

## Assessing Efficacy of Modified Triple Assessment in the Diagnosis of Breast Lump: An Observational Study

Barun Kumar

Associate Professor, Department of General Surgery, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India

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Corresponding author: Dr. Barun Kumar

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### Abstract

**Aim:** The aim of the present study was to assess sensitivity and specificity of modified triple assessment in diagnosis of breast lump.

**Methods:** The present study was conducted in the Department of General Surgery, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India for the period of 2 years and randomly selected 200 female patients with breast lump attending surgery OPD and admitted in female surgical ward surgical unit during the study period.

**Results:** Mean age was  $34.56 \pm 12.80$  years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. In present study the breast lump was present more on right side 110 patients as compared to left side 90. As from present study we can observed that most common size of lump was in range of  $>2$  cm to 5 cm in diameter in clinical breast examination are 130 patients and in 90 patients, size of lump is more than 5 cm in diameter. Most of the patients who went under clinical breast examination yield that mostly the patients with lump in firm consistency 128 patients, 2 of them had soft and other 70 patients had hard in consistency. 80% patients had well circumscribed mass with regular margins followed by Density lesion with microcalcification, irregular margins and speculation (10%). In the study, 44% patients had Fibroadenoma, 20% patients had Ductal cell carcinoma and 16% patients had Fibro adenosis. In FNAC, 65% patients had Fibroadenoma, 20% patients had Fibroadenosis and 6% patients had cyst.

**Conclusion:** Modified triple assessment is a very useful diagnostic tool to evaluate patients with breast lumps and to detect patients with breast cancers with an overall accuracy of 98%. Modified triple assessment was useful in diagnosing breast cancers at an earlier stage, with most of breast cancers detected at stage I or stage II (T1 or T2, N0 or N1, M0). It was found that triple assessment did not require hospitalization, but was performed on OPD basis, without any complications.

**Keywords:** Modified triple assessment, Clinical examination, Mammography, Ultrasonography, Fine-needle aspiration.

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### Introduction

Breast cancer is the most common site specific cancer in women and is one of the leading causes of death from cancer for women, accounting for about 20% of

cancer related deaths in women.[1,2] The accurate diagnosis and appropriate management of breast lumps is associated with anxiety and stress, both for the patients

and the caring physician. The steps in establishing a diagnosis include clinical examination, mammogram and needle biopsy. The individual components of this triple assessment are not reliable on their own in reaching a diagnosis but when combined, the diagnostic accuracy is nearly 100% and the triple test has been proposed as the gold standard for the diagnosis of breast lumps.[3-7]

In the spectrum of symptoms related to breast disease, a breast lump is the most commonly presented symptom. It may either be a manifestation of benign pathologies, such as fat necrosis, fibroadenoma, acute or chronic breast abscess, or a sinister carcinoma breast. Breast ultrasound (US) is a very important adjunct to mammography (MMG) in patients with equivocal findings. It is now widely accepted as a diagnostic modality for breast lesions. Using modern high resolution probes, majority of carcinomas of size less than 1 cm can be identified. Potential advantages of breast US are non-invasiveness, easy availability, lower cost and good accuracy rate for diagnosing breast masses.[8,9] Bassett et al found that MMG was not useful in assessing breast lesions in women less than 35 years due to denser breast tissue. On the contrary, US was helpful in avoiding unnecessary breast biopsies and was recommended as the initial examination in younger women.[10] Triple assessment, as the name indicates, includes three modalities, physical examination, imaging (mammography and/or ultrasound), and biopsy (FNAC and core biopsy). These modalities, when used individually for breast cancer screening and diagnosis, will render less reliable results as compared to when used in combination.

Patients with breast problems make up a major part of the patient load at a general surgical out-patient's clinical. With the increasing public and professional awareness each year large number of young women are being referred to general surgeons with palpable breast lump. Breast

problems can present themselves in number of ways like breast pain, nipple discharge, cystic lesions and more commonly a lump. Majority of them prove to be benign, but probability of the diagnosis of cancer not be excluded.

The aim of the present study was to assess sensitivity and specificity of modified triple assessment in diagnosis of breast lump.

### **Materials and Methods**

The present study was conducted in the Department of General Surgery, Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India for the period of 2 years and randomly selected 200 female patients with breast lump attending surgery OPD and admitted in female surgical ward surgical unit during the study period.

Women with a breast lump or suspicious change in the breast texture was included in the study. A detailed patient's history, focused clinical examination and radiological imaging (mammography, ultrasonography (USG)) and fine-needle aspiration cytology (FNAC) were used as diagnostic tools for screening of the patients for a possible malignant disease at its inception (early stage).

### **Subject and selection method**

Randomly selected 100 female patients with breast lump attending surgery OPD LBKMCH and admitted in female surgical ward surgical unit during the study period

### **Inclusion criteria**

Female patients with palpable breast lump/lumps above 15 years of age attending surgery OPD and admitted in female surgical ward.

### **Exclusion criteria**

Exclusion criteria was as follows: male patients and female patients with advanced breast cancer that makes diagnosis obvious were excluded from the study, patient not willing for FNAC, lactating mother, radiation given to the breast, acute

inflammatory conditions of the breast and obvious advanced malignancy of breast.

### Procedure methodology

This cross sectional study has included female patients selected randomly, having a breast lump/lumps in, who attended the surgery OPD or were admitted in female surgical ward of general surgery with having complaint of breast lump/lumps were assessed thoroughly as per modified triple assessment comprised of clinical breast examination, sono mammography of bilateral breast with bilateral axilla and FNAC of lump after detailed explanation about the purpose of study, to the all enrolled patients in this study, in their own language and valid consent has been obtained with assurance of confidentiality and only shared for academic purpose.

### Statistical analysis

The modified triple test (MTT) was scored as concordant if the elements had either all

malignant or all benign results. It was non-concordant if the elements had neither all malignant nor all benign results. The test results were analyzed separately in concordant and non-concordant cases. The sensitivity, specificity and accuracy were calculated by the following formula, where TP indicates true positive; TN, true negative; FP, false positive; and FN, false negative: sensitivity =  $TP / (TP+FN)$  specificity =  $TN / (TN+FP)$  accuracy =  $TP+TN / (TP+FP+TN+FN)$ . In nonconcordant cases, results of each components of triple test were analyzed separately and then in combination and then above said parameters were calculated. In non-concordant cases, triple test was scored as benign or malignant, depending upon the result of either of the two elements amongst three components.

### Results

**Table 1: Patient details**

Variables	N%
Mean age	34.56 ± 12.80 years
<b>Side affected</b>	
Right	110 (55)
Left	90 (45)
<b>Size of lump</b>	
>2 cm-5 cm	130 (65)
>5 cm	70 (35)
<b>Consistency of breast lump</b>	
Firm	128 (64)
Hard	2 (1)
Soft	70 (35)

Mean age was 34.56 ± 12.80 years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. In present study the breast lump was present more on right side 110 patients as compared to left side 90. As from present study we can observed that most common size of lump was in range of >2 cm to 5 cm in diameter

in clinical breast examination are 130 patients and in 90 patients, size of lump is more than 5 cm in diameter. Most of the patients who went under clinical breast examination yield that mostly the patients with lump in firm consistency 128 patients, 2 of them had soft and other 70 patients had hard in consistency.

**Table 2: Mammographic findings (n=120)**

Findings	No. of patients (%)
Well circumscribed mass with regular margins	96 (80)
Density lesion with microcalcification	8 (6.66)
Density lesion with irregular margins and spiculation	4 (3.34)
Density lesion with microcalcification, irregular margins and spiculation	12 (10)
Total	120 (100)

80% patients had well circumscribed mass with regular margins followed by Density lesion with microcalcification, irregular margins and speculation (10%).

**Table 3: USG impression**

Findings	No. of patients (%)
Fibroadenoma	88 (44)
Fibro adenosis	32 (16)
Galactocele	4 (2)
Traumatic fat necrosis	8 (4)
Phyllodes	12 (6)
Ductal cell carcinoma	40 (20)
Lobular cell carcinoma	16 (8)
Total	200

In the study, 44% patients had Fibroadenoma, 20% patients had Ductal cell carcinoma and 16% patients had Fibro adenosis.

**Table 4: FNAC findings**

Findings	No. of patients (%)
Fibroadenoma	130 (65)
Fibroadenosis	40 (20)
Galactocele	10 (5)
Solid mass	8 (4)
Solid mass with irregular margins	4 (2)
Cyst	12 (6)
Total	200

In FNAC, 65% patients had Fibroadenoma, 20% patients had Fibroadenosis and 6% patients had cyst.

**Table 5: Modified triple assessment**

		Histopathology		No. of patients	Sensitivity	Specificity	PPV	NPV
		Malignant	Benign					
Modified triple assessment test	Malignant	60	4	64	90.42	100	100	95.75
	Benign	00	136	136				
Total		60	140	200				

The sensitivity was 90.42% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 95.75%. P value was significant (0.000).

**Discussion**

Until a few years ago, it was generally believed that breast tumour should be excised and histologically examined to

determine its nature with certainty because the preoperative physical assessment alone was associated with too much uncertainty. Eventually, with the advent of mammography, a radiological tool became available to the surgeons to make a pre-operative diagnosis of the breast with a reasonable degree of accuracy. However, it

was the introduction of Fine needle aspiration cytology (FNAC) that changed the entire outlook to the matter. The combination of physical examination mammography and FNAC came to be called upon as the "triple test" for assessment of breast lumps and has now become the gold standard in the work-up of the same. According to National Institute for Health and Clinical Excellence (NICE) guidelines, for patients with symptoms that could be caused by breast cancer, diagnosis is made by Modified triple assessment. The combination of physical examination, sono mammography and FNAC came to be called upon as the "Modified Triple Test". The aim of our study was to the role of modified triple assessment in diagnosis of breast lump and sensitivity and specificity of modified triple assessment with regards to histopathology. Chandak NS et al in their study they have taken 50 patients in the age range of 11 to 70 years, with a mean of 38.54 years.[11]

Mean age was  $34.56 \pm 12.80$  years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. In present study the breast lump was present more on right side 110 patients as compared to left side 90. As from present study we can observed that most common size of lump was in range of >2 cm to 5 cm in diameter in clinical breast examination are 130 patients and in 90 patients, size of lump is more than 5 cm in diameter. Most of the patients who went under clinical breast examination yield that mostly the patients with lump in firm consistency 128 patients, 2 of them had soft and other 70 patients had hard in consistency. 80% patients had well circumscribed mass with regular margins followed by Density lesion with microcalcification, irregular margins and speculation (10%). Yang et al found a sensitivity, specificity and positive predictive value for clinical examination as 88%, 92%, 67%, respectively.[12]

In the study, 44% patients had Fibroadenoma, 20% patients had Ductal

cell carcinoma and 16% patients had Fibro adenosis. In FNAC, 65% patients had Fibroadenoma, 20% patients had Fibroadenosis and 6% patients had cyst. In FNAC, 65% patients had Fibroadenoma, 20% patients had Fibroadenosis and 6% patients had cyst. A study conducted by Lod Khoda et al. reveals the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of the physical examination were 66.6%, 100%,100%, 90%, and 91.6%, respectively. Various other studies also show the sensitivity of physical examination ranging from 21% to as high as 100% and the specificity from 50% to 97.8%.[13] Pande et al. in 2003 found the sensitivity, specificity, positive predictive value, and negative predictive value for ultrasound was 95%, 94.10%, 95.50%, and 93.75%, respectively.[14] Shetty et al sensitivity for a combined mammographic and sonographic assessment were 100%, the specificity was 80.1%.[15]

The sensitivity was 90.42% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 95.75%. P value was significant (0.000).

### Conclusion

Modified triple assessment is a very useful diagnostic tool to evaluate patients with breast lumps and to detect patients with breast cancers with an overall accuracy of 98%. Modified triple assessment was useful in diagnosing breast cancers at an earlier stage, with most of breast cancers detected at stage I or stage II (T1 or T2, N0 or N1, M0). It was found that triple assessment did not require hospitalization, but was performed on OPD basis, without any complications. The modalities used are either noninvasive or minimally invasive. The sensitivity was 90.42% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 95.75%. P value was significant (0.000). Thus, Modified Triple Assessment is an easily available, cost effective, least

invasive, rapid and patient compliant diagnostic tool for diagnosis of breast lump.

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