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Original article

Accuracy of needle biopsy of breast lesions visible on ultrasound: Audit of fine needle versus core needle biopsy in 3233 consecutive samplings with ascertained outcomes

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ABSTRACT

Introduction: Core needle biopsy (CNB) has progressively replaced fine needle aspiration cytology (FNAC) in the diagnosis of breast lesions. Less information is available on how these tests perform for biopsy of ultrasound (US) visible breast lesions. This study examines the outcomes of CNB and FNAC in a large series ascertained with surgical histology or clinical-imaging follow-up.

Materials and methods: Retrospective five-year audit of 3233 consecutive US-guided needle samplings of solid breast lesions, from self-referred symptomatic or asymptomatic subjects, performed by six radiologists in the same time-frame (2003–2006): 1950 FNAC and 1283 CNB. The probability of undergoing CNB as a first test instead of FNAC was evaluated using logistic regression. Accuracy and inadequacy were calculated for each of CNB and FNAC performed as *first* test. Accuracy measures included equivocal or borderline/atypical lesions as positive results.

Results: The probability of CNB as a first test instead of FNAC increased significantly over time, when there was a pre-test higher level of suspicion, in younger (relative to older) women, with increasing lesion size on imaging, and for palpable (relative to impalpable) lesions. Inadequacy rate was lower for CNB (B1 = 6.9%) than for FNAC (C1 = 17.7%), $p < 0.001$, and specifically in malignant lesions (B1 = 0.9% *vs.* C1 = 4.5%; $p < 0.001$). False negative rate was equally low for both CNB and FNAC (1.7% each test). CNB performed significantly better than FNAC for absolute sensitivity (93.1% *vs.* 74.4%; $p < 0.001$) and complete sensitivity (97.4% *vs.* 93.8%; $p = 0.001$), however specificity was lower for CNB than FNAC (88.3% *vs.* 96.4%; $p < 0.001$). Absolute diagnostic accuracy was higher for CNB than FNAC (84.5% *vs.* 71.9; $p < 0.001$) while FNAC performed better than CNB for *complete* diagnostic accuracy (95.4% *vs.* 93.2; $p < 0.008$). In the small subgroup assessed with CNB after an inconclusive initial FNAC (231 cases) there was improved complete sensitivity (from 93.8% to 97.0%) however this also increased costs.

Conclusion: FNAC and CNB were generally performed in different patients, thus our study reported indirect comparisons of these tests. Although FNAC performed well (except for relatively high inadequacy), CNB had significantly better performance based on measures of sensitivity, but this was associated with lower specificity for CNB relative to FNAC. Overall, CNB is the more reliable biopsy method for sonographically-visible lesions; where FNAC is used as the first-line test, inadequate or inconclusive FNAC can be largely resolved by using repeat sampling with CNB.

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Introduction

Preoperative diagnosis based on triple assessment inclusive of non-surgical (needle) biopsy has replaced diagnostic surgical biopsy, the latter being associated with low positive predictive value and high costs[1,2] and accounting for as much as 32% of breast screening program cost.[3] In Europe fine needle aspiration cytology (FNAC) was initially used and achieved high sensitivity.[4] Nevertheless FNAC has major limitations, including inadequate samplings, substantial false negative rates in some reports,[4–8] and operator-dependent accuracy[9]; it also provides limited information on tumour histologic features.[10] For these reasons core needle biopsy (CNB) has been increasingly replacing FNAC since the 1980's and in particular in assessment of screen-detected lesions. Following the introduction of ultrasound-guided CNB of breast lesions almost two decades ago,[11] many centres have adopted this approach for both screen-detected and symptomatic lesions, and studies have confirmed CNB high sensitivity.[12–17]

Studies comparing FNAC and CNB accuracy in biopsy of breast lesions that are visible on ultrasound (US) are invariably affected by selection to initial needle biopsy test, and there is limited information from high-quality controlled studies. We report an audit of needle biopsy accuracy from a major Italian breast diagnostic service, where both FNAC and CNB were applied by experienced operators over the same time-frame. The study center has established experience with US-guided FNAC but with increasing use of CNB in the diagnosis of solid breast lesions visible on ultrasound. The purpose of the audit was to examine the relative accuracy of FNAC and CNB in a large consecutive series of needle samplings, and to determine factors driving choice of first needle test as well as whether one test is superior to the other in this clinical setting.

Materials and methods

This is a retrospective study of 3233 consecutive needle biopsies (1950 FNAC and 1283 CNB) performed by six experienced radiologists on solid, palpable or impalpable, sonographically-visible breast lesions. Needle biopsies were from self-referred (symptomatic or asymptomatic) women who were investigated at the study centre from October 2003 to September 2006. Level of suspicion at palpation and imaging was recorded before FNAC or CNB, according to a categorical scale used in European guidelines: R2 = probably benign, R3 = indeterminate, R4 = suspicious, R5 = malignant.[18]

FNAC employed 22–23-gauge needles without aspiration.[19] Cytological smears were fixed in 95° alcohol and stained with Papanicolaou technique. CNB was performed with automated or semi-automated devices using 14-gauge needles, collecting at least two cores from each lesion. FNAC and CNB specimens were examined by dedicated breast cyto-pathologists and pathologists each with at least 15 years experience in breast diagnostics. FNAC was reported according to five categories (C1 = inadequate, C2 = benign, C3 = atypia, C4 = suspicious of malignancy, C5 = malignant). CNB was reported according to five categories (B1 = normal tissue/inadequate sample, B2 = benign lesion, B3 = lesion of uncertain malignant potential, B4 = suspicious of malignancy, B5 = malignant) as recommended by European guidelines.[18] Reference standard was surgical histology or clinical/imaging follow-up for lesions diagnosed as benign and those not undergoing surgery (follow-up mean = 1.44 years, median = 1.30 years). Benign lesions with <6 months follow-up were ineligible for this analysis. Follow-up data were available for 3233 cases (FNAC = 1950; CNB = 1283) which were included in this analysis.

Statistical analysis

The probability of undergoing CNB instead of FNAC (referent) as the first test was estimated as an odds ratio (OR) using logistic regression analysis. The effect of each considered variable (calendar year, pre-needle biopsy level of suspicion, age-group, size of the lesion on imaging, palpability) was examined in univariate analysis and also by adjusting for other variables in multivariate analysis.

Analysis of FNAC and CNB outcomes included the following measures: overall inadequacy rate (C1 or B1), inadequacy rate amongst cancers, false benign reports (C2 or B2) amongst cancers, absolute sensitivity (C5 or B5 in cancers), complete sensitivity (C3–C5 or B3–B5 in cancers), diagnostic conclusiveness (conclusive report rate: C2 + C5 or B2 + B5), specificity (true negative C1 + C2 or B1 + B2 in negative), absolute and complete diagnostic accuracy. Inadequate samples were included in the calculation of these parameters to reflect the results of the whole diagnostic procedure. Pearson Chi^2 test was used to evaluate differences between proportions. Statistical significance was set at $p < 0.05$ level.

The methods and reporting of this study considered the STARD recommendations (Statement for Reporting studies of Diagnostic accuracy).[20]

Results

For all needle biopsies included in this study (3233) CNB use increased over time relative to FNAC: 28.8% *vs*. 71.2% in 2003; 30.4% *vs*. 69.6% in 2004; 43.5% *vs*. 56.5% in 2005; 59.8% *vs*. 40.2% in 2006 (p for trend <0.01). Table 1 shows the distribution of first test FNAC and CNB – according to pre-test level of suspicion, age-groups, diameter and palpability – including estimates of the probability (OR) of undergoing as *first* test CNB instead of FNAC. The effect of each variable is expressed in terms of both crude OR (single variable effect) and also adjusted OR assuming the same distribution of all the other variables between FNAC and CNB cases. We found an independent effect of the annual interval, with an increasing probability over time for CNB of more than 60% for each of the years included. For all lesions, if the pre-test suspicion was R3 or greater,

Table 1
Probability (Odds Ratio, OR) of undergoing CNB as the first test instead of FNAC (referent).

	FNAC (1950)	CNB (1283)	Crude OR (95% CI)	Adjusted[a] OR (95% CI)
Year			1.68 (1.54–1.83)	1.61 (1.46–1.77)
Pre-needle biopsy level of suspicion				
R2	913	239	1	1
R3–R4	612	754	4.71 (3.94–5.62)	4.79 (3.95–5.80)
R5	425	290	2.61 (2.12–3.20)	2.38 (1.85–3.06)
Age-group				
≥80	169	69	1	1
70–79	202	132	1.60 (1.12–2.84)	1.77 (1.21–2.58)
60–69	189	142	1.84 (1.29–2.62)	2.56 (1.54–3.31)
50–59	253	212	2.05 (1.47–2.87)	3.17 (2.19–4.59)
<50	1137	728	1.57 (1.17–2.11)	3.19 (2.28–4.46)
Lesion size on imaging (mm)				
<10	1101	600	1	1
10–19	627	376	1.10 (0.94–1.29)	1.15 (0.97–1.38)
20–29	162	153	1.73 (1.36–2.21)	1.76 (1.34–2.30)
30–39	33	41	2.80 (1.43–3.64)	2.77 (1.67–4.62)
≥40	27	113	7.68 (4.99–11.82)	6.68 (4.21–10.60)
Palpability				
No	708	330	1	1
Yes	1242	953	1.63 (1.40–1.92)	1.38 (1.15–1.65)

(FNAC = fine needle aspiration cytology; CNB = core needle biopsy; OR = Odd Ratio; 95% CI 95% Confidence intervals; R2 = probably benign; R3 = indeterminate; R4 = suspicious; R5 = malignant).
[a] Adjusted for the other variables.

Table 2
Results and diagnostic categorization of FNAC and CNB performed as first needle test, according to ascertained final outcome.

	Final outcome (histology or follow-up)		
	Malignant	Not malignant	Total
FNAC			
C1	34	311	345
C2	13	839	852
C3	48	37	85
C4	99	6	105
C5	563	0	563
Total	757	1193	1950
CNB			
B1	6	82	88
B2	12	441	453
B3	29	68	97
B4	1	1	2
B5	643	0	643
Total	691	592	1283

(FNAC = fine needle aspiration cytology; CNB = core needle biopsy; C1 = inadequate; C2 = benign; C3 = atypia; C4 = suspicious of malignancy, C 5 = malignant; B1 = normal tissue, inadequate sample; B2 = benign lesion; B3 = lesions of uncertain malignant potential; B4 = lesions suspicious of malignancy; B5 = malignant lesion) add Euro guideline reference for categories.

the probability of performing CNB was 2–5 times greater than that for FNAC. CNB was also more likely to be performed than FNAC in younger (relative to older) women, with increasing lesion size (diameter) on imaging, and for palpable (relative to impalpable) lesions (Table 1).

Table 2 shows the distribution of FNAC and CNB reports according to ascertained final outcome. Accuracy estimates are shown in Table 3. Over time, no specific accuracy trend was evident, although there was weak evidence that CNB *complete* sensitivity increased ($p = 0.08$).

From 1950 FNAC as first test, CNB was performed in a subgroup (231 cases, 12% of FNAC) with inadequate or inconclusive FNAC reports: 24 additional cancers were detected; and complete sensitivity improved from 93.8% to 97.0% ($p < 0.003$). The addition of CNB in this subgroup also enabled a definitive diagnosis of cancer in 67 cases by upgrading to B5 (67 B5 from 31 C3 to 36 C4). CNB also clarified 31 false dubious/suspicious cytological cases (4 B1 from 4 C3; 27 B2 from 23 C3 to 4 C4), but caused 4 false atypical cases (4 B3 from 2 C1 to 2 C2). Overall, the addition of CNB to FNAC improved the specificity of the latter from 96.4% to 98.7% ($p < 0.001$) in this subgroup of selected cases. From 1283 CNB performed as first test, CNB was repeated in only 8 cases (0.6%): 2 additional cancers (B5) were detected (from initial B1 or B2) and complete sensitivity was marginally improved (from 97.4% to 97.7%).

Discussion

FNAC and CNB performance has been compared in several studies, which are summarized in Table 4[5,6,8,21–24,26–34] – these studies used various designs and the majority were based only on cases managed with surgical excision[5,8,21–24,26,27,29–33] (palpable masses[8,21,23,24,26,33] or cancers[22,29–31]). Few studies included benign lesions that were not managed with surgical excision[6,28,32,34] and, among these, only one study had adequate duration of follow-up for non-excised lesions.[6] The strengths of our study was inclusion of a relatively large series, reducing bias by including all cases evaluated with needle biopsy irrespective of whether these were managed with surgery or through clinical follow-up, and allowing adequate follow-up time. Furthermore, to our knowledge, this work represents the largest series of breast lesions undergoing ultrasound-guided needle biopsy with either FNAC or CNB or both, performed by radiologists with established experience in the use of both tests, and included consecutive self-referred asymptomatic or symptomatic women.

The limitation of our study, as also for most other studies summarized in Table 4, is that direct comparison between FNAC and CNB was not possible since paired testing was seldom performed on each subject.[5,21–24,32] Hence most estimates reported for accuracy provide *indirect* comparisons between FNAC and CNB, although our data represented tests performed in the same time-frame and by the same radiologists. Furthermore, we explored factors that were associated with the preferential choice of first test (Table 1). Although radiologists who performed needle sampling didn't follow specific criteria for selection of FNAC or CNB as first test, we found evidence in our data that CNB was preferentially used to FNAC in dubious/suspicious lesions, or larger lesions, or palpable lesions, or in younger women. Each of these variables had an independent significant effect on first-test needle biopsy choice in regression analysis. Such selection may have influenced our results, and while it is difficult to predict its exact effect, it is possible that this may have under-estimated sensitivity of FNAC relative to CNB (or conversely may have relatively over-estimated CNB sensitivity) – this should be a consideration when interpreting accuracy results.

Overall, CNB has increasingly replaced FNAC in breast services in many countries, and in some screening units in the UK use of FNAC has been abandoned completely.[25] In some services however FNAC is still used particularly for sonographically-visible lesions and for symptomatic lesions. In our setting, both tests are in use for sampling sonographically-visible lesions – the present study confirms a temporal shift from FNAC towards CNB in our service, as also reported in other studies.[25,26] This shift was independent of

Table 3
Accuracy of FNAC and CNB.

Measure of accuracy or test outcome	Estimate based on	FNAC	Estimate based on	CNB	*p*
Overall inadequate reports	C1/All FNAC	17.7%	B1/All CNB	6.9%	<0.001
Inadequate reports in cancers	C1/Cancers	4.5%	B1/Cancers	0.9%	<0.001
Benign reports in cancers	C2/Cancers	1.7%	B2/Cancers	1.7%	0.98
Absolute sensitivity	C5/Cancers	74.4%	B5/Cancers	93.1%	<0.001
Complete Sensitivity	(C3 + C4 + C5)/Cancers	93.8%	(B3 + B4 + B5)/Cancers	97.4%	0.001
Specificity	(C1 + C2)/Negative	96.4%	(B1 + B2)/Negative	88.3%	<0.001
Diagnostic conclusiveness	(C2 + C5)/All FNAC	72.6%	(B2 + B5)/All CNB	85.4%	<0.001
Absolute diagnostic accuracy	(True negative C2 + True positive C5)/All FNAC	71.9%	(True negative B2 + True positive B5)/All CNB	84.5%	<0.001
Complete diagnostic accuracy	(True negative C1 + C2 + True positive C3 + C4 + C5)/All FNAC	95.4%	(True negative B1 + B2 + True positive B3 + B4 + B5)/All CNB	93.2%	0.008

(FNAC = fine needle aspiration cytology; CNB = core needle biopsy; C1 = inadequate; C2 = benign; C3 = atypia, probably benign; C4 = suspicious of malignancy, C 5 = malignant; B1 = normal tissue, inadequate sample; B2 = benign lesion; B3 = lesions of uncertain malignant potential; B4 = lesions suspicious of malignancy; B5 = malignant lesion).

Table 4
Summary of studies reporting on the accuracy of FNAC relative to NCB.

Authors	Guide	FNAC and CNB on same lesions	N. cases	C1	B1	Complete sensitivity		Absolute sensitivity		Specificity		Study design and follow-up
						FNAC	CNB	FNAC	CNB	FNAC	CNB	
Elston CW et al., 1978[24]	CE	selected cases only	368	n/a	n/a	57.1%	80.2%	52.1%	73.5%	n/a	n/a	Retrospective study on palpable masses treated with surgical excision. Gold standard: surgical histology.
Khanna AK et al., 1991[33]	n/a	yes	86	n/a	n/a	96.8%	100.0%	n/a	n/a	100.0%	100.0%	Retrospective study on palpable masses. Gold standard: surgical histology. No follow-up of benign lesions that were not managed with surgery.
Rotten D et al., 1993[32]	US	no	1322	12.3%	n/a	92.1%	100.0%	n/a	n/a	84.8%	100.0%	Retrospective study of sonographical masses. Gold standard: surgical histology. No follow-up of benign lesions that were not managed with surgery.
Ballo MS et al., 1996[31]	CE	yes	124	n/a	n/a	97.5%	90.0%	n/a	n/a	100.0%	100.0%	Retrospective study on palpable cancers. Gold standard: surgical histology.
Hatada T et al., 2000[23]	US	selected cases only	233	8.7%	2.4%	86.9%	86.2%	n/a	n/a	78.6%	95.8%	Retrospective study on palpable masses. Gold standard: surgical histology. No follow-up of benign lesions that were not managed with surgery.
Clarke D et al., 2001[26]	n/a	yes	52	n/a	n/a	n/a	n/a	60.0%	96.0%	n/a	n/a	Prospective study on palpable symptomatic masses. Gold standard: surgical histology. No follow-up of benign lesions that were not managed with surgery.
Ibrahim AE et al., 2001[6]	US, ST	yes	298	58.7%	20.5%	34.5%	87.7%	n/a	n/a	47.6%	99.4%	Retrospective study of non-palpable lesions. Gold standard: surgical histology or clinical follow-up (mean 15.8 months; range 5–28).
Shannon J et al., 2001[5]												Retrospective study of operated lesions from asymptomatic and symptomatic women. Gold standard: surgical histology.
Screening	n/a	no	946	32.4%	21.3%	78.9%	93.1%	59.0%	89.0%	47.6%	85.5%	
Symptomatic	n/a	no	822	34.7%	4.6%	88.8%	99.5%	70.4%	98.5%	46.4%	52.7%	No follow-up of benign lesions that were not managed with surgery.
Westenend PJ et al., 2001[34]	US	yes	286	7.0%	7.0%	92.0%	88.0%	72.0%	75.0%	82.0%	90.0%	Retrospective study of suspect lesions. Gold standard: surgical histology or mammographic follow-up (duration of follow-up not specified)
Sun W et al., 2001[22]	n/a	selected cases only	209	n/a	n/a	93.8%	90.1%	65.4%	88.7%	n/a	n/a	Retrospective study of operated cancers. Gold standard: surgical histology.
Dennison G et al., 2003[21]	CE	selected cases only	143	n/a	n/a	90.4%	95.2%	n/a	n/a	n/a	n/a	Prospective study of palpable masses >2 cm. Gold standard: surgical histology or follow-up of benign lesions (1 year).
Homesh NA et al., 2005[8]	CE	yes	296	18.9%	6.1%	66.7%	92.3%	n/a	n/a	81.8%	94.8%	Randomized study on palpable operated masses. Gold standard: surgical histology.
Pilgrim S et al., 2005[30]	CE, US	yes	112	6.3%	0.9%	90.0%	99.0%	67.0%	94.0%	n/a	n/a	Retrospective study on symptomatic cancers. Gold standard: surgical histology.
Lieske B, 2006[29]	CE, US, ST	yes	763	8.0%	4.7%	82.0%	93.0%	65.0%	80.0%	n/a	n/a	Retrospective study on screen-detected cancers. Gold standard: surgical histology.
Garg S et al., 2007[28]	US	yes	50	0.0%	8.0%	78.2%	96.5%	n/a	n/a	94.4%	100.0%	Prospective study on suspect lesions. Gold standard: surgical histology or CNB results for non-operated lesions. No follow-up of benign lesions that were not managed with surgery.
Barra Ade A et al., 2008[27]	US	yes	264	14.0%	5.3%	85.6%	88.3%	68.5%	84.7%	66.7%	95.2%	Retrospective study on operated suspect lesions. Gold standard: surgical histology.
Our study, 2011	US	selected cases only	3233	17.7%	6.9%	93.8%	97.4%	74.4%	93.1%	96.4%	88.3%	Retrospective study on symptomatic and asymptomatic women. Gold standard: surgical histology or follow-up (see text)

(FNAC = fine needle aspiration cytology; CNB = core needle biopsy; CE = clinical examination; US = ultrasound guidance; ST = stereotactic guidance; C1 = inadequate; B1 = normal tissue, inadequate sample; n/a = not reported).

changes in age-distribution of patients and lesion characteristics (e.g. size, palpability). Still, a large proportion of women underwent FNAC, especially those with a probably benign pre-needle biopsy imaging score (R2).

Inadequate FNAC result is the main limit of FNAC and led to the early termination of a multicenter study in the United States designed to evaluate FNAC of non-palpable lesions.[35] Among studies comparing FNAC and CNB, FNAC inadequate rate is highly variable (from 0.0% to 58.7%)[5,6,8,23,27–30,32,34] and is relatively high on average (see Table 4). In most series C1 rate was consistently higher than B1 rate.[5,6,8,23,27,29,30] In our experience also, FNAC had a high inadequate rate of 17.7%. We chose to include inadequate FNAC reports in accuracy estimation, to assess the accuracy of the entire procedure – this inclusion could be critiqued as it might underestimate FNAC accuracy and (relatively) overestimate CNB accuracy, however it reflects the clinical reality.

This study shows that for absolute sensitivity (C5 or B5 results in cancers) CNB is superior to FNAC, in line with information from other investigators.[5,22,24,26,27,29,30,34] As for complete sensitivity (C3–5 or B3–5 in cancers) in both our series and in most published ones,[5,6,8,21,24,27–30,32,33] CNB is superior to FNAC, even though the difference is less pronounced (Table 3).[22,23,31,34] Of note, *false negative* rate was very low for both CNB and FNAC (1.7%) in our study; in contrast with other reports,[6–8] a benign cytological report was as reliable as a histological one, and the lower FNAC sensitivity was mainly due to inadequate samplings with FNAC.

In our series, CNB offered more definitive reports than FNAC, comprising either benign (C2–B2) or malignant reports (C5–B5), as reflected in the diagnostic conclusiveness estimate (Table 3). This measure is clinically relevant because in our series positive predictive value of C5 and B5 (both 100%) and the negative predictive value of C2 and B2 (98.5% and 97.4%, respectively) were very high and guide management decisions. Another different finding in our study to what has been previously reported,[5,6,8,23,27,28,31–34] is the higher specificity for FNAC compared to CNB. This was predominantly due to the higher proportion of false positive B3–4 for CNB compared to C3–4 for FNAc. In our series a greater percentage of pre-biopsy dubious/suspect (R3/R4) lesions underwent CNB than FNAC (59% *vs*. 28%), so it is possible that these more "difficult" cases managed by CNB, and more likely generating false positive findings, may have contributed to lower specificity of CNB.

Our study results are from a diagnostic strategy whereby some cases had a second needle procedure with the same technique or the other, because initial results were inconclusive or because of a discrepancy between cyto-histological reports and clinical-radiological findings. CNB after an initial FNAC represented most repeat samplings, and in these cases, the CNB improved both sensitivity and specificity of FNAC, and had the important effect of upgrading C3–C4 reports to definitive diagnosis of cancer. The sequential use of CNB after inconclusive FNAC proved an equivalent accuracy to that of CNB alone, but this may increase costs, as shown by other authors.[36] Only a very small number of initial CNB (0.6%) were unsatisfactory and required repeat CNB. Therefore, the use of the CNB as first test may be more efficient.

Conclusion

In conclusion, FNAC performed well although its relatively high inadequacy rate reduced its sensitivity, and CNB performed significantly better than FNAC on measures of sensitivity. CNB, however, was less specific than FNAC. While our data indicate that CNB is the more reliable needle test for definitive diagnosis of lesions visible on ultrasound, this interpretation should factor that several variables were associated with preferential selection to CNB as first test. A diagnostic strategy using FNAC as the first-line test would be reasonable provided that CNB is integrated as a second test to resolve inadequate or inconclusive FNAC.

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Conflict of interest

None.

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