Comparative Study of Tru-Cut Biopsy and FNAC in A Clinically Palpable Breast Lump

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ABSTRACT

Background & Objective: Fine-needle aspiration cytology (FNAC) is frequently used to evaluate a breast lump, for it is safe, reliable, and time saving outdoor procedure for evaluation of breast lumps. However, in recent times, the diagnosis of breast lesions has mostly become dependent on Tru-cut biopsies with a gradual reduction in the rate of performing fine-needle aspiration cytology (FNAC). The present study was undertaken to compare the diagnostic accuracy of Tru-cut Biopsy and Fine Needle Aspiration Cytology (FNAC) in the evaluation of a clinically palpable breast lump.

Methods: This cross-sectional study was conducted in the in Department of Surgery, Rajshahi Medical College & Hospital, Rajshahi, Bangladesh over a period of one year from July 2019 to June 2020. A total of 60 women with clinically palpable breast lumps were consecutively included in the study. All patients underwent FNAC and Tru-cut Biopsy to make a provisional (clinical) diagnosis of breast lump followed by histopathology of the excision biopsy taken during surgery to confirm the diagnosis. The diagnostic accuracies (sensitivity, specificity, positive and negative predictive values) of the two diagnostic modalities (FNAC and Tr-cut Biopsy) were then judged by comparing them with the histopathological diagnosis of the excision biopsy.

Result: In the present study majority (86.7%) of the lesions was malignant in terms of histopathology with almost all being infiltrating carcinoma (98%). Only 8(13.3%) cases were benign breast lesions and all of them were fibroadenoma. While Tru-cut or Core-needle biopsy (CNB) diagnosed 85% of the lesions as malignant, FNAC diagnosed 65% of lesions as malignant. The sensitivity of CNB was observed to be 98.1% and its specificity was 100%. In contrast, the sensitivity of FNAC was much lower (65%), although its specificity was comparable to that of CNB (100%). While the overall diagnostic accuracy of CNB was 98.3%, that of FNAC was 78.3%. The test of agreement between Tru-cut biopsy and FNAC using kappa-statistics showed that the two diagnostic modalities had moderate agreement in differentiating malignant breast tumours from the benign ones (k-value = 0.494, p < 0.001).

Conclusion: The study concluded that Tru-cut biopsy and FNAC both are hundred percent specific in excluding a benign breast lesion. However, the sensitivity of FNAC is much lower compared to that of CNB with overall diagnostic accuracy of Tru-cut biopsy being much higher than FNAC.

Key words: Tru-cut biopsy, FNAC, clinically palpable breast lump etc.

INTRODUCTION:

Breast cancer is a leading oncologic cause of death in women, but early detection saves lives. The vast majority of the breast lesions is benign and is not given significant attention as compared to malignant ones.¹ Although benign lesions are themselves not fatal, the physical and specially the psychological sufferings they cause to the affected women should not be underestimated and must be taken care of. In fact, some benign breast lesions may turn into malignancy in later part of life.¹ So, it is essential to recognize and study these lesions in detail to identify

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the high-risk group of patients and providing them regular check-up.

In Bangladesh, patients suffering from breast lump are going up. Because of the existing social circumstances, the tendency to overlook the complaints, & because female patients are hesitant to be examined by the clinicians for lump in the breast. They usually report to the clinicians when the conditions worsen or turn into malignancy.² On the other hand, there is increasing awareness with associated anxiety and stress among some women, who perceive every symptom in breast as cancer, compelling them to seek medical advice. It is sometimes difficult to determine whether a suspicious lump is benign or malignant simply from clinical assessment.³

Various diagnostic methods have been developed to evaluate the breast lumps with the goal of identifying a sensitive, specific, efficient and economical approach to reach an actual diagnosis of breast lump. Physical examination, fine needle aspiration cytology (FNAC), Tru-cut biopsy (core needle biopsy), ultrasonography, mammography, open excision biopsy, thermography all are used in the diagnostic workup of a palpable breast mass.⁴ FNAC has been proved to be of great value in the diagnosis of breast lumps. Apart from being cost-effective, it is also simple and quick while providing the cytological diagnosis.⁵ However, it has certain limitations like its inability to differentiate between invasive and in situ carcinomas, insufficient samples and false negative results. Tru-cut biopsy, also known as core needle biopsy (CNB), is now one of the useful means of obtaining histopathological diagnosis. It is relatively easy and can be performed in an out-patient basis. Its use also reduces unnecessary excisional biopsy. Lower inadequacy rates, allowing of ancillary methods, grading and typing of cancer, are the features of Tru-cut biopsy, which help to plan a definitive surgery. However, it has some limitations like pain, haemorrhage and infection. Some studies favor FNAC over Core Needle Biopsy, while others criticize its use as a good screening tool for breast lump evaluation. Some authors recommended combining the two techniques may improve the

diagnostic yield by reducing false positive and false negative rates.⁶

The high incidence of breast malignancy, its relatively easy detection at an early stage, and effective treatment in the form of conservative surgery and chemotherapy had prompted a worldwide initiation of triple assessment including a clinical (palpation), radiologic (ultrasonography or mammography), & cytological (FNAC) assessment.^{7,8} Although as a part of the triple assessment, in recent times, a gradual trend of increase in the rate of core needle biopsy (CNB) is seen replacing the previously rampant use of the FNAC. This gradual shift in the trend can be contributed by many factors although very few studies had yet conclusively proved a superiority of one procedure over the other. In this study the diagnostic accuracies of FNAC and Tru-cut biopsy or CNB in the evaluation of clinically palpable breast lump were compared to see which of the two screening procedures is better in the screening or diagnosis of breast lump in comparison with final histological diagnosis (gold standard) from excision specimen.

METHODS:

This descriptive cross-sectional study was conducted in the Department of Surgery, Rajshahi Medical College & Hospital, Rajshahi, Bangladesh between September, 2019 to September, 2020 (1 year). Approval for the study was obtained from the Institutional Review Board (IRB) of Rajshahi Medical College, Rajshahi. A total of 60 patients were consecutively included in the study. All female patients > 18 years old with a clinically palpable, suspicious breast swelling were included in the study. Patients refusing to undergo FNAC/Tru-cut biopsy, insufficient biopsy or FNAC material, diagnosed of having bacterial inflammation of breast were excluded from the study. All patients underwent FNAC and Tru-cut Biopsy to make a primary diagnosis followed by histopathology to confirm the provisional diagnosis. The variables studied were grouped as demographic variables (age and reproductive stage), the morphological and clinical characteristics of the tumour (breast involved, location of the lesion, tumour size, axillary

lymph node status, clinical diagnosis), Tru-cut biopsy profile (diagnosis, type of benign and type of malignant diseases), hormone receptor status-related variables (ER, PR and HER2-Neu), FNAC findings and histological findings (diagnosis, type of benign and malignant diseases) and pathological staging (characteristics of the tumour, nodal metastasis, distant metastasis and histological grading etc.).

Data were processed and analyzed using Statistical Package for Social Sciences (SPSS), version 23, Illinois, Chicago, USA. The test statistics used to analyze the data were descriptive statistics. While categorical data were expressed as frequency and corresponding percentage, the continuous data were presented as mean, standard deviation and range. The diagnostic accuracies (sensitivity, specificity, positive and negative predictive values) of the two diagnostic modalities (FNAC and Tru-cut Biopsy) were judged by comparing them with the histopathological diagnosis in terms of sensitivity, specificity, positive and negative predictive values, percentage of false positive and false negatives. The test of agreement between the two diagnostic modalities (Tru-cut biopsy and FNAC) was performed using kappa statistics (k-statistics), whereby a kappa value of 0-0.2 was considered as poor agreement, 0.21-0.4 fair agreement, 0.41-0.6 moderate agreement, 0.61-0.8 good agreement and 0.91-1.0 as excellent agreement. The level of significance was set at 0.05 and p < 0.05 was considered significant.

RESULT:

Thirty percent of the patients were middle-aged (40 -50 years old), 26.7% late middle-aged (50-60 years old) and 23.3% early middle-aged (30-40 years). While elderly patients (60 or > 60 years old) comprised of 11.7%, younger patients (< 30 years old) formed of 8.3% cases only. The mean age of the patients was 44.4 \pm 11.9 years with youngest and the oldest patients being 19 and 80 years old respectively (Table I). Half (50%) of the patients was at premenopausal state and half at menopausal state. The study of clinical characteristics of tumour revealed that over 58% of the patients had

right-sided involvement of the breast and the rest (41.7%) left-sided involvement. Over half (55%) of the tumours were located in the upper outer quadrant of the breast (UOQ), 26.7% in the lower outer quadrant (LOQ), 16.7% in the upper inner quadrant (UIQ) and only 1.6% in the LIQ. More than three-quarters (76.6%) of the tumours were of < 10 sq-cm size (38.3% < 5 sq-cm and 38.3% 5-10 sq-cm). The tumours were generally axillary lymph node positive (68.3%). Seventy percent of the tumours were malignant and 13.3% benign and the rest (16.7%) were suspicious (Table II).

Majority (85%) of the tumours was malignant and 15% were benign according to CNB findings. While all the benign cases were fibroadenoma, all the malignant cases were ductal carcinoma. Hormone receptor status examination showed that nearly 30% of the malignant cases were ER and 51% were HER2 Neu positive. None of the malignant tumours was PR positive. Fine Needle Aspiration Cytology (FNAC) classified 65% of the cases as C5, 13.3% as C4, 20% as C2 and only 1.7% as C1. Fifty-two (86.7%) cases were histopathologically diagnosed as malignant tumours and 8(13.3%) as benign. Of the malignant cases, 51(98.1%) were infiltrating ductal carcinoma and only 1(1.9%) was infiltrating lobular carcinoma, while all the 8(13.3%) benign cases were fibroadenoma (Table III).

Table IV shows the accuracy of Tru-cut biopsy as a screening test in differentiating malignant breast tumours from benign breast tumours. The sensitivity of Tru-cut biopsy in correctly diagnosing malignant breast tumours from benign ones was 98.1%, while the specificity of the test in correctly excluding those who did not have malignancy was 100.0%. The positive and negative predictive values of the test were 100.0% and 88.9% respectively. The percentage of false positive and false negative yielded by the test were 0% and 11.1% respectively. The overall diagnostic accuracy of the test was 98.3% (Table IV).

The sensitivity of FNAC in correctly diagnosing malignant breast tumours was 75.0%, while the specificity of the test in correctly excluding those who did not have malignant lesions was 100.0%. The

lymph node status, clinical diagnosis), Tru-cut biopsy profile (diagnosis, type of benign and type of malignant diseases), hormone receptor status-related variables (ER, PR and HER2-Neu), FNAC findings and histological findings (diagnosis, type of benign and malignant diseases) and pathological staging (characteristics of the tumour, nodal metastasis, distant metastasis and histological grading etc.).

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The sensitivity of FNAC in correctly diagnosing malignant breast tumours was 75.0%, while the specificity of the test in correctly excluding those who did not have malignant lesions was 100.0%. The

positive and negative predictive values of the test were 100.0% and 38.1% respectively. The percentage of false positive and false negative yielded by the test were 0% and 61.9% respectively. The overall diagnostic accuracy of FNAC was 78.3% (Table V).

The test of agreement between Tru-cut biopsy and FNAC using kappa-statistics revealed that the two diagnostic modalities had moderate agreement in differentiating malignant breast tumours from the benign ones (k-value = 0.494, p < 0.001) meaning that in 50% cases the two diagnostic modalities were in agreement (Table VI).

Table I. Distribution of patients by their age

Age (years)	Frequency	Percentage
No of vessel involved		
< 30	5	8.3
30 – 40	14	23.3
40 – 50	18	30.0
50 – 60	16	26.7
≥ 60	7	11.7
Reproductive status		
Premenopausal	30	50.0
Menopausal	30	50.0

*Mean age = (44.4 ± 11.9) years; range = (19 - 80) years#

Table II. Distribution of patients by clinical characteristics of the tumour

Clinical characteristics of the tumour	Frequency	Percentage
Breast Involvement		
Right	35	58.3
Left	25	41.7
Location		
UOQ	33	55.0
UIQ	10	16.7
LOQ	16	26.7
LIQ	1	1.6
Tumour size (sq-cm)		
< 5	23	38.3
5-10	23	38.3
10-20	10	16.7
≥ 20	4	6.7
Axillary lymph node status		
Positive	41	68.3
Negative	19	31.7
Clinical comment		
Benign	8	13.3
Suspicious	10	16.7
Malignant	42	70.0

Table III. Patients stratified by Tru-cut biopsy, FNAC and hormone receptor status findings

Variables	Frequency	Percentage
Tru-cut biopsy diagnosis		
Benign	9	15.0
Malignant	51	85.0
Type of benign diseases (n = 9)		
Fibroadenoma	9	15.0
Type of malignant diseases (n = 51)		
Ductal	51	85.0
Hormone receptor status		
ER status		
Negative	36	70.6
Positive	15	29.4
HER2 Neu		
Negative	25	49.0
Positive	26	51.0
FNAC findings		
C1	1	1.7
C2	12	20.0
C4	8	13.3
C5	39	65.0
Histopathological findings		
HP comment		
Malignant	52	86.7
Benign	8	13.3
Type of malignant diseases (n = 52)		
Infiltrating ductal	51	98.1
Infiltrating lobular	1	1.9
Type of benign diseases $(n = 8)$		
Fibroadenoma	8	13.3

Table IV. Diagnostic accuracy of Tru-cut biopsy against HP

Tru-cut biopsy findings	HP comment		Tatal
	Malignant	Benign	TOLAI
Malignant	51	00	51
Benign	01	08	09
Total	52	08	60

Table V. Diagnostic accuracy of FNAC against HP

FNAC findings	HP comment		Total
	Malignant	Benign	TOLAI
Malignant	39	0	39
Benign/suspicious	13	8	21
Total	52	8	60

Table VI. Agreement between Tru-cut biopsy and FNAC

Character studied or modalities of diagnosis	Measures of agreement	
	Kappa statistics	P-value
Tru-cut Biopsy FNAC	0.494	< 0.001

DISCUSSION:

Majority (86.7%) of the lesions in the present study was malignant histopathologically, which is consistent with the findings of Chandanwale and associates⁹ who demonstrated that a substantial proportion of breast lesions is malignant (87%). Majority of the malignant tumours was infiltrating carcinoma (98%). Only 8(13.3%) cases were benign breast lesions and all of them were fibroadenoma.

While Tru-cut biopsy diagnosed 85% of the lesions as malignant, FNAC diagnosed 65% of lesions as malignant. The sensitivity of Tru-cut biopsy was observed to be 98.1% and its specificity was 100%. In contrast, the sensitivity of FNAC was much lower, although its specificity was comparable to that of Tru-cut biopsy (100%). The sensitivity of FNAC varies from 77-97% in different studies¹⁰⁻¹³ and is comparable with that of the CNBs,^{10,14} although the variability range in Tru-cut biopsy is not as wide as in FNAC. The variability in sensitivity of FNAC (whether it is better than CNB or not) depends on some parameters. Of these, most important is the palpability and size of the lesion. Besides, the nature of the lesion (suspicious, benign or frankly malignant) is another significant determinant that guides the sensitivity particularly in case of FNAC. In a study Brancato and associates¹⁰ used the same operator and same lesion and performed both the procedures simultaneously in order to reduce some of the biases. The findings obtained showed that the sensitivity of both FNAC and Tru-cut biopsy is comparable in lesions < 2 cm or > 5 cm, whereas CNB performs better in lesions ranging from 2 to 5 cm with sensitivity of Tru-cut biopsy being higher in in-situ lesions and in detecting micro calcifications in mammography.¹⁵ Most of the studies have reported a high specificity rate of FNAC (92-100%).¹¹⁻¹³ Most of the studies have also reported a higher specificity for Tru-cut biopsy, especially so in lesions with suspicious diagnosis.16,17

A breast FNAC or Core-needle biopsy (CNB) is indicated in several clinical situations that have mainly diagnostic values except for some therapeutic implications of FNAC as in the case of a benign cyst © Ibrahim Cardiac Hospital & Research Institute

which can be evacuated during FNAC. Recently, the diagnosis of breast lesions has mostly become dependent on Tru-cut biopsy with a gradual reduction in the rate of performing fine-needle aspiration cytology (FNAC).¹⁸ Both the procedures have their pros and cons and outweigh each other taking into account different parameters. The diagnostic usage of these procedures includes a morphological diagnosis along with the application of necessary ancillary techniques such as performing immunochemistry for estrogen and progesterone receptors (ERs and PRs) by Tru-cut biopsy in the malignant epithelial neoplasms. Both the procedures can be performed for lesions of the breast with or without the assistance of radiology. The artillery of FNAC is fraught with its (1) rapidity of diagnosis, (2) high acceptance, (3) cost-effectiveness, (4) high sensitivity and specificity, (5) ability to sample multiple areas at a single go, (6) preoperative planning, (7) sampling of metastatic as well as the primary site, (8) performance of ancillary techniques, and (9) a rapid psychological relief to the patient following a negative diagnosis. In addition, therapeutic aspiration is also possible in case of a cyst as mentioned earlier. FNAC can be employed in both palpable and nonpalpable lesions of the breast, and it is a relatively safe procedure with a low rate of procedure-related complications. However, hematoma formation, infection, or sometimes pneumothorax (especially after axillary lymph node FNAC) can be associated with FNAC.18

Despite different studies quoting different performance rates, a true assessment of the relative superiority is often very difficult due to the involvement of multiple parameters and biases. As for example, Tru-cut biopsy in a palpable lump performed by experienced person with good yield of material and low inadequacy rate, whereas the adequacy and diagnostic sampling of FNAC material depend on the cytopathologist or radiologist working independently or in conjunction with each other performing the FNAC procedure rather than a radiologist alone and that also too varies according experience of the radiologist to the or cytopathologist. These biases are difficult to obviate

in most of the studies. Moreover, there are very few studies comparing consecutive sampling of breast lesions, where one procedure follows the other and both the methods are applied to evaluate the same lesion.

It is evident from our study and the studies compared and contrasted so far that Tru-cut biopsy is fairly comparable to that of histopathology in terms of its diagnostic accuracy and could be used as a useful screening tool in the evaluation of clinically palpable breast lump. FNAC, although has appreciably higher specificity, its sensitivity is inappreciably lower and cannot be reliably used as a screening tool for differentiation of malignant from benign breast lesions. Besides, the test of agreement (kappa-test) between the two diagnostic modalities revealed a moderate agreement (in 50% cases there was an agreement) suggesting that one test cannot be replaced by the other. In such cases the test that has both higher sensitivity and higher specificity (Tru-cut biopsy) could be selected as a test of choice for screening of clinically palpable breast lump. Before concluding the findings of the study, some of the limitations of the deserve mention.

Limitations:

1. The sample size was smaller compared to the calculated minimum sample size, which might have affected the findings of the study.

2. As different lesions were examined by different observers and as both the procedures in the same lesion were not done simultaneously, there may be some biases.

CONCLUSION:

From the findings of the study, it can be concluded that the role of Tru-cut biopsy is almost close to that of histopathology of excision biopsy taken from the breast lesions. Although Tru-cut biopsy and FNAC both are hundred percent specific in excluding a benign breast lesion, the sensitivity of FNAC is much lower compared to that of Tru-cut biopsy with overall diagnostic accuracy of Tru-cut biopsy being much higher than FNAC. So, Tru-cut biopsy could be used as a valid and reliable screening tool in the evaluation of clinically palpable breast lump.

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