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## A Study to investigate the accuracy of modified triple evaluation in preoperative breast lump diagnosis: A cross sectional hospital based study

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### Abstract

**Aims:** To evaluate accuracy of modified triple assessment in the preoperative diagnosis of patients with breast lump.

**Methods:** A descriptive cross sectional study was conducted in the Department of General Surgery, Shri Shankaracharya Institute of Medical Sciences, Bhilai, Chhattisgarh, India for the period of 1 year. A total of 400 patients with a breast lump were included in this study. A detailed history, focused clinical examination, radiological imaging and FNAC were used as diagnostic tools for screening of the patients.

**Results:** The most common age group in this study is 41 to 50 years of age. Mean age is  $38.66 \pm 15.26$  years. Youngest patient was of 10 years of age and oldest patient was 63 years of age. The result of individual components as overall M.T.T were tabled above and compared with the final histopathological examination. Result of physical examination showed sensitivity 90.88% and specificity 95.33% for diagnosing malignant breast lesion. The ultra-sonography revealed 89.66% of sensitivity, 97.89% of specificity. FNAC revealed that 95.75% sensitivity while specificity was 99.12%.

**Conclusions:** The modified triple test can reliably guide the evaluation and management of breast lump.

**Keywords:** Mammography, Ultrasonography, FNAC, Carcinoma, Modified triple assessment

### Introduction

The Edwin Smith Papyrus contains the earliest known written evidence of breast cancer, which dates back to 3000 to 2500 BC and comes from ancient Egypt <sup>[1, 2]</sup>. Breast cancer is becoming more common; it was claimed to have been responsible for more than a quarter (28 percent) of all fatalities in the United Kingdom in 2017 <sup>[3]</sup>. Improved cancer survival and reduced load on health-care personnel are both dependent on the development of innovative techniques for early cancer diagnosis <sup>[4]</sup>.

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 <sup>[5]</sup>. The incidence of breast cancer is increasing in the developing world due to increased life expectancy, increased urbanization and adoption of western lifestyles. Although some risk reduction might be achieved with prevention, these strategies cannot eliminate the majority of breast cancers that develop in low- and middleincome countries like India where breast cancer is diagnosed in very late stages. Therefore, early detection to improve breast cancer outcome and survival remains the cornerstone of breast cancer control. 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". Evaluation of a breast cancer starts with components of the triple test including clinical breast examination, mammography and fine needle aspiration alone or in combination, while open biopsy provides more data, it results in undesirable cosmetic problems <sup>[6, 7]</sup>. The triple assessment is taken as positive if any of the three components is positive and negative only if all of its components are negative for malignancy. The aim of our study was to the role of modified triple assessment in diagnosis of breast lump.

## Material and Methods

A descriptive cross sectional study was conducted in the Department of General Surgery, Shri Shankaracharya Institute of Medical Sciences, Bhilai, Chhattisgarh, India for the period of 1 year, after taking the approval of the protocol review committee and institutional ethics committee. After taking informed consent detailed history was taken from the patient or the relatives if the patient was not in good condition.

### Methodology

The technique, risks, benefits, results and associated complications of the procedure were discussed with all patients. The research was carried out in professorial surgical unit of Medical Hospital. All 400 patients had undergone surgery (lumpectomy, wide excision or mastectomy) and final histopathology report was included in this study. The patients without final histopathology report were excluded from this

study. The results of the individual components were compared with final histological examination.

### Statistical analysis

The recorded data was compiled entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 20 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages, means and standard deviations were calculated.

## Results

In present study as we can observe that most common age group in this study is 41 to 50 years of age. Mean age is  $38.66 \pm 15.26$  years. Youngest patient was of 10 years of age and oldest patient was 63 years of age. All patients presented with palpable breast lump as their most common symptoms.

**Table 1:** Age group with clinical diagnosis

Age Group	Clinical diagnosis		Total number	Percentage of malignant lesion
	Malignant	Benign		
Up to 20	—	31	31	0%
21-30	2	63	65	3.08%
31-40	20	61	81	24.69%
41-50	74	56	130	56.92%
51-60	35	25	60	58.33%
Above 60	19	14	33	57.58%
Total	150	250	400	37.5%

**Table 2:** Age group with ultrasonographic findings

Age Group	Ultrasonographic finding		Total number	Percentage of malignant lesion
	Benign	Malignant		
Up to 20	31	—	31	0%
21-30	66	2	68	2.94%
31-40	67	18	85	21.17%
41-50	56	69	125	55.20%
51-60	25	32	57	56.14%
Above 60	15	19	34	55.88%
Total	260	140	400	35%

**Table 3:** Overall findings by the components of Triple Test

Type of lesion	Clinical diagnosis	USS	FNAC/Core biopsy	Histopathology
Benign	250	260	258	248
False negative	11	9	5	
Malignant	150	94	142	152
False positive	9	8	02	

**Table 4:** Benign lesions: ultrasonographic finding

Ultrasonic diagnosis	Number of Diagnosis=260	Percentage among all benign lesion=260	Percentage among overall breast lesion=400
Fibro adenoma/Giant fibroadenoma	140	53.85%	35%
Fibrocystic disease	75	28.85%	18.75%
Inflammatory lesion	29	11.15%	7.25%
Cystic lesion	16	6.15 %	4%

**Table 5:** FNAC/Core biopsy and Histopathological confirmation

	FNAC/Core biopsy	Histopathological confirmation
Fibro adenoma	126	129
Fibrocystic	81	71
Inflammatory	28	32
Cystic	23	16
Carcinoma	142	152

**Table 6:** Specificity and Sensitivity of test

Category	Sensitivity	Specificity	PPV	NPV
Clinical diagnosis	90.88%	95.33%	94.12%	94.87%
Ultrasono graphic finding	89.66%	97.89%	95.66%	95.89%
FNAC/ Corebiopsy	95.75%	99.12%	99.36%	94.22%

The result of individual components as overall M.T.T were tabled above and compared with the final histopathological examination. Result of physical examination showed sensitivity 90.88% and specificity 95.33% for diagnosing malignant breast lesion. The ultra-sonography revealed 89.66% of sensitivity, 97.89% of specificity. FNAC revealed that 95.75% sensitivity while specificity was 99.12%.

### Discussion

To reliably detect all palpable breast tumours, doctors now utilise a combination of three procedures, namely a clinical examination, radiological imaging (mammography, ultrasound, and FNAC (pathology), all of which are referred to as the modified triple assessment (MTA).

When two or more of the three components of the triple assessment are positive for malignancy or a positive component of FNAC, the triple assessment is considered positive; otherwise, it is considered negative only if all of its components are negative for malignancy.

Mammography is a critical component in the diagnosis and monitoring of breast cancer in women. Its purpose is to describe and identify the extent of the mass, as well as to assess the breast for the presence of an occult lesion [8, 9].

The sensitivity of diagnostic mammography has been reported in most studies to be around 90% and specificity about 88% [8, 10-12]. The known false negative rate of mammography is between 8% and 10% [10]. In modified triple test, mammography has been substituted by ultrasonography. Breast ultrasound has been found to be an adjuncts to mammography in breast examination [13, 14]. Ultrasonography shows 93.1% sensitivity, 95% specificity, 93.1% positive predictive value [9, 13]. For clinical examination, Yang *et al.* (1996) reported a sensitivity, specificity and positive predictive value as 88%, 92%, and 67% respectively [15]. Current study revealed a higher sensitivity and specificity for clinical examination. However the results depend on the experience of the surgeon who is doing the examination. On a experienced hand, the clinical examination alone is a valuable test for diagnosing breast cancer. Like clinical examination, the results of ultrasonography is also depends on the competency of radiologists. On a study done by Manisha *et.al* the concordance for histopathology was 96.7% and sensitivity was 100%, specificity was 96.4%, positive predictive value was 66.7%, and negative predictive value was 100%. [10] Pande *et al.* have done a study which revealed the sensitivity, specificity, positive predictive value and negative predictive value as 95%, 94.10%, 95.50% and 93.75% respectively [16]. The current study revealed a better values for ultrasonography like above studies. Sensitivity- 89.66%, Specificity-97.89%, positive predictive value- 95.66% and negative predictive value- 95.89%. On the same study, Dr. Manisha Nigam [10] found that concordance for FNAC was 97.3%, sensitivity was 100%, specificity 97.1%, positive predictive value was 86.7% and negative predictive value was 100%. Mohammed *et al.* found that FNAC had a positive predictive value of 100%, sensitivity of 96.6% and specificity of 100% [17]. In our study FNAC had a Sensitivity- 95.75%, Specificity-99.12%, positive predictive value- 99.36% and negative predictive value- 94.22%. The current study concluded that FNAC is the best among all other

components of MDT. The final diagnosis was made based on the histopathological findings which identified 103 breast lesions as malignant lesion. Among them, only one had the negative results for all components of MDT (%). It reflects that MDT can be used as a diagnostic tool for breast cancer in clinical setting.

### Conclusion

The modified triple evaluation is a fairly accurate diagnostic technique for evaluating individuals with breast masses and detecting breast malignancies. The modified triple evaluation helped identify most breast tumours in stage I or II. It was found that triple assessment did not require hospitalization, but was performed on OPD basis, without any complications. The techniques employed are non- or minimally invasive. Thus, Modified Triple Assessment is a simple, non-invasive, quick, and patient-friendly approach for diagnosing breast lumps.

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