# Fine Needle Aspiration Cytology And Trucut Biopsy in Patients With Clinically Palpable Suspicious Malignant Breast Lump

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#### Abstract

**Background and Objectives:** Comparison of the diagnostic accuracy between Fine Needle Aspiration Cytology and Trucut Biopsy in patients with clinically palpable suspicious malignant breast lump with final post surgical (Excision biopsy or Mastectomy specimen) histo pathological examination and Comparison of Estrogen Receptor/Progesterone Receptor (**ER/PR**) status and human epidermal growth factor receptor 2 (**HER-2**)/neu status and ki67 index in selected subset of patients.

Methods: All patients attending the surgical Out Patient Department with palpable breast lump (clinically suspicious of malignancy) coming under the eligibility criteria mentioned below will be subjected for FNAC and trucut biopsy after obtaining informed consents and samples will be sent for Histo pathological examination and depends on the results further treatment will be planned (excision biopsy or mastectomy) and then the final specimen will be sent for histo pathological examination.

Result: The sensitivity of FNAC is 75%, specificity 100%, while sensitivity of tru-cut biopsy is 88%, and specificity 100% in our study.

**Conclusions:** The findings of this study showed that tru-cut biopsy is superior to FNAC in confirming breast cancer in suspicious lumps, and it is able to give definite histology of the lesion, with low cost and low complication rate as only 2% developed minimal bruising.

**Keywords:** Breast lump; breast cancer; FNAC; Trucut biopsy; IHC; ER/PR Status; her2neu; ki67.

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# I. Introduction

Breast cancer is the most common cancer in women worldwide and it is the leading cause of cancer death for women between age 20 to 59 years. It is responsible for 26% of new cancer diagnosis in females and cancer breast is responsible for fifteen percentage of the cancer related deaths in women. Breast cancer causes 5,19,000 deaths per year worldwide, and about 9,00,000 women are newly diagnosed as cancer breast every year. Breast cancer incidence is 0.26/1,00,000 in males and 20.01/1,00,000 in females. The mortality associated with cancer breast is 1.20/1,00,000 in males and 4.32/1,00,000 in females. Mortality rates due to cancer breast have increased during the past sixty years in all countries. The incidence of the cancer breast in India is on the rising trend and it is becoming the number one cancer in females making the cervical cancer to the second place. It is reported that one in twenty two women in India is likely to develop cancer breast during their lifetime. The rise of cancer breast incidence is being documented mainly in the developed cities but many cancer breast cases in rural India go unnoticed. Lack of knowledge and ignorance is mainly responsible for patients of cancer breast present in a later stage of the clinical spectrum of disease with skin involvement and fixed axillary nodes. Cancer Breast is a disease of the old age in females with the peak incidence of appearance in the 5<sup>th</sup> and 6<sup>th</sup> decades, but in India the disease appears a decade earlier in females, mostly because of shorter life expectancy for Indian women (about 65.3 years in 2005) as compared to the USA.

The management of Cancer breast needs a complex multi disciplinary team approach which include the operating surgeons, radiologists, radiotherapists, medical and surgical oncologists, pathologists, psychologists, plastic surgeons and physiotherapists. The most common clinical presentation of breast disease is palpable lump in breast; although few breast diseases can present as inflammatory lesion, nipple secretion or incidental imaging abnormalities. Even though most breast lumps are benign<sup>3</sup>, many of these patients are in anxiety of malignancy, until they had specialist assessment, and the necessary imaging or other investigations and eventual reassurance.

Clinical examination alone is difficult sometimes to determine whether a suspicious breast lump is benign or malignant. Therefore for diagnosing a breast lump, a method of definitive diagnosis is needed, who present with breast lumps at the outpatient clinic which must be accurate, easy to do in outpatient basis and reproducible. It must also be acceptable to the patient such as less pain, and can be carried out in a busy clinic

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setting without much preparation or expensive instruments and machines.

The work done by the Torsten Lowhagen and his colleagues at Karolinska institute in Stockholm in the sixtys and seventys helped to popularize a new minimallyinvasive technique for diagnosing breast lump, known as Fine-Needle Aspiration Cytology (FNAC).FNAC is now used frequently to diagnose any lump in the breast, which is clinically suspicious for malignant lump. It is beneficial in confirming the clinical impression of benign disease, which may not be subjected for subsequent biopsy. It allows more rapid diagnosis of a suspicious malignant condition in clinically non- suspicious breast masses.

The main benefit of fine needle aspiration cytology, rests in its diagnostic efficacy of malignant disease, when other available diagnostic modalities are inconclusive. Though many pathologists and surgeons have pointed to the possibility of false negative reports in diagnosis of malignant lesions, with improved diagnostic techniques and expertise available at present, a FNAC reported by an expert cytopathologist as unequivocally malignant is now considered by most surgeons a sufficient evidence to proceed to undergo a definitive surgery. But trucut biopsy is superior in sensitivity and specificity as well as accurate in diagnosing the correct type and grading of tumor as well as ER PR status and Her-2 neu and ki-67 status is breast malignancies This study was conducted to Compare the accuracy in diagnosis between Fine Needle Aspiration Cytology (FNAC) and Tru-cut or core-needle Biopsy in patients with clinically palpable suspicious malignant breast lump with final post surgical (Excision biopsy or Mastectomy specimen) histo pathological examination.

# II. Research Proposal

### Aim of the study

Comparison of the accuracy in diagnosis between Fine Needle Aspiration Cytology (FNAC) and Tru-cut or core needle Biopsy in patients with clinically palpable suspicious malignant breast lump with final post surgical (Excision biopsy or Mastectomy specimen) histo pathological examination .

## **Primary Objectives:**

- 1. To find out the correlation, including sensitivity, specificity, positive and negative predictive values, regarding the accuracy in diagnosis of FNAC and Trucut or core needle Biopsy as compared to the final histopathology examination of resected specimen.
- 2.To compare the reports of FNAC with the final biopsy report of the excised specimen in all patients
- 3.To compare the Trucut or core needle Biopsy report with the final biopsy report of the excised specimen in all patients
- 4. Specimen Yield of FNAC vs Trucut Biopsy in the diagnosis breast lump

#### **Secondary Objectives:**

- 1. Comparison of the sub types report in FNAC vs trucut biopsy report
- 2. Comparison of the sub types of carcinoma breast in FNAC and trucut biopsy vs final histopathology examination.
- 3. Comparison of hormonal receptors status such as Estrogen Receptor and Progesterone Receptor (**ER/PR**) and human epidermal growth factor receptor 2 (**HER-2**)/neu status of the trucut or core needle biopsy specimen with the final biopsy report in selected cases.
- 4. Comparison of Tumor grading in FNAC, Trucut biopsy and final histopathology specimen vs index of proliferation **Ki-67** in selected cases.

#### Eligibility criteria

## a. Inclusion criteria:

- 1.Patients belongs to Age between 16 and 70 yrs in both sexes
- 2.Clinically palpable suspicious malignant ( Hard lump, regional lymphadenopathy, restricted mobility, fixity to chest wall and skin, nipple retraction, bloody nipple discharge, fungating mass) breast lump of variable duration 3.Patients consented for inclusion in the study according to designated proforma

### **B.Exclusion criteria:**

- 1. Previous FNAC proven patients
- 2.Patients with recurrent lump
- 3.Past or current chemotherapy or any other previous treatment
- 4. clinically benign breast lumps
- 5.ECOG (Eastern Cooperative Oncology Group) performance status 4
- 6.Patients with CNS metastasis
- 7. Patient not consented for inclusion in the study.

#### Materials used:

#### FNAC:

- 1. Patient clinical history and follow up forms
- 2. Informed consent forms in English and tamil language
- 3. Needles: Fine-gauge number 23 single-use disposable needles
- 4. Syringes: Regular 10 cc single-use disposable plastic syringes
- 5. Spirit cotton
- 6. Slides: Two to three dry clean slides for preparing the smears.
- 7. Glass pencil and paper labels
- 8. Fixatives: 95% alcohol.
- 9. Stains: eosin and heamotoxyline stain.
- 10. Pathology lab requisition forms

# **Trucut Biopsy**

- 1. Patient clinical history and follow up forms
- 2. Informed consent forms in English and tamil language
- 3. Trucut biopsy needle gauge number 14 sterilisable
- 4. Spirit cotton
- 5. Betadine solution
- 6. 11 blades and no 3 BP handle
- 7. Sterile gauze pieces
- 8. 2% lignocaine
- 9. 5 ml disposable syringes
- 10. Specimen box
- 11. Glass pencil and paper labels
- 12. 10% formalin
- 13. Stains eosin and heamotoxyline stain
- 14. Pathology lab requisition forms

## III. Methodology

All patients attending the surgical OPD with palpable breast lump(clinically suspicious of malignancy) coming under the eligibility criteria mentioned above will be subjected for FNAC and trucut biopsy after obtaining informed consents and samples will be sent for Histo pathological examination and depends on the results further treatment will be planned (excision biopsy or mastectomy) and then the final specimen will be sent for histo pathological examination.

# **FNAC** Technique

- Obtaining informed written consent from the patients after explaining the FNAC procedure in detail.
- The procedure should always be done, accompanied by a female staff nurse or female attendant.
- The procedure can be performed in OPD or surgery wards without any anaesthesia
- Clean the skin over the breast lump area with spirit cotton.
- Hold the lump breast by hand and stabilize the lump.
- With the plunger of the 10ml syringe is retracted, make many passes into the breast lump till sufficient aspirated material is seen in the hub of the needle.
- Aspirate some air in the syringe after removing the needle then reattach the needle.
- Spray the aspirated material in the needle hub on the glass and make a smear.
- Fix the smear by using 95% alcohol or cytofix.
- Send the slides to pathology lab and stain with hematoxylin and eosin stain.



FIG 1- Taking FNAC from breast lump using 10 ml Syringe wih 23 G needle



FIG 1- Taking FNAC from breast lump using 10 ml Syringe wih 23 G needle

FNAC slides will be examined under light microscope by pathologist after Papanicolaou staining and separated into **Six groups:** 

# Aspiration cytology (AC)

- AC 0 no epithelial cells
- AC 1 inadequate
- AC 2- benign
- AC 3- Atypical cells. Probability of malignancy
- AC4- Suspicious for malignancy
- AC 5- Malignant.

# **Trucut biopsy:**

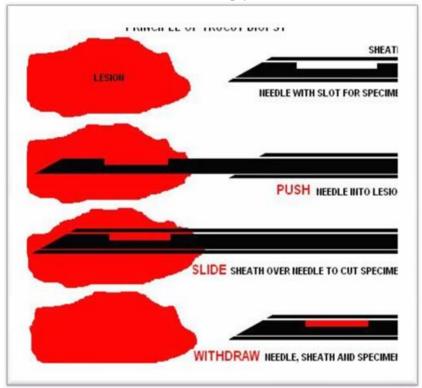


Fig 3- Line Diagram Showing Trucut Biopsy Technique



FIG 4-Infiltrating 2% Lignocaine before taking TRUCUT BIOPSY

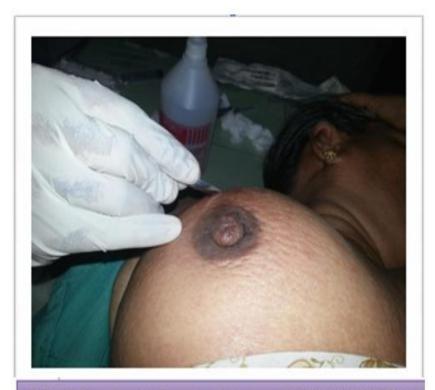


FIG 5- Making a Small Incision using 11 blade over the TRUCUT BIOPSY site

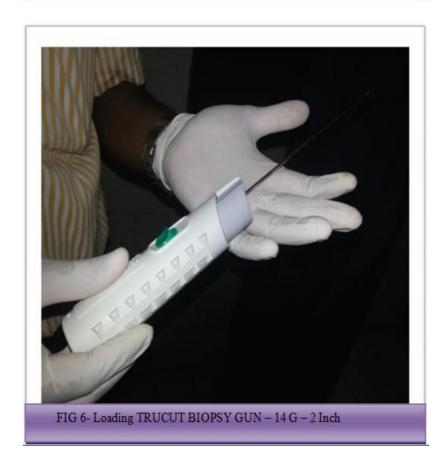




FIG 7- Firing TRUCUT BIOPSY GUN - 14 G - 2 Inch



FIG 8- Retrieving specimen from TRUCUT BIOPSY GUN into formalin bottle

#### Technique

- Obtaining informed written consent from the patients after explaining the Trucut procedure in detail.
- The procedure should always be done, accompanied by a female staff nurse or female attendant
- Local anesthesia –infiltrate 2% lignocaine 10 ml under the skin upto the lump
- Paint the area with betadine solution and clean with spirit
- Make a small stab incision in the skin over the lump
- push the trucut needle 14 gauze into the lesion
- slide the sheath over the needle to cut specimen
- withdraw needle, sheath and specimen
- place the specimen in 10% formalin containing specimen box
- send specimen to pathology lab for histo pathological examination
- After processing, sectioning and staining with eosin and hematoxylin staining, the slides will be graded according to Nottingham modification of Bloom Richardson scoring system by observing tubule formation, nuclear pleomorphism and mitotic counts

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- o Grade I → Well differentiated
- o Grade II → Moderately differentiated
- o Grade III → Poorly differentiated

Histologic grading using Nottingham Modification of scarf Bloom Richardson system

The scores are added and the grading is done as follows:

Grades

Grade I

Grade II

Grade III

89

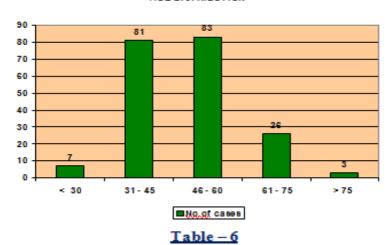
IV. Observation And Results

Table - 5

# Distribution of patients according to Age

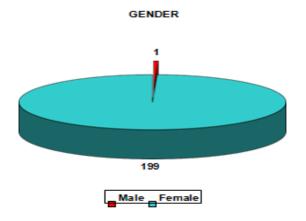
| Age Distribution<br>years | No.of cases | Percentage | Şen & Das Gupta<br><sup>80</sup> series |
|---------------------------|-------------|------------|---|
| < 30                      | 7           | 3.5        | 3.33 %                                  |
| 31 - 45                   | 81          | 40.5       | 30 %                                    |
| 46 - 60                   | 83          | 41.5       | 48.9 %                                  |
| 61 - 75                   | 26          | 13         | 14.5 %                                  |
| >75                       | 3           | 1.5        | 3.27 %                                  |
| Total                     | 200         | 100        | 100                                     |

#### AGE DISTRIBUTION



# Distribution of patients according to Gender

| Gender | No.of<br>cases | Percentage | Donegan<br>WL <sup>91</sup> et al |
|--------|----------------|------------|-----------------------------------|
| Male   | 1              | 0.5        | 1                                 |
| Female | 199            | 99.5       | 99                                |
| Total  | 200            | 100%       | 100%                              |



<u>Table - 7</u>

Distribution of patients according to the affected side of breast

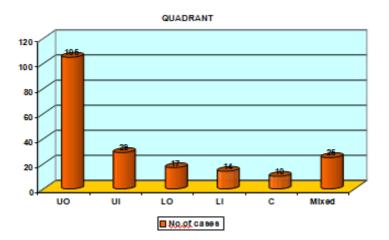
| Side      | No.of<br>cases | Percentage |
|-----------|----------------|------------|
| Right     | 108            | 54         |
| Left      | 91             | 45.5       |
| Bilateral | 1              | 0.5        |
| Total     | 200            | 100%       |



<u>Table - 8</u>

Distribution of patients according to Quadrant of Breast

| Quadrant         | No.of<br>cases | Percentage | Sen & Das<br>Gupta <sup>80</sup> series |
|------------------|----------------|------------|---|
| UPPER OUTER (UO) | 105            | 52.5       | 49                                      |
| UPPER INNER (UI) | 29             | 14.5       | 13                                      |
| LOWER OUTER (LO) | 17             | 8.5        | 11                                      |
| LOWER INNER (LI) | 14             | 7          | 7                                       |
| CENTRAL (C)      | 10             | 5          | 9                                       |
| Mixed            | 25             | 12.5       |   |
| TOTAL            | 200            | 100        | 100                                     |



<u>Table – 9</u>

<u>Distribution of patients according to size of lesion</u>

| Size (cms)     | No.of<br>cases | Percentage |
|----------------|----------------|------------|
| T2 (3 to 5 cm) | 76             | 38         |
| T3 (>5 cm)     | 124            | 62         |
| Total          | 200            | 100        |



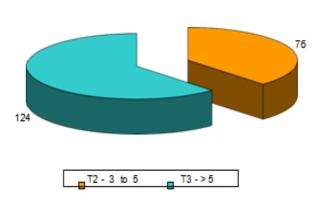


Table – 6

Patients presented with skin changes

(including Peau d' orange, skin nodules & ulceration)

| Skin changes | No.of cases | Percentage |
|--------------|-------------|------------|
| Present      | 35          | 17.5       |
| Absent       | 165         | 82.5       |
| Total        | 200         | 100        |

# SKIN CHANGES

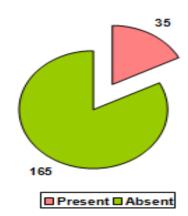
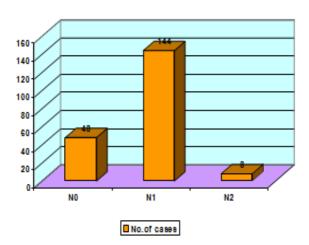


Table - 11

Distribution of patients according to Axillary lymph node status

# (clinical examination alone)

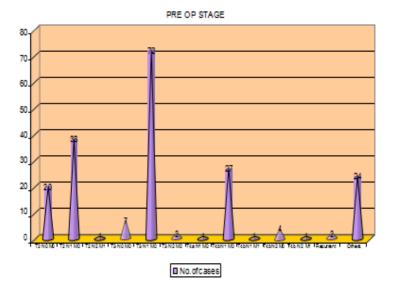
| Axillary<br>Lymph nodes | No.of<br>cases | Percentage |
|-------------------------|----------------|------------|
| N0                      | 48             | 24         |
| N1                      | 144            | 72         |
| N2                      | 8              | 4          |
| Total                   | 200            | 100        |



<u>Table - 12</u>

<u>Distribution of patients according Pre operative staging</u>

| Pre op stage |      | No.of cases | Percentage |
|--------------|------|-------------|------------|
| T2 N0 M0     | ΠA   | 20          | 12         |
| T2 N1 M0     | пв   | 38          | 23         |
| T2 N2 M1     | IV   | 1           | I          |
| T3 N0 M0     | пв   | 7           | 4          |
| T3 N1 M0     |      |             |            |
| T3 N2 M0     | ША   | 2           | I          |
| T4a N1 M0    | IIIB | 1           | 1          |
| T46 N1 M0    |      |             |            |
| T4b N1 M1    | IV   | 1           | 1          |
| T46 N2 M0    | IIIB | 4           | 2          |
| T4b N2 M1    | IV   | 1           | 1          |
| Recurrent    |      | 2           | I          |
| Others       |      | 24          | 12         |

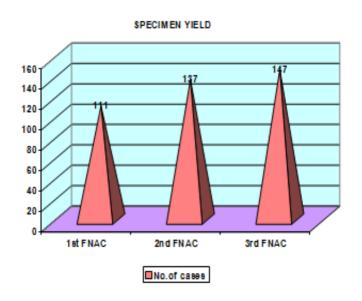


<u>Table – 13</u>

<u>Specimen yield of Fine Needle aspiration cytology</u>

| + | Specimen Yield | Total no of<br>cases | No of cases<br>showed<br>positive<br>result | Cumulative<br>No.of cases<br>Positive<br>result | Percentage |
|---|----------------|----------------------|---|---|------------|
|   | 1st FNAC       | 200                  | 111   | 111   | 55.5       |
|   | 2nd FNAC       | 89                   | 26  | 137   | 68.5       |
|   | 3rd FNAC       | 64                   | 10  | 147   | 73.5       |

FNAC samples are taken for all cases in the study (n=200). Those cases in which FNAC specimen report came as inadequate are subjected into second FNAC Sample (n=89) and third FNAC is taken for those cases reported as inadequate in  $2^{nd}$  FNAC (n=64).



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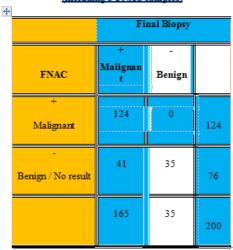
Table - 14
Specimen yield of Trucut or core needle Biopsy

| Trucut     | Total no of<br>cases | No of cases<br>showed<br>positive<br>result | Cumulative<br>No.of cases<br>Positive<br>result | Percentage |
|------------|----------------------|---|---|------------|
| 1st Trucut | 200                  | 150   | 150   | 75         |
| 2nd Trucut | 50                   | 11  | 161   | 80.5       |

Core needle biopsy samples are taken for all cases in the study (n=200). Those cases in which biopsy specimen report came as inadequate are subjected into second core needle biopsy Sample (n=50)

Table - 15

Sensitivity & Specificity of FNAC in detecting malignant Breast lesions
(including 3 FNAC samples)



| Sensitivity               | = | 124/165 x 100   | = | 75%    |
|---------------------------|---|-----------------|---|--------|
| Specificity               | = | 35 / 35 x 100   | = | 100%   |
| Positive Predictive Value | = | 124 / 124 x 100 | = | 100%   |
| Negative Predictive Value | = | 35 / 76 x 100   | = | 46.1 % |

Table - 16

Sensitivity & Specificity of Trucut Biopsy in detecting malignant Breast lesions (including 2 trucut specimens)

|                               | Final Biopsy   |             |     |  |
|-------------------------------|----------------|-------------|-----|--|
| Trucut /Core<br>needle Biopsy | +<br>Malignant | -<br>Benign |     |  |
| +<br>Malignant                | 145            | 0           | 145 |  |
| -<br>Benign / No result       | 20             | 35          | 55  |  |
|                               | 165            | 35          | 200 |  |

| Sensitivity               | = | 145/165 x 100   | = | 88%    |
|---------------------------|---|-----------------|---|--------|
| Specificity               | = | 35 / 35 x 100   | = | 100%   |
| Positive Predictive Value | = | 145 / 145 x 100 | = | 100%   |
| Negative Predictive Value | = | 35 / 55 x 100   | = | 63.6 % |

Table – 17

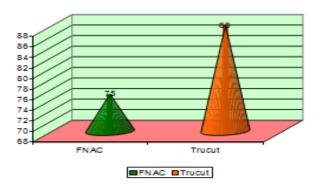
Comparison of sensitivity of FNAC & Trucut Biopsy in detecting

# malignant Breast lesion

|        | Sensitivity | Watson et al <sup>92</sup> | Gukas et al 95 |
|--------|-------------|----------------------------|----------------|
| FNAC   | 75 %        | 74%                        |                |
| Trucut | 88 %        |                            | 88.9%          |

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#### COMPARISON OF FNAC AND TRUCUT BIOPSY



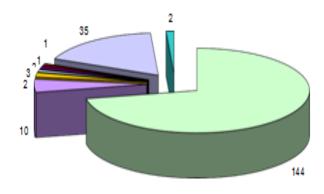
P value – 0.385 not significant

Table - 18

# Analysis of Histo pathological reports of Final specimen

| 4 |  |       |            |                  |
|---|--|-------|------------|------------------|
|   | Final Biopsy after Lumpectomy or           | No.of | Percentage | Page et          |
|   | Modified Radical Mastectomy                | cases |            | al <sup>93</sup> |
|   | Infiltrating <u>Ductal</u> Carcinoma (IDC) | 144   | 72         | 70%              |
|   | Infiltrating Lobular Carcinoma (ILC)       | 10    | 5          | 10%              |
|   | Medullary Carcinoma (MC)                   | 3     | 1.5        | 2%               |
|   | Papillary carcinoma (PC)                   | 2     | 1          | 2%               |
|   | Apocrine Carcinoma (APO)                   | 1     | 0.5        | 1%               |
|   | Benign                                     | 35    | 17.5       |                  |
|   | Defaulter                                  | 2     | 1          |                  |
|   | Total                                      | 200   | 100        |                  |
|   |  |       |            |                  |





| DIDC | DILC      | □ MC            |
|------|-----------|-----------------|
| □PC  | Defaulter | ■ APO           |
| ■NRD | □Benign   | Pallative CT/RT |

<u>Table - 19</u>

<u>Distribution of patients according to Grade of tumor in final biopsy</u>

| Grade | No.of cases | Percentage |  |  |
|-------|-------------|------------|--|--|
| I     | 16          | 8          |  |  |
| ΙĴ    | 105         | 52.5       |  |  |
| ıÏî   | 41          | 20.5       |  |  |

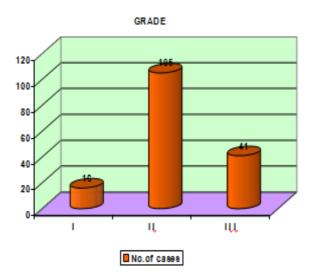


Table - 20

Distribution of Hormone Receptor cases (among 82 cases)

|           | No.of cases |    |  |  |
|-----------|-------------|----|--|--|
|           |             |    |  |  |
| ER +      | 56          | 68 |  |  |
| PR +      | 56          | 68 |  |  |
| Her 2 Neu | 43          | 52 |  |  |

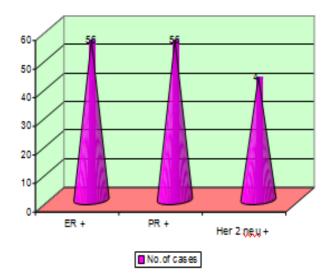
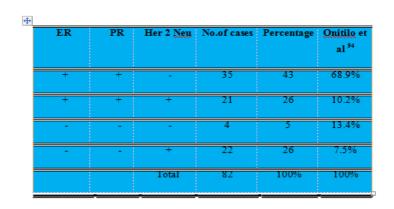
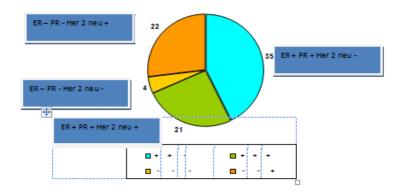


Table -21

Distribution of Hormone Receptor cases (among 82 cases)





# V. Discussion

The study was conducted in the Department of General surgery, Govt Rajaji Hospital Madurai. 200 patients presented to surgery out patient department who are coming under the inclusion criteria were included in the study. After getting consent and complete clinical examination patients were subjected to first Fine needle aspiration cytology and Core needle biopsy from the lump. If the sample result came as inconclusive or inadequate, those patients alone subjected to second and third samples of FNAC and second sample of Core needle biopsy. If all the results became inconclusive or specimen reported as benign lesion patients were subjected to excision biopsy of the breast lump for final diagnosis. Patients who diagnosed as malignant in any

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of the samples were treated according to the stage of the disease.

## Distribution of patients according to Age (Table 5)

The incidence of breast cancer is seen to increase with the age of the patient, it is primarily a disease of old age with peak incidence is 5<sup>th</sup> and 6<sup>th</sup> decades of life. But in INDIA cancer breast is seen a decade earlier comparing to other parts of the world, most probable reason is shorter longevity of life in Indian females ( around 65.3 years as per data in 2005). In our study the peak incidence of cancer breast is **41.5** % **between 46 to 60 years** and 40.5 % between 31-45 years. The sen and das gupta study<sup>80</sup> showed incidence similar to our study around 48%.

# Distribution of patients according to Gender (Table 6)

One among the 200 patients is male gender and found to have malignant disease and proceeded with modified radical mastectomy. Gender distribution ratio in our study is **1:200** whereas according to **Donegan WL**<sup>91</sup> **et al** it is 1:100

## Distribution of patients according to the affected side of breast (Table 7)

54 % of patients in our study showed right side breast lump.

# Distribution of patients according to Quadrant of Breast (Table 8)

In our study, **Upper outer quadrant is the most common site of lump breast in about 52.5% of cases** which is comparable to sen and das gupta study showed incidence similar to our study around 49%. Marashall et al so suggested that 60% of their cases had the tumor in the upper outer quadrant.

### Distribution of patients according to size of lesion (Table 9)

Most common size of lesion in our study is T3 Lesion that is size more than 5 cm without skin or chest wall fixity. **About 62 % of cases in our study belong to T3 stage**. Greater the size of the tumor, greater are the difficulties to treat. Most of our patients came from rural areas where negligence towards self and late presentation lead to a bigger size of lumps in the disease.

# Patients presented with skin changes (Table 10)

**17.5** % of cases presented with skin changes which include peau d orange appearance, skin nodules and ulceration. It comes under T4b locally advanced cancer breast.

# Distribution of patients according to Axillary lymph node status (Table 11)

Earlier studies had shown that 78% of patients present with palpable axillary lymph nodes. In our study about 76 % of patients presented with palpable axillary nodes. 4 % presented with multiple fixed nodes. Axillary lymph node status is an important prognostic factor in carcinoma breast as well as in deciding chemotherapy. Distribution of patients according Pre operative staging (Table 12)

Majority of the patients in our study belongs to STAGE III- 64%, and STAGE II in 39 % cases. Most of our patients came from rural areas where negligence towards self and late presentation lead to a later stages disease which adversely affect the prognosis and the overeall survival.

# Specimen yield of Fine Needle aspiration cytology (Table 13)

FNAC samples are taken for all cases in the study (n=200). Those cases in which FNAC specimen report came as inadequate are subjected into second FNAC Sample (n=89) and third FNAC is taken for those cases reported as inadequate in 2<sup>nd</sup> FNAC (n=64). Cumulative of all the 3 FNAC sample showed a **specimen yield of 55.5** % in 1<sup>st</sup> FNAC, 68.5% in 2<sup>nd</sup> FNAC and in 3<sup>rd</sup> FNAC 73.5% which include both benign and malignant breast lesions according to final biopsy.

# Specimen yield of Trucut or core needle Biopsy (Table 14)

Core needle biopsy samples are taken for all cases in the study (n=200). Those cases in which biopsy specimen report came as inadequate are subjected into second core needle biopsy Sample (n=50). Cumulative of all the 2 samples showed a **specimen yield of 75 % in 1**<sup>st</sup> **corecut, and 80.5% in 2**<sup>nd</sup> **corecut** which include both benign and malignant breast lesions according to final biopsy.

Sensitivity & Specificity of FNAC and core needle biopsy in detecting malignant

### Breast lesions (Table 15 to 17)

Sensitivity of the FNAC in our study is 75% which is comparable to Watson et al <sup>92</sup> which has a sensitivity of 74% in their study. Sensitivity of the core needle biopsy in our study is 88% which is comparable to Gukas et al <sup>95</sup> which has a sensitivity of 88.9% in their study

| Authors                  | Year (N)   | Sensitivity | Specificity | PPV   | NPV   | Diagnostic Accuracy |
|--------------------------|------------|-------------|-------------|-------|-------|---------------------|
| Husain and Rikabi        | 2011 (275) | 98.1%       | 100%        | 100%  | 98.9% | 99.3%               |
| Lacambra et al <u>12</u> | 2011 (464) | 96%         | 99%         | 99%   | 94%   |                     |
| Ahmed et al <u>13</u>    | 2010 (80)  | 94.64%      | 91.3%       |       |       | 94.87%              |
| Bdour et al <u>10</u>    | 2009 (175) | 97%         | 100%        |       | **    | 100                 |
| Brunner et al <u>14</u>  | 2009 (120) | 95%         | 100%        | 100%  | 90%   |                     |
| Kulkarni et al <u>15</u> | 2009 (819) | 97.7%       | 94.2%       | 93.1% | 98.1% | 95.5%               |
| Homesh et al <u>16</u>   | 2005 (296) | 92.3%       | 94.8%       | 100%  | 100%  | 93.4%               |
| Gukas et al <u>17</u>    | 2000 (112) | 88.9%       | 96.8%       |       | 20    | 93.5%               |

Various studies have been done already to determine the efficacy and usefulness of both FNAC and tru-cut or corecut biopsy. The results vary from one study to another study. FNAC has been found to have a sensitivity ranging from 84% to 97.5% and a specificity of more than 99% to 100% in various studies.

Tru-cut/core cut biopsy was reported to have a sensitivity around 90% and a specificity 100% in various studied published. However, various authors have different opinions on which method is better. Masood and Smith used open surgical biopsy to confirm cytologically negative and suspicious breast lump cases and directly operate only on those cases with positive cytologic diagnosis. On the contrary, Ciatto required histological confirmation for suspicious lesions and positive aspirations and did not treat either negative cases or eventual false negatives. The ideal approach for women with suspicious malignant breast lump is the triple assessment approach including the clinical, cytology, and imaging studies like mammography, but this assessment is not sufficient for decision of treatment, because FNAC reports still have high percentage of uncertainty, also lack many important information about the histopathological type of tumor, tumor grade, receptor status such as ER/PR/Her2neu, and intrinsic behavior of the tumor. All of these information are of great importance for the correct preoperative evaluation by both surgeon and oncologist for further treatment planning. P value calculated in this comparison is 0.385 which is not significant. Even though the P value calculated in this study showed no significant difference of core needle biopsy over FNAC, core needle biopsy has many added advantages as mentioned earlier.

# Analysis of Histo pathological reports of Final specimen (Table 18 to 19)

Infiltrating ductal carcinoma Grade II is the most common subtype in our study. 72% of patients belong to IDC and 52.2 % belong to grade II the results of our study in comparable to Page et al<sup>93</sup>

|                       | Ductal | Lobular | Medullary l | Mucinous | Tubular | Mixed | Others |
|-----------------------|--------|---------|-------------|----------|---------|-------|--------|
| Page et al. (60)      | 70%    | 10%     | 5%          | 2%       | 3%      | 2%    | 8%     |
| Rosen <sup>(61)</sup> | 75%    | 10%     | 9%          | 2%       | 2%      | -     | -      |
| Adedayo A             | 2.7%   | 12.1%   | -           | -        | -       | 7.1%  | 8.1%   |
| et <u>al</u> (22)     |        |         |             |          |         |       |        |

### Distribution of Hormone Receptor cases (among 82 cases) (table 20-21)

Secondary objective of our study is to find out the hormonal status of cancer breast patients. 82 patients were selected among the 200 cases and the results were as given in the tables 20 to 21. About 52% of

our study patients showed Her2 neu positivity. When comparing to many western studies like Onitio Et al94 which showing 17.7% Her2 Neu positivity, many studies conducted in India showing high Her2neu positivity. It would be fruitful to have IHC group profiling of breast cancers in our country as this would generate more statistics for future research.

#### VI. Conclusion

The sensitivity of FNAC is 75%, specificity 100%, while sensitivity of tru-cut biopsy is 88%, and specificity 100% in our study.

Many studies confirmed the usefulness of a systematic use of core needle biopsy for diagnosis of cancer breast, even when good quality clinical, radiological, and histological examinations together are undertaken for proper diagnosis. The tru-cut or core needle biopsy of palpable breast lesions based on histological study of the tissue specimens can provide all reliable information needed. Core biopsy permits a pre operative knowledge of the histological type of tumor and prognostic parameters (receptor status, proliferative activity, ploidy, and expression of oncogenes and antioncogenes such as c-erbB-2 and p53), so tru-cut or corecut biopsy will guide the operating surgeon and the oncologist for ideal modern therapeutic strategy in surgical decision making as a team approach. It also permits the eventual use of neoadjuvant therapy either hormonal or chemotherapy. The sensitivity, specificity, and diagnostic efficacy obtained in our study by tru-cut or core needle biopsy were comparable to those reported in the literature. The higher efficacy of tru-cut / core needle biopsy obtained in our study of palpable lesions, in addition to its simplicity and safety, might also offer a new management strategy in patients with non palpable suspicious breast lesions with the use of ultrasound or other image-guided core biopsy techniques With ultrasound-guided or mammography guided techniques, it can be considered a safe alternative both to lumpectomy and incisional biopsy, which should be avoided in non palpable lesions. USG guided biopsy for small palpable lesions and Mammogram guided biopsy for non palpable lesions help in improving the sensitivity of the core needle biopsy results.

The tru-cut/ core biopsy is well tolerated by patients, easy to perform, relatively inexpensive and suitable for use in outpatient clinics. Using the core needle biopsy specimen for detecting the hormone receptor status and Her2 Neu status would be useful in starting neoadjuvant therapy as well as for post operative adjuvant therapies. Hence all cases of cancer breast should be subjected for IHC study in the future for giving a better treatment for all breast cancer patients.

Preventive methods such as Screening mammography, self breast examination and clinical breast examination are useful in identifying the early breast lesions which should be made available mainly to the rural population in India where patients present at later stages of disease. Further studies are needed to compare the blind core needle biopsy with Mammogram or USG guided biopsy techniques which are essential in detection early breast cancer cases. Further studied are also required to find out the reason behind increasing number of Her 2 neu receptor positive cases in Indian population.

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