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Original Article

Diagnostic Utility of Tru-cut Biopsy in Clinically Palpable Breast Lump: A Study in Central India

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Abstract

Background: To evaluate clinically palpable breast lump with goal of sensitive, specific and economical approach had been developed so far. Fine-needle aspiration cytology (FNAC) was most practiced method due to its accuracy, cost-effectiveness, and easy to perform. FNAC is a reliable diagnostic tool provided it is positive for malignancy but negative or inconclusive report cannot rule out malignancy. Tru-cut biopsy (TCB) is a very accurate, safe, economical, and less invasive day care procedure for definitive diagnosis of palpable breast lump as it provides sufficient tissue for histopathological examination and can also be used for immunohistochemistry and receptor (ER, PR, and Her) study which has great therapeutic value. Hence, TCB is thought to be accurate alternative and superior either to FNAC or incisional biopsy with high diagnostic accuracy of 98.2%.

Objective: Our aim is to find out the diagnostic accuracy of TCB as compared to FNAC for the evaluation of palpable breast lump and also to analyze sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy (ODA) of TCB in suspicious breast lesion.

Material and Methods: Our study is a prospective analytical hospital-based study conducted in the Department of General Surgery, R. D. Gardi Medical College, Surasa, Ujjain (MP), India. Sixty-four females between 25 and 75 years of age with clinically palpable breast lump were enrolled for the study. FNAC and TCB of breast lump were done with TCB gun and 18G needle of all study subjects. The reports of FNAC, TCB, and final histopathology report from subsequent post-operative specimen were recorded and analyzed.

Results: In our study, 64 patients of age group 25–75 years with palpable breast lump were enrolled. Maximum of the study subjects were more than 40 years. Benign breast lesions were common in younger age group and fibroadenoma was the most common among them. Whereas malignancy is common in the elderly and older age group, infiltrating ductal carcinoma was the most common malignancy. In our study, sensitivity and specificity of FNAC were 80% and 93%, respectively, whereas for TCB were 97% and 100%, respectively. ODA we found for FNAC of 87% and for TCB of 98%.

Conclusion: Palpable breast lump is a common surgical disease which needs proper evaluation. FNAC is well-accepted procedure but FNAC reports still have percentage of uncertainty. FNAC report still have percentage of uncertainty in differentiating benign and malignant breast lesion.Even if FNAC confirm malignancy it could not be able to provide information about histological type, grade and receptor status which have great importance for preoperative evaluation. TCB is an accurate, reliable, safe, and easy to perform method for establishing the diagnosis for palpable breast lump and alternative and superior to FNAC. TCB can replace FNAC and can routinely be used as a part of triple assessment for suspicious breast lesion.

Key words: Breast lump Tru-cut biopsy, FNAC, Sensitivity, Specificity

INTRODUCTION

Breast lump is one of the most common complain encountered in surgical outpatient department (OPD) which can be divided into two major categories, benign and malignant. Various diagnostic methods have been developed to evaluate the breast lump with goal of identifying a sensitive, specific, efficient, and economical approach to diagnose. For several years, fine-needle aspiration cytology (FNAC) was the most practiced method for the pathological diagnosis of breast masses due to its accuracy, cost-effectiveness, and easy to use.[1] FNAC was thought to be great value provided it is positive for malignancy but negative FNAC cannot rule out malignancy. The advent of tru-cut biopsy (TCB) for breast lesion

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assessment became the first step toward the new concept in breast cancer care.[2]

TCB is a very accurate, cost effective, safe, easy to perform in OPD settings, and less invasive. It provides sufficient tissue for histopathological evaluation to differentiate benign and malignant lesion to categorize each group in different subtypes.[3] Paraffin block of TCB can be used for immunohistochemistry study for receptor (ER, PR, and HER2) study which has extra-therapeutic value.[4]

Due to all these advantages, TCB for palpable breast mass is thought to be accurate alternative and superior to FNAC and incisional biopsy with a high diagnostic accuracy of 98.2%.

In the study, we aim for the evaluation of palpable breast lesion, we aim to find out diagnostic accuracy of TCB in comparison with FNAC confirmed by final histopathological report from subsequent post-operative specimen.

MATERIALS AND METHODS

This study is a prospective hospital-based study conducted at the Department of General Surgery, R. D. Gardi Medical College, Surasa, Ujjain (MP), India, from January 2019 to March 2020. Before commencement of the study, approval was sought and obtained from the institution ethics committee.

Sixty-four females of age group 25–75 years presented with palpable breast lump of variable duration to OPD and subsequently admitted and treated in all surgical unit at R. D. Gardi Medical College, Ujjain, were enrolled as study subject.

Methodology

A detailed history and thorough physical and local examination of patient of age group 25–70 years, having palpable breast lump were carried out and recorded in pro forma. FNAC of breast lump done in all patients. The patient was explained about the procedure and informed consent was taken for TCB.

TCB was done under local anesthesia with TCB gun with needle (18G).

After manual localization and immobilization of the lump, under complete aseptic precaution, 2% lignocaine infiltrated in skin. A nick is made in the skin with a No.11 blade for insertion of needle. Tru-cut needle inserted into lump and fired and biopsy specimen was obtained. Usually, 2–3 passes are made with different angulation of the needle and at least four bits of tissue from breast lump are collected. The quantity and quality of the material obtained was judged after immediate immersion of the specimen in fixative (usually 10% formalin) and after labeling, the sample was sent to pathology department for histopathological examination.

The tiny cuts made were approximated with band aid or micropore.

The report of FNAC, TCB, and final histopathology report from subsequent post-operative specimen available (from modified radical mastectomy [MRM]/wide excisional mastectomy) were recorded.

Each TCB diagnosis was matched with the histopathology results and labeled as follows.

A) True positive – where positive result for malignancy and non-malignancy is confirmed in the histopathological study for post-surgical specimen.
B) False positive – where positive TCB result for malignancy was not confirmed in the histological study of specimen found.
C) True negative – when negative result for TCB and no malignancy in post-surgical specimen.
D) False negative – when negative TCB result for malignancy is obtained but carcinoma is detected in histopathological study of post-surgical specimen.

Using the following formula, sensitivity (SN), specificity (SP), positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy (ODA) were calculated.

$$\text{Sensitivity } (SN) = \frac{TP}{TP + FP}$$

$$\text{Specificity } (SP) = \frac{TN}{TN + FN}$$

$$\text{Positive Predictive value } (PPV) = \frac{TP}{TN + FN}$$

$$\text{Negative Predictive Value } (NPV) = \frac{TN}{TP + FP}$$

$$\text{Overall Diagnostic Accuracy } (ODA) = \frac{TP + TN}{FP + FN + TP + TN}$$

McNemar's test was applied to calculate the P value association between the variable studies and statistical significance (near 1) evaluated.

RESULTS

In our study, 64 females of age group 25–75 years with palpable breast lump enrolled.

This prospective observational study carried out on 64 female patients with palpable breast lump attended in surgery OPD and admitted for diagnosis and definitive treatment in surgical ward of RD Gardi Medical College and associated CRGH Hospital, Ujjain (MP).

Out of 64 cases, maximum of cases, that is, 22 cases (34.37%) fall in the age group of 25–40 years and rest 42 (65.63%) were more than 40 years of age. About 78%, that is, 50 patients were married and 22%, that is, 14 patients were unmarried.

According to clinical presentation, 32 patients presented with lump duration <4 months, 22 patients presented with lump duration between 5 and 9 months, and 10 patients with more than 9 months. Complaint of pain was present in 13 patients and absent in 51 patients. Nipple discharge presents in seven patients and nipple retraction in five patients. Skin changes were present, that is, Peau D'orange in 15 patients and skin ulceration in two patients.

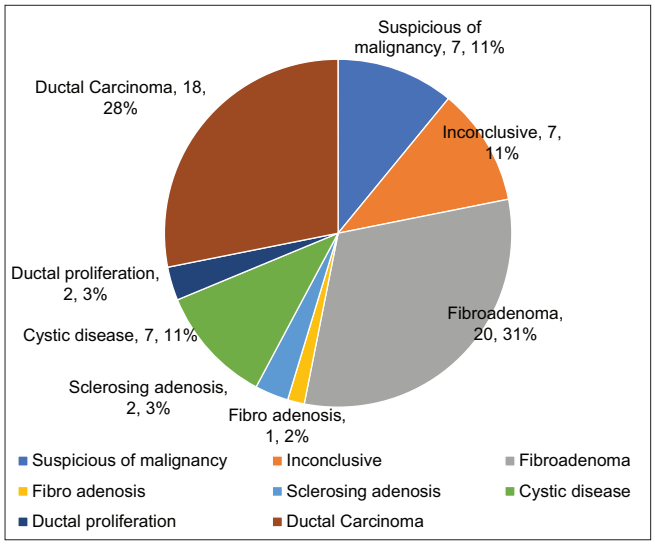

Figure 1: Distribution of cases according to FNAC findings. FNAC: Fine-needle aspiration cytology

According to FNAC findings, out of 64 cases, 20 patients were having fibroadenoma (31%). Eighteen patients (28%) were having ductal carcinoma. Seven (11%) patients report came out to be suspicious of malignancy. In other 7 (11%) patients, FNAC was inconclusive [Figure 1].

On TCB out of 64 patients, 30 patients were having infiltrating ductal carcinoma (47%). Twenty-four patients diagnosed with fibroadenoma (37.5%). Four patients (6.25%) were having fibroadenosis. Only one patient was having infiltrating lobular carcinoma [Figure 2].

Out of 64 patients, three patients not turned up for definitive surgical treatment. Out of 61 cases, MRM done in 32 patients (50%). Excision/lumpectomy done in 29 patients (45%).

Out of 61 patients, histopathology report of post-surgical specimen positive for malignancy was 31 (30 infiltrating ductal carcinoma and one infiltrating lobular carcinoma). Rest were reported as benign breast disease [Figure 3].

Out of 18 cases which were diagnosed as malignant in FNAC, 16 (89%) were malignant in histopathology too and two was benign. Out of 29 patients diagnosed with benign, 25 (86%) were benign in histopathology too and four were malignant. Thus, SN of FNAC in diagnosing disease is 80%. Moreover, SP is 93%. PPV was 89% and NPV was 86%. ODA of the test was 87%.

Among 32 cases which were malignant in TCB, all (100%) were malignant in histopathology too. Out of 32 cases,

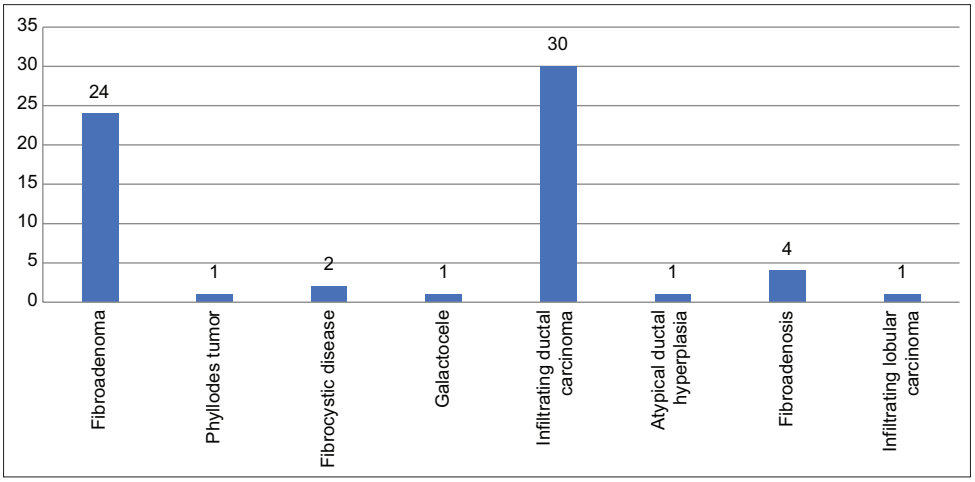

Figure 2: Distribution of cases according to TCB findings. TCB: Tru-cut biopsy

three cases were lost in follow-up, out of 29 cases which were benign in TCB, one was malignant and 28 (96.55%) were benign. Thus, SN of TCB in diagnosing malignancy is 97% and SP is 100%. The PPV was 100% and NPV was 97%. The ODA of the test was 98%. McNemar $P = 0.998$ is statistically significant. The degree of agreement (Kappa) between the two tests is 0.967 (96%) [Table 1].

DISCUSSION

Breast lump is the most common problem affecting female population, leading to morbidity and mortality. Breast cancer is the most common cancer surpassing cervical cancer in terms of mortality in female.

Breast lump can occur in any female at any age group from adolescence to the geriatric (old) age group. Majority of breast lumps hormone dependent and subjected to continuous physiological change during life. In younger age groups, breast lumps are generally benign but risk of malignancy increases with increase in age.

FNAC is a well-accepted procedure in the developing countries due to its low cost, safe, and affordable with rapid results, pain is minimal, and no further care is needed.[5] In this study of 64 patients on FNAC examination, 20 patients (31.25%) were diagnosed as having fibroadenoma. Eighteen patients (28.12%) were diagnosed having ductal carcinoma. Report of seven patients came suspicious of malignancy and seven was inconclusive. FNAC findings were compared with final histopathological examination report, the SN of FNAC came out to be 80%, SP of the FNAC was 92% with PPV of 89% and NPV of 86%. Many studies have documented the usefulness of FNAC with SN as high as 89–98% and SP of >99%. Many other studies have documented the superiority of TCB over FNAC. In this current prospective study, we have got a SN of 97%, SP of 100%, PPV of 100%, NPV of 97%, and ODA of 98%. There was only one false-negative report which was benign on TCB but came out to be malignant on final HPE report.

As compared with other research [Table 2] on diagnostic usefulness of TCB, the current study has surpassed all other studies with 98% diagnostic accuracy for TCB.[11-13]

Table 1: Result

	SN	SP	PPV	NPV	ODA
Clinical assessment	75%	90%	89%	70%	82%
FNAC	80%	93%	89%	86%	87%
TCB	97%	100%	100%	97%	98%

FNAC: Fine-needle aspiration cytology, TCB: Tru-cut biopsy, SN: Sensitivity, SP: Specificity, PPV: Positive predictive value, NPV: Negative predictive value, ODA: Overall diagnostic accuracy

Table 2: Comparision with other studies

Studies	Year	Number of patients	SN	SP	PPV	NPV	ODA
Martin *et al.*	2016	79	98.67%	100%	100%	80%	98.73%
Lacambra *et al.*[6]	2011	464	96%	99%	99%	94%	-
Ahmed *et al.*[7]	2010	80	94.64%	91.3%		-	94.87
Brunner *et al.*[8]	2009	120	95%	100%	100%	90%	-
Kulkarni *et al.*[9]	2009	819	97.7%	94.2%	93.1%	98.1%	95.5%
Homesh *et al.*[10]	2005	296	92.3%	94.8%	100%	100%	93.4%
Rikabi and Hussain[3]	2013	275	95.1%	100%	97.2%	98.2%	98.2%
Our Result	2020	64	97%	100%	100%	97%	98%

SN: Sensitivity, SP: Specificity, PPV: Positive predictive value, NPV: Negative predictive value, ODA: Overall diagnostic accuracy

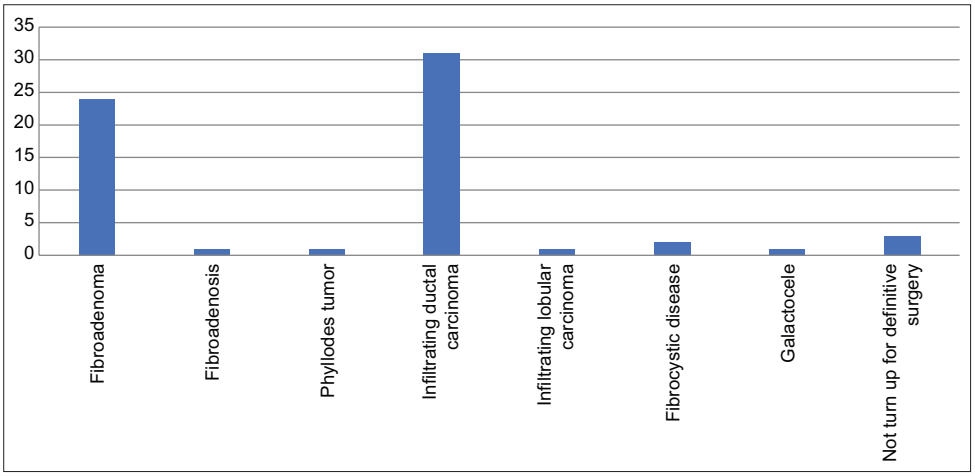

Figure 3: Distribution of cases according to surgical final histopathological report

The TCB of palpable breast lesions is based on histological study of tissue specimens which can provide all the reliable information. Core biopsy permits a pre-operative knowledge of the histological type and prognostic parameters such as estrogen and progesterone receptor status which is very useful in formulating a treatment protocol.[5,14,15]

CONCLUSION

Palpable breast lump is a common surgical disease which needs proper evaluation. Benign breast lump is common in younger age group, whereas malignancy in the elderly and older age group. More care should be taken in evaluation between above age groups, that is, 25–40 years where possibility of benign and malignant both can occur. FNAC is well-accepted procedure in the developing countries due to its low cost, safe, rapid results, and less pain.

FNAC reports still have percentage of uncertainty. FNAC do not provide information about the histological type, grade and receptor status while evaluating breast lump.

TCB is an accurate, reliable, safe, and easy to perform method for establishing the diagnosis for palpable breast lump and alternative and superior to FNAC and incisional biopsy with high diagnostic accuracy of 98%.

TCB can replace FNAC because it permits histological study of tissue specimen and pre-operative knowledge of histological type and prognostic parameters such as receptor status and proliferative activity.

TCB can routinely be used as a part of triple assessment for suspicious breast lesion in the developing countries.

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