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“CLINICO-SONOGRAPHICAL AND HISTO-PATHOLOGICAL PREDICTORS FOR ACCURATE DIAGNOSIS OF THE BREAST LUMP”

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Abstract

Background: With increased awareness about breast cancer, many women with breast lumps are attending clinics. Though benign breast lumps are most common, they may be associated with morbidity and have become cause for concern to patients. Triple assessment by clinical, radiological and pathological examination is a standard approach in the evaluation of breast lumps. Even in cases of benign breast diseases, multimodality tests are being preferred to give reassurance to patients. This study was aimed to study distribution of various benign breast lumps in relation to age at presentation, to identify sensitivity and specificity of clinical breast examination, Ultrasonography (USG) and Fine needle aspiration cytology (FNAC) methods in the evaluation of benign breast lumps and to compare with final histopathological diagnosis. **Material and methods:** This Prospective Observational Study was Conducted in Our Hospital, a 500 bedded multi-

disciplinary hospital. This hospital has a Comprehensive cancer centre exclusive to cancer patients. Subjects who presented with symptomatology of BL or pain throughout the study duration made up the study population. Patients who visited the surgical OPD in the surgical department constitute the study population. The study involved those research participants who met the inclusion criteria. This study was conducted from December 2020–July 2022. A total of 100 patients were included out of the total female examined and who met the inclusion criteria. **Results:** The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of histopathological findings were found to be 98.6%, 96.4%, 99%, and 90% respectively. Clinical examination presented a sensitivity of 97.8%, specificity of 68.2%, PPV of 92%, and NPV of 93.4%. Whereas, it was 98.3%, 71.4%, 93.1%, and 91.5% in the USG examination. In our study there were 30% of patients who had breast complaints however on evaluation there was no BL or disease was found. During our study 2 male patients with gynecomastia were found however they did not have any BLs. **Conclusion:** BL and BL with pain were the most common symptom observed in subjects followed by nipple discharge, BL with nipple discharge, and nipple discharge respectively. Fibroadenoma was the most common finding in the majority of the patients followed by fibrocystic disease, phyllodes tumour, duct papilloma duct ectasia, and galactocele. Histopathological examination was significantly correlated with clinical and USG examinations. Histopathological examination is more effective in the determination of benign breast disease compared to other modalities however, a combination of clinical and USG examination could be similarly effective as histopathology. Further studies are warranted to confirm the present study findings.

INTRODUCTION

“A breast lump (BL) is any discrete mass noticed by the patient, significant other (most likely relative or spouse), or physician. Rarely, non-palpable masses may be detected by screening mammography” [1]. The number of cases of breast cancer (BC) presents initially with a new breast mass [2]. Both in males and females, benign lesions are more prevalent than malignant ones. 60 to 80% of breast masses are benign overall. However, the main fear about BLs is their association with BC. The most frequent form of cancer in women over 40 is BC. Additionally, 1 in 11 women is known to have BC. [1]

The formation of BLs in women is also known as fibrocystic disease and several women suffer from this disease. These lesions are frequently bilateral, and they are frequently accompanied by pain and discomfort that worsens soon before the menstrual cycle. These lesions are often noticed suddenly, accompanied by dull pain [1]. Furthermore, fibroadenomas are also firm BLs seen in young women of age between 15 to 30 years. [1, 2] They are substantial, firm, well-defined, movable masses that are typically painless. However, they can quickly fluctuate in size during puberty, pregnancy, menopause, or when receiving hormone therapy. [1]

Most women experience worry when they find a BL. In order to rule out malignancy and treat the presenting symptoms, a patient with a breast mass undergoes a diagnostic assessment. The patient's age, risk status, type of breast lesion, and the scope of the evaluation are all factors to consider. [3] Various modalities are available for the analysis of a BL including mammography, histopathology, and ultrasonography (USG). A BL is a very sensitive matter for the patient, therefore accurate, non-invasive, and speedy diagnosis aids in reducing the worry that comes with it and results in early, effective treatment.

However, in resource-limited settings, the availability of modern diagnostic tools may not be available [6]. Moreover, there is a lack of data concerning the accuracy of diagnostic modalities such as clinical, sonographic, and pathological diagnosis of a BL [4, 5]. Therefore, the current study was undertaken to study and associate the clinical, sono-mammographic, and pre-operative histopathological findings (FNAC or core biopsy) of the benign BLs and derive an accurate diagnosis and formulate a standardized approach toward a BL. In the present study, X-ray mammography is not included, as at

our institution it was not available during the study period.

AIM AND OBJECTIVES

Aim:- To study and correlate the clinical, sonographical (sono-mammographical) and histopathological findings (pre-operative FNAC or core biopsy) of a BL and to derive an accurate diagnosis.

Objectives:-

1. To study and correlate the clinical, sonographical (sonomammographical) and histopathological findings (pre-operative FNAC or core biopsy) findings of a BL.
2. To differentiate various presentations of benign BL.

MATERIAL AND METHODS

This Prospective Observational Study was Conducted in Our Hospital, a 500 bedded multi-disciplinary hospital. This hospital has a Comprehensive cancer centre exclusive to cancer patients. Subjects who presented with symptomatology of BL or pain throughout the study duration made up the study population. Patients who visited the surgical OPD in the surgical department constitute the study population. The study will involve those research participants who met the inclusion criteria. This study was conducted from December 2020–July 2022. A total of 100 patients were considered out of the total females examined and who met the inclusion criteria.

Inclusion criteria:

1. All Subjects with a mass/lump in the breast.
2. Patients complaining of pain in the breast
3. Both females and males will be included
4. Lactating females
5. Biopsy-proven benign breast lesion.

Exclusion criteria:

1. Patients with 99% malignancy
2. LABC (Locally advanced BC)
3. Nipple-areolar complex involvement
4. Strong family history of breast carcinoma
5. Female operated/treated on the opposite breast

Methodology:

Valid informed consent was taken from all the included patients prior to the initiation of the study. A detailed history and clinical examination including “general physical, systemic and local examination” of both breasts was performed. USG of both breasts was conducted. Histopathology of benign breast lesions was performed and considered the gold standard. In present study, X-ray mammography was not included, as in our institute it was not available during the study period. Patients who came with symptomatology of BL but had no obvious finding on clinico sonographical examination were excluded from the study and accounted for 30% of all the patients screened. Male patients with gynecomastia were examined but were excluded from the study.

Statistical analysis:

Data was added to the MS Excel sheet and then imported to SPSS V 1.2.5001 software. Continuous variables were shown in mean \pm SD whereas, categorical variables were presented in percentage and frequency. Diagnostic measures of various modalities were computed. Correlation between variables was assessed using the Pearson correlation coefficient test. “ $P < 0.05$ was considered statistically

significant”.

RESULTS AND OBSERVATIONS

In this study majority of participants (33%) belonged to the 41-50years age group followed by 27%,23%,10% and7% of the patients belonged to 31-40years, 21-30years, >50years, and <20 years age categories respectively. The detailed distribution of subjects according to age categories is described in table 1.

Table no. 1 Distribution of Subjects According to age Categories

Age (years)	Frequency (n)	Percentage (%)
<20	7	7
21-30	23	23
31-40	27	27
41-50	33	33
>50	10	10
Total	100	100

Patient presentation: BL and BL with pain were the most common symptom observed in 54% and 26% of women respectively. Whereas, 11%, 4%, 3%, and 2% of women had “breast pain, BL with pain and nipple discharge, BL with nipple discharge, and nipple discharge respectively”. The distribution of subjects according to symptoms is illustrated in table 2.

Table no. 2 The Distribution of Subjects according to Symptoms.

Symptoms	Frequency (n)	Percentage (%)
BL	54	54
BL with pain	26	26
BL with nipple discharge	3	3
BL with pain and nipple discharge	4	4
Breast pain	11	11
Nipple discharge	2	2
Total	100	100

Breast side: The right breast was found to be affected in the majority of women (53%) followed by the left breast (42%). In 7% of the women, both breasts were affected. The distribution of subjects according to the affected breast side is depicted in table 3.

Table no. 3 The Distribution of subjects according to affected breast side.

Breast side	Frequency (n)	Percentage (%)
Right	53	53
Left	42	42
Both	7	7
Total	100	100

Breast site:

In 34%, 21%, 18%, and 14% of the patients, the upper outer quadrant, lower outer quadrant, upper inner quadrant, and lower inner quadrant were the affected breast sites respectively. Whereas, central

portion and multiple breast sites were involved in 5% and 8% of the patients respectively.

Clinical examination:

Clinical examination suggested fibroadenoma in 84% of the patients, phyllodes tumour in 4% of the subjects, and fibrocystic disease in 8% of the patients; whereas duct papilloma, duct ectasia, galactocele was found in 1%, 1%, and 2% of the patients respectively. The distribution of subjects according to clinical examination is shown in table 4.

Table no 4. The distribution of subjects according to clinical examination.

Clinical examination	Frequency (n)	Percentage (%)
Fibroadenoma	84	84
Phyllodestumor	4	4
Fibrocysticdisease	8	8
Galactocele	2	2
Ductpapilloma	1	1
Duct ectasia	1	1
Total	100	100

USG Examination:

USG examination suggested fibroadenoma in 82% of the patients, phyllodes tumor in 4% of the patients, and fibrocystic disease in 11% of the patients whereas, duct papilloma, duct ectasia, galactocele was found in 1%, 1%, and 2% of the patients respectively.

Histopathological examination:

Histopathological examination suggested fibroadenoma in 69% of the patients, phyllodes tumor in 7% of the subjects, and fibrocystic disease in 18% of the subjects whereas, duct papilloma, duct ectasia, galactocele was found in 3%, 2%, and 1% of the patients respectively. The distribution of subjects according to histopathological examination is shown in table 5.

Table no 5. The distribution of subjects according to histopathological examination.

Histopathological examination	Frequency (n)	Percentage (%)
Fibroadenoma	69	69
Phyllodes tumor	7	7
Fibrocystic disease	18	18

Galactocele	1	1
Duct papilloma	3	3
Duct ectasia	2	2
Total	100	100

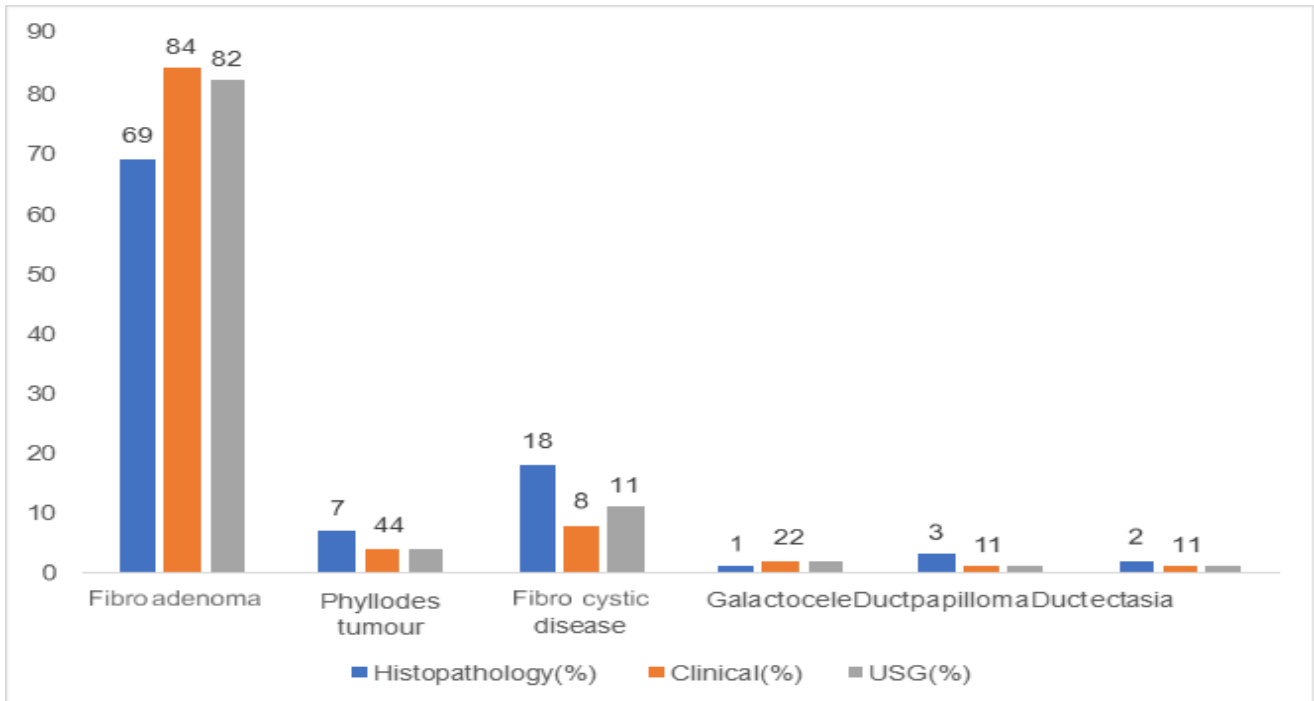


Figure 1: Correlation between histopathological, clinical, and USG examination

Table 6. Predictive measures of histopathological, clinical and ultrasound examinations

Statistics	Examinations		
	Histopathological	Clinical	USG
Sensitivity	98.6%	97.8%	98.3%
Specificity	96.4%	68.2%	71.4%
PPV	99%	92%	93.1%
NPV	90%	93.4%	91.5%

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of histopathological findings were found to be 98.6%, 96.4%, 99%, and 90% respectively. Clinical

examination presented a sensitivity of 97.8%, specificity of 68.2%, PPV of 92%, and NPV of 93.4%. Whereas, it was 98.3%, 71.4%, 93.1%, and 91.5% in the USG examination.

In our study there were 30% of patients who had breast complaints however on evaluation there no BL or disease was found. During our study 2 male patients with gynecomastia were found however they did not have any BLs.

DISCUSSION;

The study was intended to study and correlate the clinical, sonographically, and histopathological findings of breast tissue lesions to derive an accurate diagnosis. A total of 100 women with breast lesions (BLs) were examined using histopathological, clinical, and ultrasonographic (USG) methods. In this study, 33% of the participants were in the 41-50 years age category, while 27%, 23%, 10%, and 7% of the patients belonged to the 31-40 years, 21-30 years, >50 years, and <20 years age categories, respectively. In the study by Kumar B. et al., the majority of patients were in the 21-30 years age group, followed by the 31-40 years, 11-20 years, 41-50 years, and >50 years age groups. Various other studies have shown predominance in different age groups. The differences in the results may be due to different study sites, lifestyles, socioeconomic statuses, inclusion criteria, etc.

In this study, most women presented with BLs (80%), including BLs alone and BLs with pain (54% and 26%, respectively). In the study by Mima M. et al., 87% of the patients presented with BLs, whereas it was 87.4% and 72.35% in the studies by Foncroft LM et al. and Ratanchaikamont T et al., respectively. Similar to our study, Kumar B. et al. reported BL and BL with pain in 58.66% and 22% of the patients, respectively. Literature has suggested the prevalence of BLs ranges from 12.8% to 37.3%. In this study, 11% of patients presented with breast pain. Furthermore, 4%, 3%, and 2% of women had BLs with pain and nipple discharge, BL with nipple discharge, and nipple discharge, respectively. These results are analogous to the study by Kumar B. et al.[37]

Here, we noted that in 53% and 42% of women, the right and left breast were affected, respectively, while in 7% of the participants, both breasts were affected. Similarly, in the study by Kumar B. et al., a higher incidence of benign breast disease was reported on the right side (52%), followed by the left side (42%) and both sides (6%). In the present study, the most common site involved was the upper outer quadrant, followed by the lower outer quadrant, upper inner quadrant, and lower inner quadrant. In contrast, the central portion and multiple breast sites were involved in a few patients. These findings are comparable with the studies by Kumar B. et al. and Mallikarjuna et al.[37,48]

In this study, histopathological examination was considered the gold standard. Here, fibroadenoma was the most common finding, followed by fibrocystic disease, phyllodes tumor, duct papilloma, duct ectasia, and galactocele, which is similar to the outcomes of Bangaru H et al., Sangma MBM et al., and Chandanwale SS et al. Furthermore, Bangaru H et al. and Sangma MBM et al. suggested that the incidence of fibroadenoma was higher in the 21-30 years age group, while fibrocystic disease was more prevalent in the 31-40 years age group.[49,50]

In this study, the diagnosis of BL using clinical and USG examinations was compared with histopathological examination. The histopathological results suggested fibroadenoma in 69% of the patients, whereas clinical and USG examinations indicated it was present in 84% and 82% of patients, respectively. Histopathological examination suggested phyllodes tumor in 7% of the patients, while clinical and USG examinations suggested it in 4% of patients. Fibrocystic disease was identified in 18% of the women by histopathological examination, whereas clinical examination and USG suggested it in 8% and 11% of women, respectively. Histopathological examination indicated galactocele, duct papilloma, and duct ectasia in 1%, 3%, and 2% of the patients, respectively, whereas

clinical and USG examinations suggested these conditions in 2%, 1%, and 1% of women, respectively. Histopathological examination was significantly correlated with clinical examination and USG examination ($P=0.004$). These findings are consistent with the study by Bangaru H et al.[49]

In this study, we computed predictive measures for all diagnostic modalities. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of histopathological findings were found to be 98.6%, 96.4%, 99%, and 90%, respectively. Clinical examination showed a sensitivity of 97.8%, specificity of 68.2%, PPV of 92%, and NPV of 93.4%. For the USG examination, these values were 98.3%, 71.4%, 93.1%, and 91.5%, respectively. Bangaru H et al. suggested in their study that clinical examination had a sensitivity of 98.8%, specificity of 65.9%, PPV of 91.3%, and NPV of 93.1%. USG showed values of 98.3%, 71.4%, 93.1%, and 91.5% for sensitivity, specificity, PPV, and NPV, respectively. Histopathological examination in their study had values of 97.2%, 96.4%, 99.1%, and 89.8% for sensitivity, specificity, PPV, and NPV, respectively [49]. These findings are comparable with the present study findings. Moreover, in another study conducted by Kapoor B et al., clinical examination showed 87.5% sensitivity, 92.8% specificity, 93.3% PPV, and 86.6% NPV. Radiological examination had a sensitivity of 81.2% and a specificity of 92.8%, with a PPV and NPV of 92.8% and 81.2%, respectively. They suggested that compared to histopathology, fine needle aspiration cytology had 100% sensitivity [52].

This study suggests that histopathological examination is more effective in determining benign breast disease compared to other modalities; however, a combination of clinical and USG examinations could be similarly effective as histopathology. The strength of the study was the adequate sample size and uniform application of the protocol. Patients of all age groups were included in this study.

The limitations include the fact that the investigator was not blind, and the study was conducted at a single center, which could have introduced bias. Additionally, the sample size was relatively small and did not meet the required criteria, as the study was part of a postgraduate thesis and was constrained by time limitations. Ideally, randomization would have involved simple stratified random sampling, but due to limited resources, the study was conducted at a single center using convenient sampling. Furthermore, other diagnostic modalities were not assessed. Generalization could be improved with a larger sample size. The study recommends a multicenter, single-blind study with a large sample size that includes all variables. Patients who were not diagnosed with any breast disease were excluded from the study, accounting for 30% of all patients screened. Male patients with gynaecomastia were examined but were omitted from the study.

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