Cancers

Low index palpatory findings

Threshold for any biopsy or imaging study

Young women < 35 and post menopausal with negative imaging



FNAB Accuracy Palpable Breast

- Sensitivity 65% - 98%
- Specificity 34% - 100%

Giard R and Herman SJ
Cancer Apr 15, 1992
Vol 69, No 8, p. 2104



FNAB Accuracy – Impact of Training in Sampling Technique

	Sensitivity	Specificity
• With Training	98%	100%
• Without Training	75%	100%

Definition of training in sampling technique:

- > 100 cases during up to one year supervised by experienced teacher with proven track record.



Ljung et al
Cancer (Cancer Cytopathology)
2001; 93: 23-268

The problem with FNAB

CME for OBGYN doctors

FNAB is useful and quick....safe and simple

10 ml syringe, 21 guage needle

Mass stabilized...needle inserted...vacuum is maintained on the syringe while moving the needle for a few passes through the lesion.

Release suction...withdraw..push onto slide..smear

Send to experienced cytopathologist

In experienced hands false pos <1% and false negative rate 5%





FNAB as part of Triple Test in palpable lesions

- Reported False neg rate FNAB alone 7%
- When applying Triple Test
False negative rate 0%

Lau S et al
The Breast Journal
Vol 10 No 6 2004
p. 487-491



Accuracy Core Biopsies

Guided by:

Palpation

False Negative

0 – 13%

Ultrasound

0 - 12%

Stereotactic

0.2 – 8.9%



Image Guided Core Needle Biopsy Accuracy

Strategy: Increase number of cores/weight of tissue

	Sensitivity with 5 14 guage cores	Recommended no of cores 14 guage
Mass Lesions	98%	5-6
Ca++	91%	15
Arch. Dist	86%	15
US-guided	98%	5-12 cores

Operator dependent



Brenner RJ et al
AJR Am J Roentgenol
166:341-346 1996

Number of Cores Needed – Mass Lesions

- Germany 3
- Sweden 3
- Spain 3

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British Journal Cancer
2005; 92:231-5

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2004; 45(2):142-7

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Acta Radiol.
2005; 46(7):690-5



Comparison FNAB vs. Core bx

Palpable, without guidance

	Sensitivity	Specificity	
CNB (3+)	90%	100%	Ballo/Sneige Prospective
FNAB (3)	97.5%	100%	Ballo/Sneige
CNB	85%	100%	Antley/Layfield Retrospective
FNAB	99%	99.5%	Antley/Layfield



Ballo M, Sniege N.
Cancer, Aug 15, 1996
Vol. 78 No 4 p 773

Antley C, et al
The Breast Journal
Vol 4 No 1 1998 p 3-7

Comparison FNAB vs Core Needle Bx

Non-Palpable with US-guidance

	PPV	NPV	
FNAB (2)	76-100%	46-99%	Pisano, et al
FNAB	100%	99%	Symmans, F et al
CNB	100%	95%	Symmans, F et al

Rec added CNB for inv.

Pisano, et al

Radiology June 2001

Vol 219 No 3 p. 785

Symmans, F et al

Cancer Mar 1 1999

Vol 85, No 5 p. 1119



UCSF US Guided FNAB Breast (Consecutive cases for 7.5 years)

- Total 1356 cases
- 300 cases with histologic follow-up of any kind at UCSF
- 173 cancers (13%) of Total 1356
 - 6% Triaged to histology, mostly CNB
 - 94% Dx by FNAB alone



Algorithm at UCSF- US-guided bx of Non-palpable lesions

- Average 2 FNAB samples with Quick Stain
- If material deemed adequate, and preliminary diagnosis is c/w imaging finding = Done.
- If material insufficient or preliminary diagnosis inconsistent with imaging or atypical and do not expect to be able to reach definitive diagnosis = Convert to histology, usually core biopsy
- 6 % converted to primarily Core Needle Biopsy



UCSF US Guided FNAB Breast

- Reasons for histologic exams:
 - Insufficient FNAB
 - Discrepancy cytology/ imaging
 - Atypical cytology findings
 - Patient or physician request



UCSF US-guided N = 1356

- 6% triaged to histology
- 98.3% sensitivity
- 100% specificity
- No treatment delay



UCSF US-guided N = 1356

- 3 (1.8%) of 173 cancers reported benign by FNAB
- All 3 grade I ca \leq 1.1cm
- No treatment delay, all discordant cyto-imaging



UCSF US-Guided FNAB

Cytologic Diagnosis (N)	Rapid Review Vs Final Cytology
Benign (66)	93%
Malignant (126)	98%



UCSF US-guided N = 1356

- 80 (6%) of total cases triaged to histology, mostly CNB
- 23 cancers (29% of 80) converted





The World Is Flat
A BRIEF HISTORY OF
THE TWENTY-FIRST CENTURY

Thomas L. Friedman
Farrar, Straus and Giroux

NATIONAL BESTSELLER



The World Is Flat
A BRIEF HISTORY OF
THE TWENTY-FIRST CENTURY
Thomas L. Friedman



Factors for success

- Accuracy
- Cost
- Patient satisfaction

Speed



Conclusions

- FNAB is operator dependent
- Fairly successful in 1980s, limited number of better trained operators. Lowered accuracy in 1990s as more operators without training joined in.
- FNAB and CNB should be used in the context of the Triple test (clinical and/or imaging findings)
- Under defined conditions the accuracy of FNAB and CNB are high and similar.
- FNAB is faster, less costly and better tolerated by patients than CNB and similar procedures.

