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Diagnostic Validity of FNAC and Trucut Biopsy with Post Operative Histopathological Report in Cases of Breast Lumps at a Tertiary Care Center

Aditi Vijay Dalvi[1] and Hemant Borse[2*]

[1]Former PG Resident, Department of General Surgery, Dr. Vasantrao Pawar Medical College Hospital and Research Centre, Nashik - 422003, Maharashtra, India
[2]Professor, Department of General Surgery, Dr. Vasantrao Pawar Medical College Hospital and Research Centre, Nashik - 422003, Maharashtra, India; drhborse@gmail.com

Abstract

Introduction: Lump in breast is a common complaint in surgical practice. The lesions of the breast have diverse aetiology and presentation may range from a benign tumour, cyst or a malignancy. The diagnostic methods for palpable breast lumps should be rapid, inexpensive, most accurate and least invasive to evaluate and distinguish between benign and malignant lumps in outpatient clinics. Thus, patients are more compliant and surgeons can be more certain about the definitive management. **Aims and Objectives:** In the present study, we aimed to evaluate the diagnostic accuracy of FNAC and TRUCUT biopsy in screening of palpable breast lumps by taking histopathological reports as gold standard. **Materials and Methods**: It is a Diagnostic validity test, undertaken in the department of surgery in a tertiary care centre. Data collection was done by extensive history taking, clinical examination, FNAC, TRUCUT biopsy and post-operative histopathology. **Results**: Study was conducted on 145 patients. Out of the total, 99 (68.3%) reports were benign pathologies; fibroadenoma (61.6%) was the most common, while 46 (31.7%) were malignant pathologies and intra-ductal carcinoma was the most common (40 out of 46 cases; 88.9%). Overall diagnostic accuracy of FNAC was 93.1%, whereas that of TRUCUT biopsy was 96.6%. **Conclusion**: We thus conclude that both FNAC and TRUCUT biopsy are accurate methods in breast diagnostic practice. The methods are complementary and depend on the skill and experience of the individuals performing the sampling and interpretation. The clinicians should also know the advantages and disadvantages of both the procedures to decide accordingly.

Keywords: Breast Lumps, Diagnostic Validity, TRUCUT Biopsy, FNAC

1. Introduction

One of the common complaints in surgical practice is lump in breast. The breast lumps have multiple factors affecting the aetiology and clinical presentation ranging from a Simple cyst, benign tumour and malignancy[1]. All breast lesions are neither malignant nor all the benign lesions progress to cancer; however, the diagnostic validity can be increased by a combining various preoperative tests (like clinical examination, radio-diagnosis, fine-needle aspiration cytology and TRUCUT biopsy). These modalities are more accurate, reliable, and acceptable in comparison to a single diagnostic procedure, despite of having their own technical limitations[2].

The diagnosis of palpable breast lumps, the investigations should be rapid, economic, precise and minimally invasive to identify and distinguish between malignant and benign lumps on OPD basis. FNAC is a relatively easy, dependable, non-traumatic, inexpensive, complication- free technique, easily repeatable with better

*Author for correspondence

patient compliance for the evaluation of breast lesions. The use of Core Needle biopsy or TRUCUT biopsy is a very useful means for deducing the final diagnosis. It is can be performed on an outpatient basis without much inconvenience, thus avoiding an excisional biopsy. However, the procedure is more cumbersome, expensive and time consuming as compared to FNA procedure[3,4].

In the present study, we aimed to evaluate the diagnostic validity of FNAC and TRUCUT biopsy in screening of breast lumps which are palpable, keeping histo-pathological reports as gold standard.

2. Aims and Objectives

1. To study clinical profile of the patients presenting with breast lump.
2. To study diagnostic validity of FNAC with histopathology in cases of breast lump.
3. To study diagnostic validity of TRUCUT biopsy with histopathology in cases of breast lump.

3. Material and Methods

3.1 Study Area

Department of General Surgery of Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, Maharashtra.

3.2 Study Population

The study group consists of patients with breast lumps visiting the OPD and admitted in the General Surgery department.

3.2.1 Inclusion Criteria

All female patients with palpable breast lumps between the age group (15-80 yrs.) visiting the surgical wards, giving consent for TRUCUT biopsy and/or FNAC pre -operatively and HPR post operatively.

3.2.2 Exclusion Criteria

- Male patients with lumps to be excluded.
- Patients not consenting to be a part of this study.
- Patients with extensive metastasis and non-operative cases.

3.3 Study Design

Evaluation of a diagnostic test.

3.4 Sample Size Calculation

Sample size of minimum 145 cases

$n= (Z_{1-\alpha/2})^2 * Sens (1-sens) / d^2 *Prev$

Where; n- Sample size, $Z_{1-\alpha/2}$ – Z value at 10% error (1.96), Prev – 27% Prevalence of disease, d –allowable error, Sens- Estimated sensitivity

3.5 Study Duration

August 2017 to December 2019

4. Methodology

After admission to the hospital, a detailed clinical history and examination of the patient was done. Relevant investigations were undertaken to arrive to a diagnosis.

Mammography, sono-mammography, FNAC and TRU CUT biopsy were done as screening tests in suspicious breast lumps.

4.1 Fine Needle Aspiration Cytology

4.1.1 FNAC- Materials

Equipment for FNAC includes- needle (23 G), disposable syringe 10 cc, gloves, microscopic glass slide, fixative (isopropyl alcohol), alcohol sponges, sterile gauze and containers.

4.1.2 FNAC – Method

After explaining the FNAC procedure to the patient, an informed consent should be obtained area with the sterile gauze. Needle is inserted in to the lesion and aspirated with multiple passes keeping the needle in. Then a glass slide prepared and smeared. For fixation isopropyl alcohol is used. Infection, tumor dissemination, hematoma formation are a few known complications.

4.2 TRUCUT Needle Biopsy/Core Needle Biopsy

4.2.1 TRUCUT Materials

The following equipment is used:

- TRUCUT gun with a 14-gauge needle.

- Sterile container with formalin.

4.2.2 TRUCUT Method

- Cleaning of the skin (sterilization).
- Application of surface anaesthetic.

Manual localization and immobilization of the lesion is done before introduction of needle. Biopsy specimens are obtained, minimum six, through different angles of the needle into the lesion and thereby immersed in the fixative.

Histopathological reporting was done routinely to confirm the diagnosis, for evaluation of Ca breast stage and grade. The treatment plan was focused on early detection, anticipation and management of the possible complications.

5. Results

In the present study including 145 participants, the mean age among the cases was 46.32 years and 34.5% cases were above 50 years of age. Out of the total, 87.6% were married while 12.4 were unmarried. A total of 66.9% cases were from lower socio-economic class while 33.1% were from middle socio- economic class (Table 1).

Most of the lumps had Soft consistency (47.6%), while 26.9% and 20% had firm and hard consistencies respectively. Majority lumps were in the Left (25.5%) or Right (15.9%) upper outer quadrant (Table 2).

Table 1. Distribution of study cases as per socio-demographic variables

Socio-demographic Variables	N- 145	%
1. Age group (years)		
a. </= 20	11	7.6%
b. 21-30	17	11.7%
c. 31-40	31	21.4%
d. 41-50	36	24.8%
e. 51-60	39	26.9%
f. >60	11	7.6%
2. Marital status		
a. Unmarried	18	12.4%
b. Married	127	87.6%
3. Socio-economic class		
a. Lower	97	66.9%
b. Middle	48	33.1%
c. Upper	0	0.0%

Table 2. Distribution of the study cases as per clinical profile

Clinical Profile	N-145	%
1. Lump consistency		
a. Cystic	8	5.5%
b. Soft	69	47.6%
c. Firm	39	26.9%
d. Hard	29	20.0%
2. Side & Quadrant		
a. LLI	3	2.1%
b. LLO	16	11.0%
c. LUI	13	9.0%
d. LUO	37	25.5%
e. RLI	3	2.1%
f. RLO	35	24.1%
g. RUI	15	10.3%
h. RUO	23	15.9%

Out of the total 145 cases, 99 (68.3%) were benign pathologies while 46 (31.7%) were malignant pathologies (Table 3, Chart 1).

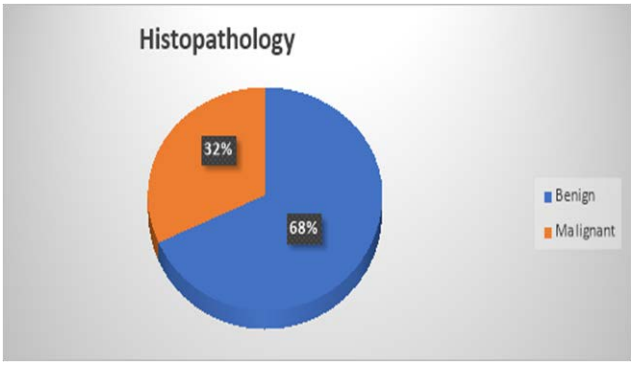

Chart 1. Distribution of the study cases as per histopathology report

Fibroadenoma (61.6%) was the commonest benign pathology followed by acute mastitis (12.1%) (Chart 2) and the most common malignant pathology was intra-ductal carcinoma (40 out of 46 cases; 88.9%) followed by phyllodes tumour (n-3; 6.7%) (Chart 3).

As per FNAC report, 69.7% cases were benign while 30.3% were malignant (Chart 4) and as per TRUCUT biopsy report, 69% cases were benign while 31% were malignant (Chart 5).

FNAC's sensitivity and specificity was 87% and 96% while PPV and NPV was 90.9% and 94.1%. Overall diagnostic accuracy was 93.1% (Table 3).

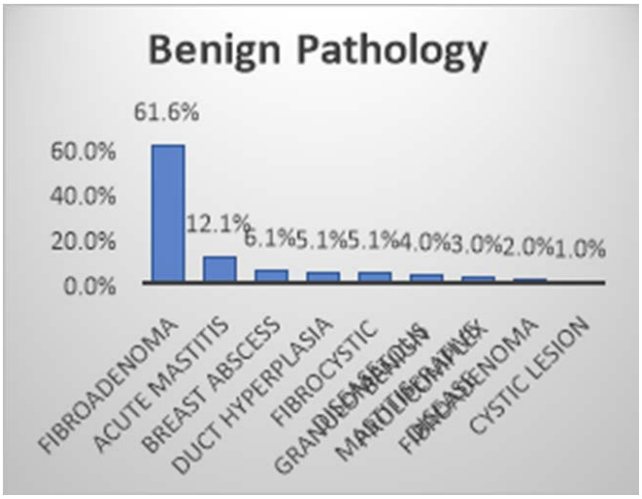

Chart 2. Benign breast lumps among study participants

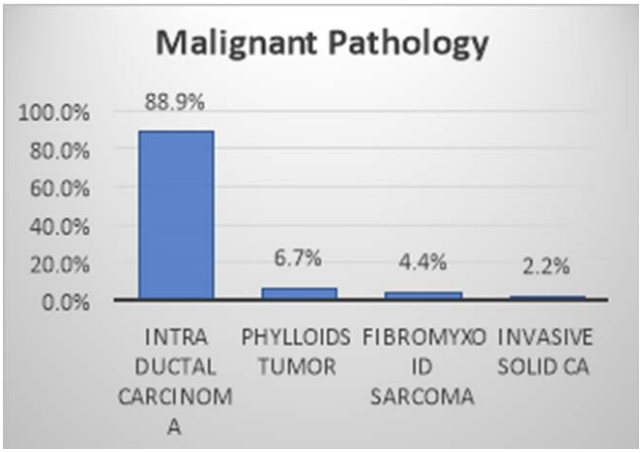

Chart 3. Distribution of the study cases as per types of benign and malignant pathologies

Sensitivity and specificity of TRUCUT biopsy was 93.5% and 98% while PPV and NPV was 95.6% and 97%. Overall diagnostic accuracy was 96.6% (Table 4).

6. Discussion

Breast is an apocrine gland – a modified sweat gland derived from ectoderm, acts as secondary sexual organ in females. It is rudimentary in males. It acts as mammary glands in females which produce and secrete milk to nourish the infants[1]. Development, functioning and involution of the breast are influenced by a variety of hormones like, oestrogen, progesterone, prolactin, oxytocin, thyroid profile, cortisol, and growth hormone and function.

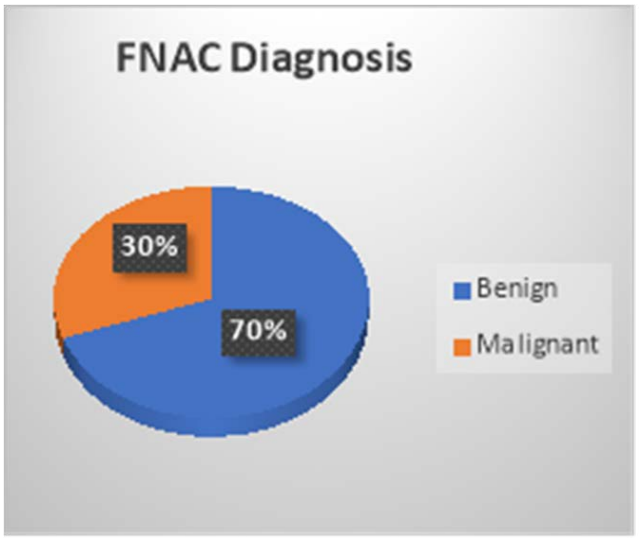

Chart 4. Distribution of breast lumps as per FNAC diagnosis

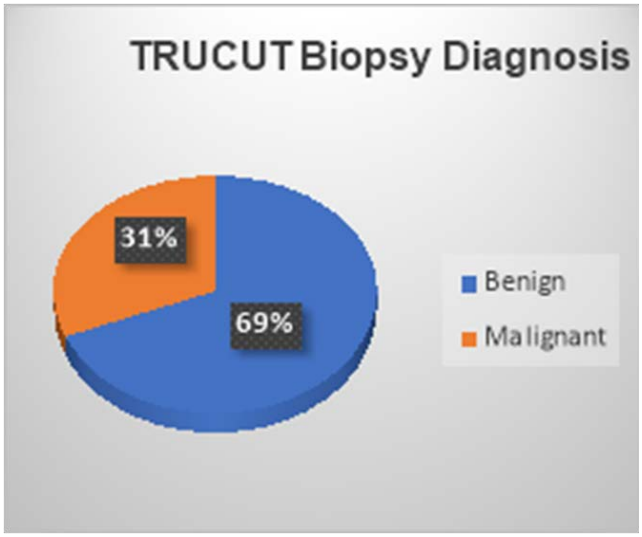

Chart 5. Distribution of breast lumps as per TRUCUT biopsy

Table 3. Diagnostic validity of fine needle aspiration cytology with histopathology

FNAC	Histopathology		Total
	Benign	Malignant	
Benign	**95**	**6**	**101**
Malignant	**4**	**40**	**44**
Total	99	46	145

Parameters	%
Sensitivity	87.0%
Specificity	96.0%
PPV	90.9%
NPV	94.1%
Accuracy	93.1%

Table 4. Diagnostic validity of TRUCUT biopsy with histopathology

TRUCUT biopsy	Histopathology		Total
	Benign	Malignant	
Benign	97	3	100
Malignant	2	43	45
Total	**99**	**46**	**145**

Parameters	%
Sensitivity	93.5%
Specificity	98.0%
PPV	95.6%
NPV	97.0%
Accuracy	96.6%

Breast lump is one of the most common presenting complaints to surgery departments. Most of these patients, however, are in a state of heightened anxiety until they have undergone specialist assessment, the necessary investigations and eventual reassurance. Hence the diagnostic validity of an investigation for palpable breast lump should be quick, economical, precise and minimally invasive and able to distinguish between malignant and benign lumps in OPD. Hence, this study was conducted in order to evaluate and compare the findings of FNAC and TRUCUT biopsy taking histopathology as gold standard.

6.1 Demography

Breast cancer incidence rates increase sharply with age, becoming substantial before age 50 years. During the pre-menopausal years, in incidence the rate of increase is common around the world, approximately 8%-9% per year[5,6]. In breast cancer incidence, the rate of increase continues lifelong but substantially slows down after menopause, to approximately 2%-3% per year[7]. Reproductive hormones are responsible for this correlation of incidence and the menopausal status.

Mean age of the study cases in present study was 46.32 years with 65.5% cases were below 50 years of age and 34.5% above 50 years of age. Most of the cases belonged to 21-40 years of age group (33.1%). Following is the comparison with other studies. Table 5 shows the comparison of mean age of breast lump patient from various studies.

Table 5.

Study	Homesh *et al.*[8]	Purthi *et al.*[9]	Hass *et al.*[10]	Present study
Mean age	33.36	46.12	48.9	46.32

6.2. Marital Status

In present study, out of total 145 cases, 87.6% were married while 12.4% were unmarried. They concluded that being married at the time of diagnosis of breast cancer improves survival regardless of patient and tumour characteristics. Compared to other studies as given below (Table 6).

Table 6.

Study	Dawood SS *et al.*[11]	Hass *et al.*[10]	Present study
Married patients	56.8%	56%	87.6%

6.3 Socio-Economic Status (SES)

High socioeconomic status (SES) is defined by high income and/or high education level. This has been linked to an increased breast cancer risk. Increased risk is not only due to the higher SES itself, but rather due to differences in risk factors exposure in those women.

For example, compared to women of lower SES, women of higher SES are more likely to: drink alcohol, have fewer children, have their first child at a later age, not able to breast feed, use post-menopausal hormone therapy (postmenopausal hormones). Each of these factors increases breast cancer risk[12-19]. In present study, a total of 66.9% cases were from lower socio-economic class while 33.1% were from middle socio-economic class. In a study by Haas *et al.*[10], 78.5% cases of breast lump were from low to middle socio-economic strata (Table 7).

6.4 Evaluation of Breast Lump

A complete Clinical Breast Examination (CBE) includes an assessment of breasts and the chest, axillae, and regional lymphatics. In pre-menopausal women, the CBE is best

Table 7.

Study	Kanchan *et al.*[22]	Kiran *et al.*[23]	Hirachand *et al.*[24]	Vijaybharti *et al.*[25]	Adesunkanmi AR *et al.*[26]	Mansoor *et al.*[27]	Present study
M/C lump	Fibro-adenoma	Fibro-adenoma	Fibro-adenoma	Fibro-adenoma	Fibro-adenoma	Fibro-adenoma	Fibro-adenoma

done when breast tissue is least engorged, that is a week after the menses. Patient is examined in sitting, hands above the head, bending forward position, thus inspecting the breasts for any asymmetry, nipple discharge, obvious lumps and skin changes, such as dimpling, inflammation, and nipple retraction or inversion.

Benign tumours are usually smooth, soft to firm, and mobile, with well-defined margins. Diffuse, symmetric thickening, which is common in the upper outer quadrants, is indicative of fibro-cystic changes. Malignant tumours usually are hard, immobile, and fixed to surrounding skin and soft tissue, with poorly defined or irregular margins[20]. However, mobile or immobile lumps still can be carcinomatous. Infective lesions such as mastitis, cellulites are tender, with local temperature rise and they may be more circumscribed if an abscess has formed. Patients with inflammatory breast cancer may present with similar symptomatology thus care should be taken.

In present study, most of the lumps had a soft consistency (47.6%) while 26.9% and 20% cases had firm and hard consistency respectively. A total of 53% cases involved right side of the breast while 47% involved left side. Most of the lumps are in left (25.5%) or right (15.9%) upper outer quadrant followed by right (24.1%) and left (11%) lower outer quadrant.

6.5. Type of Breast Lesion

In present study, out of the total 145 cases, 99 (68.3%) were benign pathologies while 46 (31.7%) were malignant pathologies. Common benign pathology was fibroadenoma (61.6%) followed by acute mastitis (12.1%) while the commonest malignant pathology was intra-ductal carcinoma (40 out of 46 cases; 88.9%) followed by phyllodes tumour (n-3; 6.7%) (Table 8).

6.6 TRUCUT Biopsy *vs* Histopathology

In present study, Sensitivity and specificity of TRUCUT biopsy was 93.5% and 98% while PPV and NPV was 95.6% and 97%. Overall diagnostic accuracy was 96.6%.

Table 8.

Study	Martin EC *et al.*[21]	Kanchan *et al.*[22]	Present study
Benign lumps	51%	83.15%	68.3%
Malignant lumps	45%	16.85%	31.7%

Youk *et al.*[28] in their study showed TRUCUT biopsy is an accurate and reliable method to diagnose breast lumps, with sensitivity (96%) and compare well with those determined by surgical excision. In a literature review that compared 49 studies, Jackman and Marzoni[29] found surgical biopsy to have a mean cancer miss rate of only 2.0% (range, 0-7.9%). For stereotactic 14-gauge TRUCUT biopsy, the sensitivity for a breast mass was 95.6% in the Radiologic Diagnostic Oncology Group V (RDOGV) trial[30], and the acceptable rate for breast lesions was 95% in a meta-analysis by Verkooijen *et al.*[31]. Martins EC *et al.*[32] in their study observed the accuracy rate of TRUCUT biopsy as 95%. Smith DL *et al.*[33] observed concordance in 100% malignant cases. Crystal *et al.*[34] observed the sensitivity of RUCUT biopsy for the diagnosis of breast cancer as 96.3%.

6.7 FNAC *vs* Histopathology

In present study, FNAC was able to diagnose most of the cases correctly. FNAC had a sensitivity and specificity of 87% and 96% respectively, while PPV and NPV was 90.9% and 94.1%. Overall diagnostic accuracy was 93.1%.

The sensitivity and specificity of FNAC observed in present study as compared to various other studies in literature are in (table 9).

Table 9.

Author	Sensitivity	Specificity
Langmuir *et al.*[35]	90%	94%
Park *et al.*[36]	77%	92%
Naggada *et al.*[37]	95.70%	98.70%
Aziz *et al.*[38]	85.30%	100%
Feicher *et al.*[39]	89.90%	99.30%

Mehmood *et al.*[40]	94.10%	96%
Callaco *et al.*[41]	92.10%	98.60%
Kamphausen *et al.*[42]	90%	100%
Kanchan *et al.*[22]	87.55	100%
Vijaybharti *et al.*[25]	97.18%	98.74%
Zhang Q *et al.*[43]	97.10%	97.30%
Present Study	87.0%	96.0%

Recently, the FNAC has become an increasingly popular technique utilized in the diagnosing of palpable breast lumps owing to it distinct advantages of being sensitive, specific, expedient, economical, and safe.

It greatly compliments the clinical and radiological examination and permits rapid diagnosis in more than 95% of the cases. Thus, it is commonly used as a part of the triple assessment in a case of breast lump. In cases where FNAC results are not definitive or where the cell type and quantification are needed, Core biopsy or open biopsy are still indicated.

7. Conclusion

We thus conclude that FNAC and TRUCUT biopsy both are accurate methods in diagnosing breast lumps. The methods are complementary and depend on the skill and experience of the individuals performing the sampling and interpretation. In a setting with limited resources and triple assessment, a judicious use of FNAC is preferable over TRUCUT biopsy, especially in screening programs with palpable lumps. The surgeons should also know the pros and cons of both procedures and choose wisely. We strongly oppose the general tendency of performing TRUCUT biopsy in all cases without a clinico-radiological consideration.

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