

Diagnostic Accuracy of Core Needle Biopsy of Breast Lesions at Al-Demerdash University Hospital, Ain Shams University

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Abstract: Background: Once a breast lesion is suspected on basis of clinical and radiological impression, pathological evaluation is fundamental to establish its definitive diagnosis. Core needle biopsy (CNB) is a far less invasive procedure than excisional biopsy and clearly more reliable than fine needle cytology. As such CNB represents the diagnostic tool of choice to complement the pre-management tertiary assessment. Nonetheless, technical errors as well as inherent restrictions of limited biopsy samples might ameliorate the diagnostic efficiency of CNB. **Objectives:** To evaluate the concordance of CNB and excisional biopsy results of breast lesions in Al-Demerdash hospital and spot light on potential causes of non-concordance when present. **Methods:** Comparison of CNB and excision biopsy results to investigate rate of discordance and delineate potential underlying causes for CNB incompetency in these cases. CNB results were categorized as B1, B2, B3, B4 and B5 for objective analysis. Final diagnosis of excisional and/or the open surgical biopsy results were used as the gold standard for evaluation of the diagnostic accuracy of CNB. Correlation with available pre-biopsy clinical and sonomamographic data was also applied. **Results:** 126 cases of CNB specimens were included in this study with conclusive diagnosis of a benign lesion in (7.9%) as compared to 17.5% in final diagnosis and conclusive diagnosis of a malignant lesion in (69.8%) as compared to 84.6% in final diagnosis, thus accuracy of CNB as a diagnostic tool mounted to an absolute sensitivity of 84.6%, and full Specificity 68.1%. The non-conclusive CNB result comprised (18.2%) of cases was attributed to inadequacy of sample material in (82.6%) and diagnostic pitfalls in (17.3%). Diagnostic pitfalls were encountered in B3 category (6.3%) and B4 category (3.9%). **Conclusions:** Core needle biopsy is an accurate, sensitive and specific method for pre-management evaluation of breast lesions. CNB proved to be a single independent predictive factor as compared to other pre-management clinical and radiological background data.

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Key words: Core Needle Biopsy, Breast Cancer, Diagnosis.

1. Introduction

Core needle biopsy (CNB) has become the standard diagnostic method for the pathological evaluation of breast lesions detected by mammography. Numerous studies have verified the high specificity, sensitivity and diagnostic accuracy of CNB in breast lesions in general and breast cancer in particular. Furthermore, the extended use of this diagnostic method has led to a drastic reduction in the number of open surgical biopsies for benign lesions⁽¹⁻⁶⁾.

As a rule, pathologists can determine whether a lesion is benign or malignant on the basis of the CNB sample with a high level of interobserver agreement⁽⁷⁻⁹⁾. Nevertheless, a small percentage of cases do not abide to this rule, management decisions of these cases are thus based on the results of open surgical biopsy, along with comprehensive radiologic-pathologic correlation^(10,11).

According to recent guidelines for non-operative diagnostic procedures and reporting in breast cancer screening June 2016, CNB is categorized into five

categories (B1-B5) with different connotations as to therapeutic management of patients to help the pathologist give a therapeutically orientated diagnosis. This categorization can also be used as a standardized method for quality assurance among different working groups^(12,13).

These five categories, reproducible unequivocal diagnosis is obtained in B2 (benign) and B5 (malignant) categories. B1 category usually reflects artefactual procedure or biopsy showing only normal like structures, in this latter situation, the CNB won't be conclusive and would probably reflect improper CNB targeting. On the other hand, B3 and B4 categories are inconclusive by default because both categories reflect uncertainty regarding the biologic behavior of the lesion. Such uncertainty is principally related to the pathologic nature of the lesion mandating more panoramic assessment to overview a constellation of pathologic findings to assign a diagnosis; a factor that is unfulfilled in CNB due to its limited tissue yield. Spindle cell lesions, atypical intraductal proliferations, as well as papillary lesions

are the most common encounters of B3 and B4 categories (RCP). Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening ⁽¹⁴⁾.

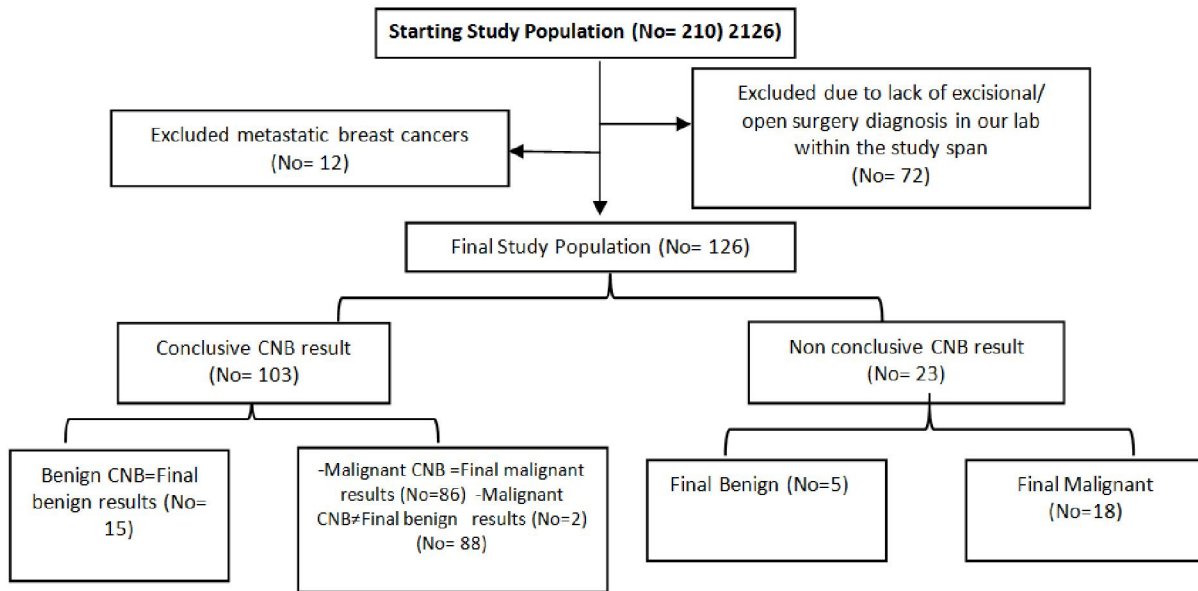
Optimization of CNB procedures along with proper categorization of CNBs can guarantee an efficient contribution of this tool in tertiary assessment of breast lesions. Such clarity in initial diagnosis would thus allow clinicians to take insightful decisions and set competent management plans.

Our study focused on the diagnostic efficiency of CNB in Al Demerdash University Hospital to verify its reliability and explore potential pitfalls of its practice.

2. Material and Methods

This is a retrospective cross sectional study for 126 patients who underwent core needle biopsy for various breast lesions (from January 2015 till January 2019) in Al-Demerdash pathology lab at Ain shams university hospitals. CNB of female patients presented by primary breast lesions were included; where breast CNB lacking subsequent excision specimen in our lab where excluded. Collecting Patient’s age, radiological BIRADs score from archived files were done.

Description of the study population is displayed in the following flowchart.



Re-evaluation of CNB biopsy for proper classification according to CNB categories (B1, B2, B3, B4 and B5) was done to set more objective tool of comparison and analysis according to recent guidelines for non-operative diagnostic procedures and reporting in breast cancer screening June 2016. (Table1) CNB and excision biopsy results were compared to investigate the rate and causes of

disconcordance. Excisional biopsy and/or the open surgical biopsy results were used as the gold standard for evaluation of the diagnostic accuracy of CNB. Data were entered and analyzed using IBM-SPSS software (version 25). Quality assurance statistics were calculated according to Quality assurance guidelines for breast pathology services (2016).

Table 1: CNB diagnostic categories.

CNB category	Interpretation
B1	Normal tissue/ uninterpretable
B2	A core is classified as B2 benign when it contains a benign abnormality
B3	This category represents lesions of uncertain malignant potential
B4	This includes situations in which the decision suspicious but not definite of malignancy.
B5	This category is appropriate for cases of unequivocal malignancy on core biopsy.

3. Results

The histological diagnosis of our 126 CNB cases were compared with the diagnosis of post excisional

biopsy. Our study included only females with age range from 20 to 80 years, mean age was 50.8 ± 12.9. The mean age in benign cases was 39±12.5 and

53.1±11.7 in malignant cases with statistically significantly higher age in malignant lesion as compared to benign lesion (p value <0.0005).

In this study 100/126 cases had pre CNB BIRADs reporting. 26 (20.6%) cases with no available BIRADs before CNB. One case with BIRADs1 (0.7%), none of our cases had a BIRADs2 score (0%), 7 (5.5%) cases with BIRADs 3, 32 cases with BIRADs4 (25.4%), 60 cases with BIRADs 5(47.6%).

Comparison of radiological results in terms of BIRADs score and the excisional biopsy results showed a statistically significant correlation between BIRADs score and results of excisional biopsy. Column comparisons showed a significantly higher correlation of BIRADs 3 in benign lesions and BIRADs 5 in malignant lesions with p value <0.0005.

The cases were classified by CNB diagnostic category in to five categories, where, 88/126 of cases were classified as B5 (69.8%), 5/126 cases as B4 (3.9%), 8/126 cases as B3(6.3%), 15/126 cases as B2 (11.9%) and 10/126 cases as B1(7.9%).

Among the 126 cases of this study 22/126 were finally diagnosed as benign (17.5%) and 104/126 were finally diagnosed as malignant (82.5%).

Correlating CNB and excisional biopsy diagnosis revealed the following:

- Among the 10 cases of B1 category; excisional biopsy revealed 3 (30%) benign cases and 7 (70%) malignant cases.

- Among the 15 cases of B2 category; excisional biopsy revealed concordant benign diagnosis in the 15 (100%) and revealed absence of malignant lesions in this category.

- Among the 8 cases of B3 category; excisional biopsy revealed 2 (25%) benign cases and 6 (75%) malignant cases.

- Among the 5 cases of B4 category; excisional biopsy confirmed suspicion of malignancy in all cases 5 (100%) and revealed absence of benign lesions in this category.

- Among the 88 cases of B5 categories; excisional biopsy revealed false initial interpretation as benign in 2 (2.9%) and 86 with concordant confirmation as (97.7%) malignant cases.

Comparison of results from CNB to the final of excisional biopsy showed a statistically significant correlation between CNB categories and results of excisional biopsy in B2 for benign lesions and B5 for malignant lesions. With p value <0.0005 and χ^2 66.045. (table 2)

Table 2: Comparison of CNB and final excision biopsy result:

CNB category	Excisional biopsy result		χ^2	P _{MC}
	Benign (n=22) NO (%)	Malignant (n=104) NO (%)		
B1	3 (30%)	7 (70%)	66.045	<0.0005
B2*	15 (100%)	0 (0.0%)		
B3	2 (25%)	6 (75%)		
B4	0 (0.0%)	5 (100%)		
B5*	2 (2.9%)	86 (97.7%)		

Moreover, CNB results are considered **conclusive** if it falls in the unequivocal B2 category (benign) and B5 category (Malignant), and **non-conclusive** if it falls in B1 (normal, uninterpretable), B3 (Uncertain malignant potential with or without epithelial atypia) or B4 (suspicious). Conclusive group were further subdivided into concordant and non-concordant. Also, the non-conclusive group are subdivided into adequate and non-adequate.

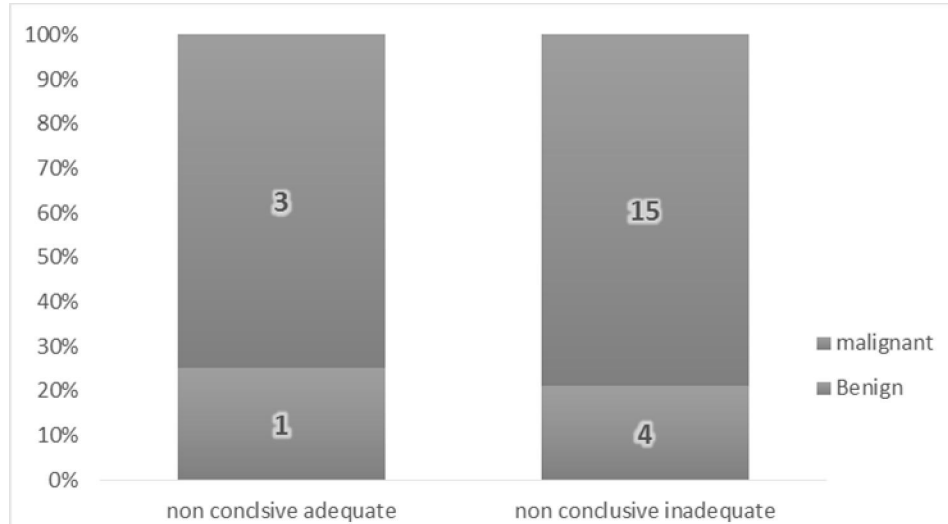
Correlating CNB and excisional biopsy diagnosis revealed concordance in 92 (73%) cases with 10 (10.8%) benign cases and 82 (89.1%) malignant cases.

Two cases (1.6%) showed major discordance in the sense of initial CNB classification as B5

(malignant) and final excisional biopsy diagnosis as benign thus accounting for false malignancy positive results.

Also 9 (7.1%) cases showed minor discordance (when disagreement between the two results was regarding lesion identification within concordant classification as benign versus malignant.)

Twenty three cases (18.2%) were non conclusive. Among these 23 cases 19 cases were inadequate (82.6%) and 4 cases were non-conclusive due to diagnostic pitfalls (17.3%). The non-conclusive inadequate group showed 4/19 (21.1%) to be benign and 15/19(78.9%) to be malignant in final excision biopsy assessment (Graph 1).



Effect of biopsy inadequacy in non-conclusive CNB result in benign and malignant lesions.

Among the 4 non-conclusive cases with diagnostic pitfalls; 3 cases turned out to be malignant in excisional biopsy. Two of which were initially categorized as B4 in CNB with a diagnosis of sclerosing adenosis vs. invasive carcinoma and another as spindle cell neoplasm while the third was

initially diagnosed in CNB as sclerosing adenosis with atypia and was categorized as B3. The fourth case turned out to be benign (phyllodes tumor) was initially diagnosed in CNB as proliferating spindle cell suggestive of phyllodes vs fibromatosis and was categorized as B3. (table 3).

Table 3: Efficiency of CNB in diagnosis of breast lesions:

		Conclusive or not	Excisional biopsy result	
			Benign (n=22) NO. (%)	Malignant (n=104) NO. (%)
Conclusive (B2,B5)	concordant	Conclusive concordant	10 (10.8%)	82 (89.1%)
	discordant	Conclusive (major discordance)*	2 (100%)	0 (0.0%)
		Conclusive (minor discordance)	5 (55.5%)	4 (44.4%)
Non conclusive (B1,B3,B4)**		Non conclusive adequate	1 (25%)	3 (75%)
		Non conclusive inadequate	4 (21%)	15 (78.9%)

According to the Royal College of pathologists guidelines for non-operative diagnostic procedures and reporting in breast cancer screening (2016), the quality assurance for CNB results in our lab showed absolute sensitivity 84.6%, specificity 68.1%, positive predictive value of B5 diagnosis 97.7%, positive predictive value of B4 diagnosis 100%, and positive predictive value of B3 diagnosis 75%.

4. Discussion

Being both reliable and noninvasive, CNB has become the technique of choice for preoperative diagnosis of symptomatic or mammographically detected breast lesions (15,16,17,18). Its established that higher diagnostic accuracy qualified CNB to replace fine-needle aspiration cytology in most of routine practice (2,19,20,21). One of the advantages conferred by CNB is a reduction in the rate of inconclusive samples which occurs more commonly in fine needle aspiration

cytology (22). Furthermore, it provides satisfactory tissue material allowing further ancillary tests that can allow characterization the neoplasm if needed.

In this study, the internal validation, i.e. placing each actual diagnosis into a category, has shown that the test is conclusive in a high percentage of cases (81.7%), enabling benign lesions (B2: 11.9%) to be distinguished from malignancies (B5: 69.8%), with clear, definitive therapeutic implications.

Indeed, it's quite noticeable that the introduction of CNB has led to a reduction in surgery on benign lesions. Rubin et al. (23) argued that the use of CNB can reduce the need for excisional biopsies in cases which are benign and do not require excision. In our study of CNB cases, 22/126 were finally diagnosed as benign (17.5%) and 104/126 were finally diagnosed as malignant (82.5%). The strikingly higher number of malignant cases in our study is essentially related to our selection criteria which excluded cases without

subsequent excision, this certainly reflects that open surgeries has been planned for malignant lesions much more than benign lesions, thus further emphasizing the value of CNB in sparing patients of benign lesions unnecessary surgical procedures.

In our study mischievous incidences with mountable effect on management decisions were exceptional, these included diagnostic discordance between CNB and excision, this was encountered in the conclusive group where among cases initially diagnosed as B5 (88 cases), excisional biopsy revealed false initial interpretation as benign in 2 (2.9%) and 86 with concordant confirmation as (97.7%) malignant cases. Hence the positive predictive value of B5 is (97.7%). One of these two cases took chemotherapy before excisional biopsy and the dissected lymph nodes were positive for malignancy.

Another established scenario for deficient yield of CNB result is the diagnosis of lesions with uncertain malignant potential B3: (6.3%) and, to a lesser extent, those in category B4 (3.9%). It is not possible to establish a definitive therapeutic approach for this group of lesions and diagnostic surgery is usually recommended⁽²⁴⁻²⁷⁾. In such categories the positive predictive value for CNB of B3 lesions was (75%) and of B4 lesions reached up to (100%). None the less, a more conservative therapeutic approach was advisable in these cases. Similar to what was seen by Woodcock et al. several authors have proposed mammographic follow-up in cases of papillary lesions and radial scar without atypia, provided these histologic results correlate well with the radiologic findings⁽²⁸⁻³³⁾.

In our work, the B3 category accounted for (6.3%) and the B4 category accounted for (3.9%). We tried to spot the underlying features of these biopsies; it turned out that whilst (25%) of B3 & (40%) of B4 were actually among the diagnostic pitfalls established to fall in these categories by default of their pathologic features, the remaining (75%) of B3 and (60%) B4 were rather attributed to sample inadequacy. The cut off of an adequate CNB material range from 2 to 4 cores as reported by *Fishman et al.*⁽³⁴⁾, *Murta De Lucena et al.*⁽³⁵⁾.

Moreover, crushed, artefactual biopsies with necrotic or clotted blood material were also non conclusive and were categorized by default of its definition into the B1 category which comprised 7.9% of our cases. MinKowitz et al. and Clarke et al. emphasized that the level of experience in the technique of using CNB has a significant impact on the yield of CNB^(22,36).

Despite of these exceptions, CNB proved efficient in diagnosis of breast lesions with reference to excision in our study, with an overall sensitivity of 84.6% and specificity of 68.1%.

In their review of literature, Nguyen et al showed that CNB had almost the same level of accuracy as excisional biopsy⁽³⁷⁾. This was further confirmed by Elvecrog et al in a study of one hundred women with palpable masses⁽³⁸⁾. Several other studies have also shown the high sensitivity and specificity of CNB biopsies and their usefulness in the management of breast tumors^(39,22). The sensitivity of CNB seen in these various studies ranged from 85.5% to 99% while their specificity ranged from 85.5 to 100%^(5,13,22,39,40). Nevertheless, comparison between different studies is difficult, given the differences in diagnostic criteria or in the statistical methodology employed.

Woodcock et al have recommended the correlation of clinical and radiological findings in cases of CNB suspected to be false negative⁽⁴⁰⁾.

Moreover, Analyzing age, radiological BIRADS score and CNB category in relation to the final classification of the breast lesions as benign vs malignant revealed each of the age and the CNB category to present a single predictive factor in contrast BIRADS score that did not.

It is also evident that comparison of results from radiological BIRADs score and the excisional biopsy showed a statistically significant correlation between BIRADs score and results of excisional biopsy. Column comparisons showed a significantly higher correlation of BIRADs 3 in benign lesions and BIRADs 5 in malignant lesions.

The use of these diagnostic categories enables standardized, homogeneous evaluation of the diagnostic accuracy of the technique^(13,39).

Conclusion

Although the diagnostic CNB categories might seem restrictive at times, they help to concentrate the pathologist's diagnostic impression. In addition, the CNB categories helps the pathologist to uniformly formulate their reports, which in turn has surely improved the communication between clinicians and pathologists hence it allows dealing with a category with definite therapeutic implications.

Moreover, it standardize the methods of analyzing the diagnostic accuracy of the test, this system of analysis has enabled us personally to confirm that our CNB results surpass the minimum recommended standards and even the preferred standards. Also, the detection of deviations in one or more of these indicators enabled us analyze the deficiency to be eventually corrected.

Also we launched two important conclusions in our study; the first is that proper tertiary assessment is mandatory for proper management, and setting a common understandable objective language is crucial for achieving this goal, thus reporting CNB in terms of their categories would complement the pathological

report in the best way to fulfil this role. Second is that CNB technique and CNB adequacy may interfere with the diagnostic efficiency of CNB and in such cases this doesn't necessitates an alternative excision but rather repetition of CNB with optimized practice and proper pathological, clinical and radiological collaboration.

Thus we advocate that, in every case, a parallel use of the diagnostic categorization (B1–B5) with histopathological diagnoses together with detailed mammographic–pathologic correlation.

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