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A PROSPECTIVE LONGITUDINAL STUDY TO DETERMINE THE DIAGNOSTIC ACCURACY OF TRU-CUT BIOPSY IN THE DIAGNOSIS OF BREAST LUMPS

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ABSTRACT

Background: Breast cancer represent leading tumor among women, accounts for 25% of female cancer, a leading cause of cancer-related deaths among women. Breast cancer treatment can be highly effective if disease is being diagnosed early. Among diagnostic tools, trucut biopsy is less costly, but provide sufficient tissue to make accurate histological diagnosis. This study aims to determine diagnostic accuracy of trucut biopsy in pre-operative diagnosis of breast lumps, and to study clinical profile of patients with breast lumps. **Methods:** A prospective longitudinal study was conducted over two years (May 2022 to June 2024) in the Department of Surgery at the Regional Institute of Medical Sciences (RIMS), Imphal, Manipur. Study included 90 patients aged 13 years to 80 years with breast lumps who underwent surgery for this. **Results:** This study found mean age for breast lumps 45.5 yrs, with majority of cases in the 31-60 years age group. Majority of lumps were in upper outer quadrant (38.9%) followed by lower outer and upper inner quadrant. Malignancy was diagnosed among 64.4% patients, of these majority were invasive ductal carcinoma (86.7%), followed by phyllodes tumours (5%), invasive lobular carcinoma (3.3%), invasive papillary carcinoma (3.3%) and medullary carcinoma (1.7%). Within benign tumours, majority were fibroadenoma (76.7%), followed by fibroadenosis (10.0%), fibrocystic disease (10.0%) and adenomyoepithelioma (3.3%). **Conclusion:** 90 female patients with palpable breast lumps were studied and above findings noted. The results suggest diagnostic accuracy of trucut biopsy is comparable to histopathological excisional biopsy.

KEYWORDS

Trucut biopsy, Breast lump(s), Breast cancer.

INTRODUCTION

Comprising both epithelial and connective tissue components, the breast functions as a modified sweat gland situated between the superficial pectoral fascia and the subdermal layer of adipose tissue. Numerous benign and malignant disorders can develop in the breast. Breast lumps, local discomfort, changes in the breast's size, shape, or look, dimpling, redness of the skin overlaying the breast, changes in the appearance or areola of the nipple, nipple discharge, etc. are all signs of breast illnesses. Breast cancer may develop from the duct or lobule lining epithelium. At first, the malignant growth is contained inside the duct or lobule (in situ), where it usually doesn't produce any symptoms and has little chance of spreading (metastasising).[1]

Breast cancer continues to be the most common tumour in women, and its prevalence is increasing globally.[2,3] With an average age of 50 to 70 years and a higher frequency in industrialised nations, it makes for over 25% of female malignancies.[4,5] In 2020, 2.3 million women worldwide received a breast cancer diagnosis, and 685,000 of them died as a result. In women, it is also the most prevalent non-skin cancer and the second leading cause of cancer-related deaths, behind lung cancer.[6.] It is responsible for 13.5% of all female malignancies in India.[7].

In terms of morbidity and mortality, breast cancer therapy may be quite successful, particularly if the illness is detected early. An outstanding clinical eye, superior imaging, and the right pathological procedures are all necessary to guarantee an accurate diagnosis. To distinguish between benign and malignant breast lesions, diagnostic techniques like Tru-Cut Needle Biopsy (TCNB) and Fine-Needle Aspiration Cytology (FNAC) are frequently used. Ellis and Martin initially used FNAC for the cytologic assessment of solid lesions in New York in 1930.[8]. Fine needle aspiration cytology (FNAC) was the most widely used technique for the pathological diagnosis of breast masses for a number of years.[9–11]

However, in 2-36% of instances, FNAC is detrimental due to sample inadequacy, false negatives, and the inability to distinguish between invasive tumours and hyperplasia and intraepithelial or intralobular lesions. Furthermore, atypical ductal and lobular hyperplasia, hypocellular carcinoma, benign and malignant papillary lesions, fibroepithelial tumours, and mucinous malignancies cannot be accurately detected by FNAC.[12]

Many surgeons have shifted to the Tru-Cut biopsy (TCB) since its introduction in recent years because it provides enough tissue for pathologists to produce an accurate histological evaluation. Before

surgery, it is the initial method of choice for diagnosing breast lesions.[13]Tru-cut biopsy may be completed fast, with no scarring or deformity, and is far less expensive and intrusive.[14] It gives pathologists enough tissue to accurately diagnose a patient histologically.[15.] With a Tru-Cut biopsy, the volume of tissue taken and the impact on breast distortion on mammography are both minimal.[16,17] Notwithstanding its benefits, TCNB is more intrusive than FNAC, necessitating greater technical know-how and occasionally resulting in greater patient pain.

There are still a lot of unanswered questions about the efficacy of tru-cut biopsy in the literature, even with the improvements in diagnostic methods. Since many developing nations lack a national screening program and have low levels of breast cancer awareness, breast cancer assessment by FNAC or tru-cut biopsy has been regarded as the standard of care for more than ten years, but it is still not a common practice in many of these nations. Hence, it became imperative to conduct a comprehensive analysis of the diagnostic accuracy of tru-cut biopsy in terms of the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) among patients with breast lumps in a tertiary care centre, which could help to establish a more definitive understanding of the diagnostic accuracy of tru-cut biopsy. The objectives of the current study are To study the diagnostic accuracy of Tru-cut biopsy in pre-operative diagnosis of breast lumps and the clinical profile of patients presenting with breast lumps.

MATERIALS AND METHODS

Study Design:

A prospective longitudinal study was conducted among the patients with breast lumps attending the outpatient department or admitted to the Department of Surgery at the Regional Institute of Medical Sciences (RIMS), Imphal.

Study Duration And Population:

The study was conducted for a period of two years, from May 2022 to June2024.The study included all the patients with breast lumps attending the outpatient department or admitted to the Department of Surgery at the Regional Institute of Medical Sciences (RIMS), Imphal.

Inclusion Criteria

Patients (with)

1. aged >13 years and <80 years with breast lumps
2. breast lesion who underwent surgery: mastectomy/wide local excision or MRM or excisional biopsy.
3. giving consent for TRU-CUT biopsy and/ or FNAC pre-operatively and histopathological examination of the operative specimen

Exclusion Criteria

1. Male patients with breast lesions/ lumps
2. Patients with extensive metastasis and non-operative cases
3. Patients on anticoagulant therapy or having bleeding disorders

Sample Size And Estimation

The sample size was calculated using the formula for the sensitivity of a diagnostic test N= (Zα/2)2 SN(100-SN))/L2

Where
N = Sample size

$Z^{\alpha/2=}$ 1.645 at 90% Confidence Interval

SN = Sensitivity of Tru-cut Biopsy = 93.5% (Dalvi AV et al.)[49]

L = Absolute Allowable Error = 6% Hence, by substituting the values in the formula $N = (1.645)^2 (93.5) (100-93.5))/6^2 = 90$ patients with breast lump.All the eligible patients during the study period were recruited using convenience sampling until the sample size was reached.

Armamentarium:

- **Predesigned proforma** consisting of socio-demographic characteristics, clinical history, investigations, Tru-cut biopsy findings, and postoperative biopsy findings
- Tru-cut gun with an 18-gauge needle
- Lignocaine 2% solution with adrenalin
- Blade size 11
- Sterile container
- HPE result of tru-cut biopsy and operative biopsy

Data Collection:

The study was conducted after clearance from the institute's ethics committee. A predesigned proforma was used to collect the socio-demographic characteristics, clinical history, and laboratory investigations of eligible patients. Tru-cut biopsy was performed using a Tru-cut gun with an 18-gauge needle. After manual localisation and immobilisation of the lesion under a complete aseptic technique, a 2% lignocaine- infiltrating anaesthetic was administered, and a skin incision was performed. A biopsy specimen was obtained through four successive insertions with different angulations of the needle into the lesion core. After immediate immersion of the specimen in a fixative, its quantity and quality were judged and sent to the histopathology department. The HPE report of the TRUCUT biopsy specimens was then compared with the HPE report of follow-up procedures, including surgical procedures like mastectomy, excision biopsy, wide local excision, or MRM.

Statistical Analysis:

Data was entered and analysed in IBM SPSS statistics version 26.0 for Windows [Armonk, NY: IBM Corp]. Quantitative data are summarised as mean and standard deviation or median and interquartile range, depending on the type of distribution, and categorical variables are presented as frequency and percentages. The diagnostic accuracy of Tru-cut biopsy in pre-operative diagnosis of breast lumps is expressed as sensitivity, specificity, positive predictive value, and negative predictive value. An independent samples t-test was used to determine the association between continuous variables. Fisher's exact test was used to assess the association of a family history of breast cancer with malignant breast lesions. A p-value of less than 0.05 was considered statistically significant.

RESULTS:

A total of 90 patients with breast lumps attending the outpatient department or admitted to the Department of Surgery with breast lumps surgery were included in the study. The mean age of the study participants was 45.5 (14.5) years. The median age of the study participants was 45.5 (35.0-55.2) years, with a minimum of 19 years and a maximum of 75 years. **(Figure 1). Table 1** and **Figure 2** show that the majority (35.6%) of the study participants were 46- 60 years, followed by 31.1% between 31-45 years. **Table 6** and **Figure 7** show that the majority (38.9%) of patients presented with a lump in the upper outer quadrant followed by the lower outer (18.9%) and upper inner quadrant (15.6%). The mean age of menarche among the patients was 13.3 (1.4) years. The mean age of menarche was 13.0 (12.0-14.0) years, with a minimum of 11 years and a maximum of 16 years. **(Figure 8)** None of our study's patients were on OCPs.**Table 7** shows that clinically, malignancy was diagnosed among 64.4% (95% CI: 53.6%-74.1%) patients, of which 62.2% were diagnosed as carcinomas and the remaining 2.2% were diagnosed as phyllodes tumours. Of 35.6% of patients with benign diagnoses, 33.3% of patients were diagnosed with fibroadenoma, and the rest were diagnosed with fibroadenosis. Overall, histopathological examination diagnosed 60 (66.7% [95% CI:55.8%- 76.0%]) cases as malignant neoplasm. Of those with malignancy, 52 (86.7%) were invasive ductal carcinoma, 3 (5.0%) were phyllodes tumour, 2 (3.3%) were invasive lobular carcinoma, 2 (3.3%) were invasive papillary carcinoma and the remaining 1 (1.7%) was medullary carcinoma with fibrocystic change. The remaining 30 (33.3%) cases were diagnosed as benign tumours, of which 23 (76.7%) were fibroadenoma, 3 (10.0%) were fibroadenosis, 3 (10.0%) were fibrocystic disease, and the remaining 1 (3.3%) was diagnosed as adeno-myoepithelioma on HPE. **(Table 8). Table 10** shows the predictive accuracy of tru-cut biopsy in the diagnosis of malignant breast lesions when compared with histopathological diagnosis. It was found that the sensitivity, specificity, and positive and negative predictive values of the tru-cut biopsy were 96.7%, 100%, 100%, and 93.8%, respectively. The accuracy of tru-cut biopsy in the diagnosis of malignant breast lesions was 97.8%. **Table 11** and **Figure 10** show that modified radical mastectomy was performed in 63.4% of patients, followed by lumpectomy among 32.2% of patients. Of two patients with mastectomy, toilet mastectomy was performed for two patients because of fungating breast mass. **Table 12** shows that the mean age of the patients was significantly higher for patients with malignant breast mass compared to benign lesions (52.7 years vs 30.9 years; p<0.001).**Table 13** shows that the malignancy of breast tumours was significantly higher among the patients with a family history of breast cancer (p=0.043). **Table 14** shows no significant association between age at menarche and malignant breast mass among the study participants (p=0.288).

Plate I: Study Tools for Tru-cut Biopsy including (a) Tru-cut Biopsy gun with 18 gauge needle, (b) Surgical Blade No. 11, (c) Lignocaine 2% with Adrenaline, (d) Sterile Container, (e) Sterile marker, (f) Sterile Disposable Syringe 5cc and 10cc

Plate II: A case of Right Breast Lump diagnosed as Invasive Ductal Carcinoma both in Tru-cut Biopsy and HPE of the operative specimen (Modified Radical Mastectomy)

Plate III: A case of Locally Advanced Breast Carcinoma of the right breast

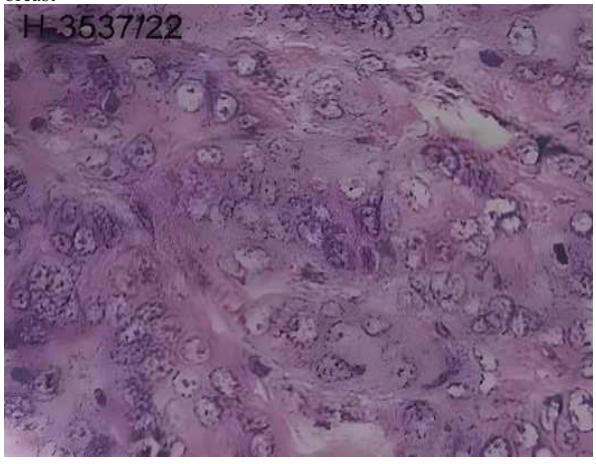
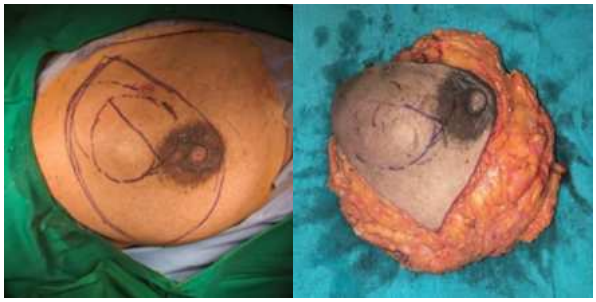


Plate IV: HPE picture of the locally advanced breast carcinoma diagnosed as Invasive Ductal Carcinoma (Not Otherwise Specified) on Tru-cut Biopsy



(a) (b)

Plate V: (a) A case of Right Breast Lump diagnosed as Malignant Phyllodes Tumour on both Tru- cut Biopsy and HPE of the operative specimen (Ductal Carcinoma on FNAC) (b) The specimen of Total Mastectomy of Right Breast of the same patient

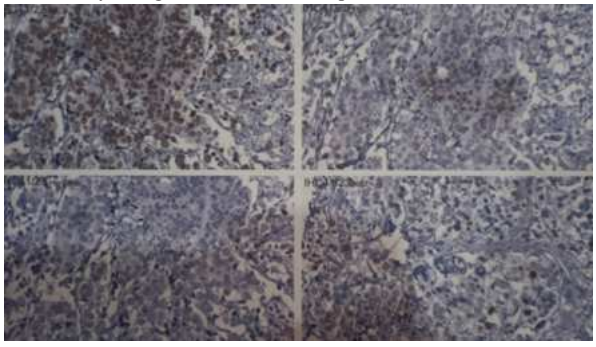


Plate VI: HPE and IHC of Tru-cut Biopsy (Core biopsy) diagnosed as Invasive Ductal Carcinoma with ER positive, PR positive, HER-2 neu negative & Ki67 10%

DISCUSSION

In both developed and developing countries, breast cancer is the most common malignancy among women worldwide. Early identification and treatment are essential because of its high incidence and fatality rates. Tissue samples from breast tumours that raise clinical suspicions must be evaluated. In the treatment of breast cancer, fine needle aspiration cytology (FNAC) is important for preoperative pathological evaluation. However, tru-cut biopsy is gradually replacing FNAC in many industrialised nations since it is seen to be more beneficial and provides more specific information about the masses. Although some studies have found that TCNB has a greater diagnostic accuracy, its enhanced invasiveness and related hazards have not been consistently measured across various groups.

The average age of the research participants was 45.5 years, and almost two-thirds of the patients were between the ages of 31 and 60. Additionally, patients with malignant breast masses had a substantially higher mean age (52.7 years vs. 30.9 years; $p<0.001$) than those with benign tumours. Women between the ages of 40 and 60 are most likely to have breast lumps, both benign and malignant. The formation of cysts and other masses might result from changes in oestrogen and progesterone levels throughout the perimenopause and menopause, which is the primary cause of this predominance. Furthermore, the risk factors for breast cancer, which include environmental effects, lifestyle choices, and extended exposure to oestrogen, build up over time and raise the possibility of breast masses.

Additionally important are genetic predispositions, which frequently show up in the later reproductive years and include abnormalities in the BRCA1 and BRCA2 genes. Additionally, the typical age of breast cancer diagnosis is 62 years old, according data from the American Cancer Society.[54] Numerous more investigations carried out abroad corroborate the findings of our investigation. For example, the average age of the research participants in a study by Oluwasola AG et al.18 was 47 years. Participants in a research by Kinjal JS et al.[22] were 55.2 years old on average. The investigations by Tchaou M et al.[25], Günes ME[34], and Siddiqui RP et al.[46] had very identical mean ages.

Another notable observation in our study is that the family history of breast cancer was present among 13.3% of patients with breast lumps, and there was a significant association of family with malignant breast lesions. In a study by Tchaou M et al[25], a family history of breast cancer

was reported among 11.1% of patients. In a survey by Altintas Y et al[24], a family history of breast cancer was present among 12.1% of patients. Literature also shows that about 5% to 10% of breast cancer is hereditary (due to a single gene mutation),[55] with BRCA mutations accounting for about 30% of these high-risk breast cancer families.[56] Lifetime risks for heredity as an aetiology in the general population are 12% for breast cancer.[57] A number of other gene mutations, such as TP53 (related to Li-Fraumeni cancer syndrome), CDH1 and PTEN (tied to Cowden disease), and STK11 (linked to Peutz-Jeghers syndrome), have also been connected to an increased risk of breast cancer.58Histopathological analysis revealed that 60 patients (66.7% [95% CI: 55.8%-76.0%]) were malignant neoplasms overall. Of these cancerous cases, invasive ductal carcinoma accounted for 86.7%, phyllode tumours for 5.0%, invasive lobular carcinoma for 3.3%, invasive papillary carcinoma for 3.3%, and medullary carcinoma with fibrocystic alteration for 1.7%. It was determined that the remaining 30 instances (33.3%) were benign tumours. Histopathological analysis revealed that 76.7% of these benign instances were fibroadenomas, 10.0% were fibroadenosis, another 10.0% were a fibrocystic disease, and 3.3% were adeno-myoepitheliomas.

59% of the biopsies in a research by Oluwasola AG et al.[18] were found to be malignant. A comparatively larger 83.6% of respondents in a survey by Samantaray S et al.[19] received a malignant diagnosis. 46.4% of patients in a study by Altintas Y et al.24 had cancer. On the other hand, research by Ahmed M. et al.[21] and Rikabi A. et al.[15] revealed a reduced percentage of malignant cases. Notably, in our study, 95.4% of postmenopausal women had malignant breast tumours upon presentation.

One of our study's key conclusions is that the tru-cut biopsy's sensitivity, specificity, and positive and negative predictive values were, respectively, 96.7%, 100%, 100%, and 93.8%. Tru-cut biopsy has a 97.8% diagnostic accuracy rate for malignant breast lesions. As can be seen in the table below, our study is one of several that have a greater predictive validity for tru-cut biopsy. Tru-cut biopsy offers enough tissue for an accurate assessment, making it similar to histopathology in the diagnosis of malignant breast lesions. It obtains core tissue samples that preserve the architecture of the lesion, allowing for in-depth analysis and cancer type identification. Immunohistochemical analysis, which is essential for detecting certain markers, can be performed on the acquired tissue. But the sensitivity, specificity, and accuracy of a research by Oluwasola AG et al.[18] were lower—86%, 71%, and 80.4%, respectively. Comparing the results of our investigation to a study by Tripathi K et al.[38], the sensitivity was 85.2%, specificity was 92.8%, PPV was 95.8%, NPV was 76.5%, and diagnostic accuracy was 87.8%. These contradictory findings may stem from differences in the sample size as well as from differences in the clinical and demographic characteristics of those studies.

Strengths And Limitations

The fact that a representative sample of patients was used in the study is one of its advantages. As a result, the study's findings may apply to a population in a comparable environment. However, because of the convenience sampling method used, the possibility of selection bias could not be completely eliminated. Because various lesions were inspected by different observers, there was also a chance of interobserver bias; however, it might be claimed that this was minimised because the observers were properly educated. Our research shows that Tru-Cut biopsy has diagnostic accuracy comparable to histopathology, making it a promising screening tool for clinically palpable breast lumps. As a result, it may be incorporated into routine examinations, particularly in settings with limited. By preventing needless procedures in individuals who have been accurately identified with benign breast lesions using Tru-Cut biopsy, this approach may lower expenditures. It also supplies enough tissue for pathologists to make an appropriate histological diagnosis in individuals with malignant lesions. However, further thorough multicentric research might strengthen the conclusions of our study.

CONCLUSION

The study comprised 90 individuals with breast lumps in total.The average age of the research participants was 45.5 years, and almost two-thirds of the patients were between the ages of 31 and 60.A somewhat higher percentage (52.2%) came from rural regions.13.3% of patients with breast lumps had a family history of breast cancer.The patients' average menarche age was 13.3 years. Clinically, 64.4% (95% CI: 53.6%-74.1%) of the patients had a cancer diagnosis.A lump in the upper outer quadrant was seen in the majority of patients (38.9%), followed by the lower outer and upper inner quadrants.By using histological analysis, 60 cases (66.7% [95% CI:55.8%-76.0%]) were found to be malignant neoplasms.

The remaining 1 (1.7%) had medullary cancer with fibrocystic change, whereas 52 (86.7%) had invasive ductal carcinoma, 3 (5.0%) had phyllodes tumours, 2 (3.3%) had invasive lobular carcinoma, and 2 (3.3%) had invasive papillary carcinoma.Of the 30 patients (33.3%) that remained, 23 (76.7%) had fibroadenoma, 3 (10.0%) had fibroadenosis, 3 (10.0%) had fibrocystic disease, and 1 (3.3%) had an HPE diagnosis of adeno-myoepithelioma. All of these cases were classified as benign tumours.Tru-cut biopsy's sensitivity, specificity, and positive and negative predictive values were, respectively, 96.7%, 100%, 100%, and 93.8%.

Tru-cut biopsy has a 97.8% diagnostic accuracy rate for malignant breast lesions.Malignancy was substantially correlated with both age and a family history of cancer.Our research shows that Tru-Cut biopsy has diagnostic accuracy comparable to histopathology, making it a promising screening tool for clinically palpable breast lumps. As a result, it may be incorporated into routine examinations, particularly in settings with limited resources.However, the results of our study may be strengthened by more thorough multicentric research.

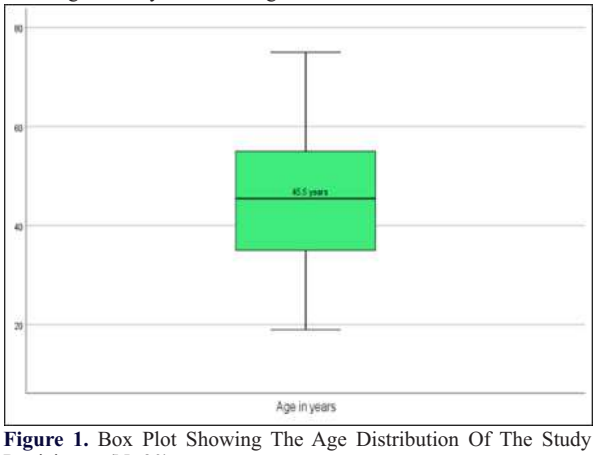


Figure 1. Box Plot Showing The Age Distribution Of The Study Participants (N=90)

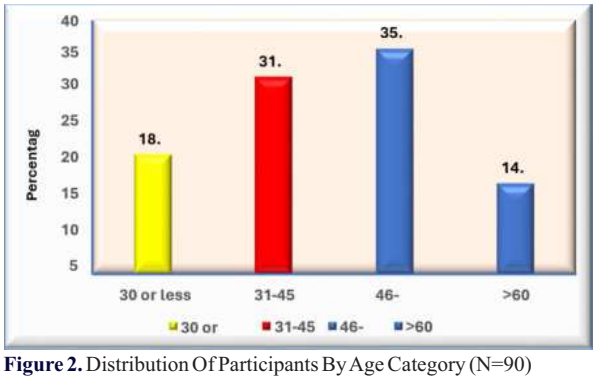


Figure 2. Distribution Of Participants By Age Category (N=90)

Table 6. Distribution Of The Study Participants By Their Quadrant (N=90)

Quadrant	Frequency (n)	Percentage
Upper outer	35	38.9
Lower outer	17	18.9
Upper inner	14	15.6
Lower inner	12	13.3
Nipple areola complex	12	13.3
Total	**90**	**100.0**

Table 7. Distribution Of Study Participants By Their Clinical Diagnosis (N=90)

Clinical diagnosis	Frequency (n)	Percentage (95% CI)
Benign	32	35.6 (25.9-46.4)
Malignant	58	64.4 (53.6-74.1)
Total	**90**	**100.0**

Table 8. Distribution Of Study Participants By Their Histopathological Examination Findings (N=90)

Histopathological Diagnosis	Frequency (n)	Percentage (95% CI)
Benign	30	33.3 (23.9-44.1)
Malignant	60	66.7 (55.8-76.0)
Total	**90**	**100.0**

Table 9. Distribution By Type Of Diagnosis Among The Post-menopausal Women (N=44)

Histopathological Diagnosis	Frequency (n)	Percentage
Malignant	42	95.4
Benign	2	4.6
Total	**90**	**100.0**

Table 10. Predictive Accuracy Of Tru-cut Biopsy In The Diagnosis Of Malignant Breast Lesions (N=90)

Tru-cut Biopsy Diagnosis	Histopathological diagnosis	
	Malignant	**Benign**
Malignant	58 (True positive)	0 (False positive)
Benign	2 (False negative)	30 (True negative)
Sensitivity = 96.7% Specificity = 100% Positive predictive value = 100% Negative predictive value = 93.8% Accuracy = 97.8%		

Table 11. Distribution Of The Study Participants By The Type Of Surgery (N=90)

Type of surgery	Frequency (n)	Percentage
Modified radical mastectomy	57	63.4
Lumpectomy	29	32.2
Excision biopsy	2	2.2
Mastectomy	2	2.2
Total	**90**	**100.0**

Table 12. Association Of Age With Malignant Breast Mass (N=90)

Histopathological diagnosis	Age in years		p-value
	Mean	**SD**	
Malignant	52.7	11.0	<0.001
Benign	30.9	8.2	

Table 13. Association Of Family History Of Breast Cancer With Malignant Breast Mass (N=90)

Family history of breast cancer	Histopathological diagnosis		p-value*
	Malignant n (%)	**Benign n (%)**	
Yes	11 (91.7)	1 (8.3)	0.043
No	49 (62.8)	29 (37.2)	

Table 14. Association Of Age At Menarche With Malignant Breast Mass (N=90)

Histopathological diagnosis	Age in years		p-value
	Mean	**SD**	
Malignant	13.3	1.4	0.288
Benign	13.1	1.5	

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