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Triple Assessment of Palpable Breast Lumps at a Rural Setup – Standard Procedure Continues To Prove Its Efficacy

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Abstract | **Original Research Article**

Background: This study aimed to assess palpable breast lumps with triple assessment test and correlate them with histopathological result. ***Methods:*** This was a prospective observational study conducted in a rural setup at PES Institute of Medical Sciences and Research, Kuppam, from DECEMBER 2016 to JUNE 2018 which included all female patients, irrespective of age, with clinically palpable breast lump(s). Patients with breast abscess, antibioma, mastitis, infected cyst, mammary fistula, prior breast surgery and breast trauma were excluded from the study. Totally 100 patients were studied. ***Results:*** Of the 100 patients, Clinical Breast Examination (CBE) and Fine needle aspiration cytology (FNAC) showed similar results; 66 as benign and 34 as malignant with sensitivity and specificity of 98.5% and 94.3% respectively. Radiological diagnosis showed benign nature in 64 patients and malignancy in 36 patients with a sensitivity and specificity of 96.9% and 97.1% respectively. Using these parameters a triple test score was calculated (taking at least 2 out of 3 components pointing towards similar diagnosis) which showed 66 as benign lesions and 34 as malignancies and gave a sensitivity of 98.5% and specificity of 97.1%. Based on these findings appropriate surgeries were done and specimen was sent for Histopathological examination (HPE) which revealed that 65 patients had benign lesions whereas 35 patients had malignancies. ***Conclusions:*** This study highlights the importance of triple assessment in diagnosing various palpable breast lesions with its high sensitivity and specificity, it's impact on the surgical decision making and final HPE correlation.

Keywords: Triple assessment test, Breast lumps, FNAC, CBE, USG, Mammogram, HPE.

INTRODUCTION

One-fourth of the women suffer from breast disease in their lifetime [1]. A breast lump is of great concern to a patient and is also a challenge to the diagnostic acumen of the treating surgeon [2]. Presence of a space-occupying lesion in the breast [3] raises suspicion of being benign or malignant, more latter than former, which is the reason so much importance is given to the diagnosis and management of breast lumps. Breast lumps in the rural setting are more a matter of concern in terms of malignancy and financial issues rather than cosmesis. The triple assessment is the combined use of clinical, cytological and radiological modalities [4] together to obtain a pre-operative near accurate diagnosis following which treatment is planned accordingly.

The present study utilizes the modalities of triple assessment to determine the incidence of various breast lesions in patients, presenting to the Department of General Surgery, PESIMSR, Kuppam, with palpable breast lumps. Then this study will discuss histopathological findings and it's correlation with triple test. The data generated in this study will be used to understand the disease pattern in palpable breast lumps in a rural area and will comment on the current status of care in rural setups along with the options which can be availed for a better management of the patient.

Aim and objectives of the study

Triple test assessment of palpable breast lumps in a rural setup to find the incidence of benign and malignant lesions, correlate the HPE of the operative specimen with triple assessment data.

PATIENTS AND METHODS

This was a prospective observational study conducted at PES Institute of Medical Sciences and Research in a rural setup from DECEMBER 2016 to

JUNE 2018. This study included female patients, irrespective of age, with clinically palpable breast lump(s) who presented to general surgery OPD at PESIMSR, consented and underwent required workup followed by surgical management for the same. Patients with breast abscess, antibioma, mastitis, infected cyst, mammary fistula, prior breast surgery and breast trauma were excluded from the study.

All the patients who were selected on the above criteria, had a complete history taken, relevant clinical examination and baseline investigations done, underwent cytological and radiological analysis, metastatic workup (if necessary) and appropriate surgery as per standard guidelines. HPE of the operative specimen was done, and further surgical management initiated accordingly if needed.

Entire clinical and diagnostic data of each patient was recorded in the clinical proforma prepared beforehand, specifically designed for this study. Important information related to each case was analyzed using SPSS software. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated. Ethical committee clearance was obtained from our institution for this study.

OBSERVATIONS AND RESULTS

A total of 100 patients with palpable breast lumps satisfying the inclusion and exclusion criteria were admitted in the surgical ward of PESIMSR, Kuppam, and work up was done accordingly and they underwent surgery as per the triple test results. HPE correlation was done. All the findings were noted and analyzed.

On CBE 62 were fibroadenomas, 34 felt like malignant lumps, 2 were fibroadenosis and 2 were phylloides tumour. On radiological examination 61 had Fibroadenoma picture and 36 showed features of malignancy. Fibroadenosis, phylloides tumour and lipoma were seen in 1 patient each.

In FNAC 59 had fibroadenomas, 33 had a malignant picture, 5 were phylloides tumours, 1 lipoma, 1 fibroadenosis and 1 showed plexiform neurofibromatosis. Triple test final result (Where atleast 2 among the three tests pointed towards a single diagnosis) concluded 62 as fibroadenomas, 35 as carcinomas, 2 as phylloides tumour and 1 as lipoma (Table 1). In cases of malignancies, as diagnosed by triple test, no patient had any distant metastasis on workup.

Table-1: Triple Test Results

Triple test diagnosis	Number of patients	Percentage
Fibroadenoma	62	62
Lipoma	1	1
Phylloides tumour	2	2
Carcinoma	35	35

HPE (Table 2) revealed 56 specimens as fibroadenomas, 33 as carcinomas, 4 as fibroadenosis, 4 as benign phylloides tumours and one each of lipoma, malignant phylloides tumour and plexiform neurofibromatosis.

Table-2: HPE Results

HPE diagnosis	Number of patients	Percentage
Fibroadenoma	56	56
Fibroadenosis	4	4
Lipoma	1	1
Phylloides tumour (benign)	4	4
Phylloides tumour(malignant)	1	1
Plexiform neurofibromatosis	1	1
Carcinoma	33	33

DISCUSSION

A breast lump, with its wide variety of differentials, is of great concern to both patient and doctor [5]. Breast lumps are actually quite common, especially in the child bearing age group[6], most of them are benign, which appear and resolve by themselves (hormonal influence) [7] or remain asymptomatic throughout the life, without having any impact on daily life or causing any physical damage.

Triple assessment was adopted as the main stream modality where with clinical, radiological and minimally invasive cytological/histological techniques; a near accurate diagnosis can be established [8,9]. Once established a clear management plan and outcome can be discussed with the patient with confidence.

Most of the breast lumps will be categorized under the term benign breast disease [10-12], which includes all nonmalignant conditions of the breast and typically do not convey any increased risk of

malignancy. Patients with benign breast conditions are often first seen by their primary care physician or their gynecologist. But at the same time, a malignant lesion diagnosed at its earliest stage [13] might have a best prognosis possible, also cutting down on the amounts that need to be spent for chemo or radiotherapy.

Breast cancer is the most common cancer in women both in the developed and less developed world [14]. It is estimated that over 508 000 women died in 2011 worldwide due to breast cancer (Global Health Estimates, WHO 2013) [15]. Although breast cancer is thought to be a disease of the developed world, almost 50% of breast cancer cases with 58% of deaths occur in less developed countries [14].

Incidence rates vary greatly worldwide from 19.3 per 100,000 women in Eastern Africa to 89.7 per 100,000 women in Western Europe. In most of the developing regions, the incidence rates are below 40 per 100,000[14]. The lowest incidence rates were found in most African countries, but here too breast cancer incidence rates seems to be increasing [14].

Breast cancer is ranked as number one among the cancers affecting Indian women with age-adjusted rate as high as 25.8 per 100,000 women and mortality of 12.7 per 100,000 women. Data reports from various latest national cancer registries were compared for incidence, mortality rates. The age-adjusted incidence rate of carcinoma of the breast was found as high as 41 per 100,000 women for Delhi, followed by Chennai (37.9), Bangalore (34.4) and Thiruvananthapuram District (33.7)[16].

Breast cancer survival rates vary greatly worldwide, ranging from 80% and over in North America, Sweden, and Japan to around 60% in middle-income countries and below 40% in low-income countries [17]. The low survival rates in less developed countries can be attributed mainly to the lack of early detection programmes that results in a high proportion of women presenting with a late-stage disease, as well as to the lack of adequate diagnostic and treatment facilities. Patients with a diagnosis of benign lesion who insisted on getting operated or in whom surgeon made a choice to operate were only included in this study.

Coming to the fate of the triple test diagnosis of malignancies (n=35), most of them were invasive carcinomas with or without axillary lymph nodal involvement and no evidence of distance metastasis. Most of the HPE results (n=32) correlated well with the triple test diagnosis, i.e., invasive ductal carcinomas where as one lump turned out to be a malignant phylloides tumour which was mentioned earlier. The other one was plexiform neurofibromatosis, a rare entity, which is nerve sheath neoplasm, for which further syndromic workup was planned. All the patients with malignancies including the uncommon ones were referred to the in-hospital medical oncologist for further workup and management. Only one lump diagnosed as malignant in the triple test turned out to be an atypical variant of fibroadenoma on HPE, so no further management was planned.

This study done at a rural setup tries to re-emphasize the importance of triple assessment results in diagnosing various breast lesions presenting as lumps. It has high sensitivity, specificity, PPV and NPV value and is superior compared to its individual components read separately.

This study also establishes the importance of the triple test in surgical decision making. But in a rural setup because of various constraints from patient side and variability of surgeon's choice, breast-conserving surgery was not attempted. Following are the various correlations of the study results, sensitivity, and specificity, PPV and NPV.

Correlation of clinical breast examination (CBE) diagnosis with histopathological examination (HPE)

The clinical assessment of the palpable breast lump correlated well with the final gold standard HPE report with findings as mentioned in Table 3. The relatively low specificity can be attributed to the different experience values of the consultants who examined the patients.

Table 3 – CBE correlation with HPE

CBE	Correlation	HPE report	
		Benign	Malignant
	Benign	64	2
	Malignant	1	33

Sensitivity	98.5%
Specificity	94.3%
Positive predictive value	97.0%
Negative predictive value	97.1%

Correlation of fine needle aspiration cytology (FNAC) diagnosis with histopathological examination (HPE)

FNAC (Table 4) also had similar values of sensitivity and specificity as the clinical breast examination and was very useful in diagnosing a plexiform neurofibromatosis in which a cytological evaluation can be relied upon.

Table-4: FNAC correlation with HPE

FNAC	Correlation	HPE report	
		Benign	Malignant
	Benign	64	2
	Malignant	1	33

Sensitivity	98.5%
Specificity	94.3%
Positive predictive value	97.0%
Negative predictive value	97.1%

Correlation of radiological diagnosis with histopathological examination (HPE)

Radiological diagnosis (Table 5), compared to CBE and FNAC, proved to be a little superior in specificity (94.3 vs. 94.3 vs. 97.1) and PPV (97 vs. 97 vs. 98.4).

Table-5: Radiological diagnosis correlation with HPE

Radiology	**Correlation**	**HPE report**	
		Benign	Malignant
	Benign	63	1
	Malignant	2	34

Sensitivity	96.9%
Specificity	97.1%
Positive predictive value	98.4%
Negative predictive value	94.4%

Correlation of triple test diagnosis with histopathological examination (HPE)

The triple test result, which was obtained by a similar 2 out of three modalities method, proved to be near accurate in diagnosing the breast lumps (Table 6). The only area where it was not of much help was in benign phylloides tumour patients because it could pick up only two out of four of these lesions. Because of this reason these two patients in whom the diagnosis was confirmed by excision biopsy had to undergo a second procedure, i.e., total mastectomy. In one patient the lesion was misinterpreted as malignancy and MRM was done, but it turned out to be a fibroadenoma on HPE.

Table-6: Triple test correlation with HPE

Triple test	**Correlation**	**HPE report**	
		Benign	Malignant
	Benign	64	2
	Malignant	1	33

Sensitivity	98.5%
Specificity	97.1%
Positive predictive value	98.5%
Negative predictive value	97.1%

It is a well-established fact that tumours in general and malignancies, in particular, arise from the superolateral quadrant (SLQ) of the breast due to the presence of bulk of breast tissue in that area. Findings in this study are no different because 30 patients presented with breast lumps in SLQ and 20 among them had malignancy. Benign lesions were more abundant in the medial/ inner quadrants (n=41). Inferomedial quadrant (IMQ) had the least incidence of malignancy, and the central zone had the least number of lesions overall.

Overall the incidence of benign versus malignant lesions in a rural setup, their presentation, different modalities of triple assessment and their efficacy in diagnosing the breast lumps with final histopathological correlation was discussed in detail in this study.

Compared to a study by Jan Masooda *et al.* on 200 patients with breast lumps, the present study triple test results yielded high PPV (93.3% vs 98.5%); but the NPV (100% vs 97.1%), sensitivity (100% vs 98.5%)

and specificity (99.3% vs. 97.1%) were marginally low[18].

Limitations of the study are that the sample size is small, study is non-randomised, pre-operative diagnosis, surgeries and histopathological confirmation was done by a multitude of personnel.

CONCLUSIONS AND SUMMARY

The importance of triple assessment test in diagnosing various breast lesions was discussed in this study and should always be kept in mind. As the test can be performed even in a rural setup and also with its high sensitivity, specificity, PPV and NPV it should be considered as a first line of investigation in diagnosing the lesions. As this test is on par with histopathology with marginally differing results it can be easily relied upon for near accurate diagnosis and surgical decision making.

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Declarations

Ethical approval: Institutional Ethics Committee approval obtained.

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