

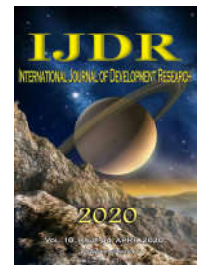


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'TRIPPLE TEST SCORE' – A RELIABLE AND ACCURATE MEANS OF RAPID DIAGNOSIS OF BREAST LUMPS

¹Deepa P. Jahagirdar and ^{*2}Sneha G. Ramteke

¹Associate Professor, Department of General Surgery, Govt. Medical College, NAGPUR

²Senior Resident, Department of General Surgery, Govt. Medical College, NAGPUR

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**Corresponding author: Sneha G. Ramteke,*

ABSTRACT

Introduction: In Breast cancer there is paradigm shift towards its prevention and early detection. Currently a combination of three tests, i.e. physical examination (PE), sonomammography (MM) and Fine needle aspiration cytology/biopsy (FNAC) called as triple assessment test, is used as Gold standard in diagnosing all palpable breast lumps. **Materials and Methods** This study was conducted in the Department of General Surgery, Government Medical College, Nagpur, spanning 2 years from June 2015 to November 2017. A total of 100 patients with a palpable breast lump of age ≥ 35 years were evaluated. A detailed history, thorough PE, MM and FNAC were used as diagnostic tools to screen the patients. The aim was to evaluate accuracy of triple assessment in early diagnosis of breast lump. **Outcome measures:** physical examination, mammography, and FNAC were each assigned a score of 1, 2, or 3 for benign, suspicious and malignant results; the triple test score (TTS) is the sum of these scores. The TTS has minimum score of 3 (concordant benign) and maximum score of 9 (concordant malignant). **Results:** the TTS ≤ 4 were benign on final biopsy (100% specificity) and a TTS ≥ 6 turned out to be malignant on final biopsy (100% sensitivity).

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INTRODUCTION

The commonest clinical presentation in majority of breast pathology is a lump. A breast lump may be either benign or malignant. Distinction of benign from malignant is of paramount importance for patient care and management. Physical, psychological and financial cost of investing benign breast disease, primarily to exclude malignancy are substantial. The accuracy of diagnosis of breast carcinoma on physical examination is only 70% even in the most experienced hands⁽¹⁾. To come to a definitive diagnosis, clinical judgement needs to be supported by specialized investigations. The two techniques currently available that have excellent patient tolerability are mammography and fine needle aspiration cytology^{(2),(3)}. There are numerous reports which emphasize that if clinical examination, mammography and fine needle aspiration are combined which is known as 'Triple Test', the accuracy of diagnosis reaches 100%⁽⁴⁾. The objective of this study is to determine the efficacy of 'Triple test score' in evaluation of breast lump.

MATERIALS AND METHODS

The present study was a prospective study conducted on females over 35 years of age having palpable breast lump, presenting in Outpatient department of General surgery, Government Medical College, Nagpur. Duration of study was from June 2015 to Nov 2017 and a total of 100 cases were studied. The cases were taken consecutively without any selection bias provided they satisfied eligibility criteria. Each patient were subjected to clinical examination, mammography and fine needle aspiration in that order with subsequent histopathologic study of biopsy specimen.

Inclusion Criteria

- 1) All female patient presenting to surgery OPD of age more than 35 years with palpable breast lump
- 2) Cases in which all the three components of triple test are studied.

Exclusion Criteria

- 1) Patients with mass clinically larger than 4cm, or skin retraction and palpable axillary lymph nodes
- 2) Patients having ulcerated and fungating growth
- 3) Patients with inflammatory breast lesions
- 4) Pregnant females

Informed consent was taken for physical examination and investigations, giving due respect to maintain the patients privacy and keep her comfortable; the study was approved by the Ethical committee of Institute.

Algorithm

Every component of each individual test was assigned a score of 1, 2, or 3 points for benign, suspicious or malignant finding. The Triple test was scored as concordant if the elements had either all malignant or all benign results. It was nonconcordant if the elements had neither all malignant nor all benign results. Triple test was scored benign or malignant depending upon the results of 2 variables of TT(triple test) , which means it was scored benign if two variables gave benign results and vice-versa.

Statistical Analysis

Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of each test for the TTS and its components were determined from the standard formulas as follows:

$$\begin{aligned} \text{Sensitivity} &= \text{TP}/\text{TP}+\text{FN} \\ \text{Specificity} &= \text{TN}/\text{TN}+\text{FP} \\ \text{PPV} &= \text{TP}/\text{TP}+\text{FP} \\ \text{NPV} &= \text{TN}/\text{TN}+\text{FN}; \end{aligned}$$

where TP-true positive, TN-true negative, FP- false positive, FN- false negative, PPV- positive predictive value, NPV- negative predictive value.

The kappa statistic was calculated for each individual methods and their combination. TTS (triple test score) has minimum score 3 (concordant benign) and maximum score of 9 (concordant malignant).

RESULTS

Table 1. Age wise distributions of breast lump

	35-40yrs	41-50yrs	51-60yrs	MORE THAN 60yrs
BENIGN	43	19	01	00
MALIGNANT	09	18	07	03
TOTAL	52	37	08	03

Table 1 shows that as age increases, the incidence of lump being malignant increases. In this study population, 63 females had benign breast lump and remaining 37 had malignant lump as shown in Fig 1. Table 2 shows that majority of females presented with breast lump and then with pain.

Table 2. Clinical presentation of study population

	lump	pain	discharge
Benign	50	10	03
Malignant	32	04	01

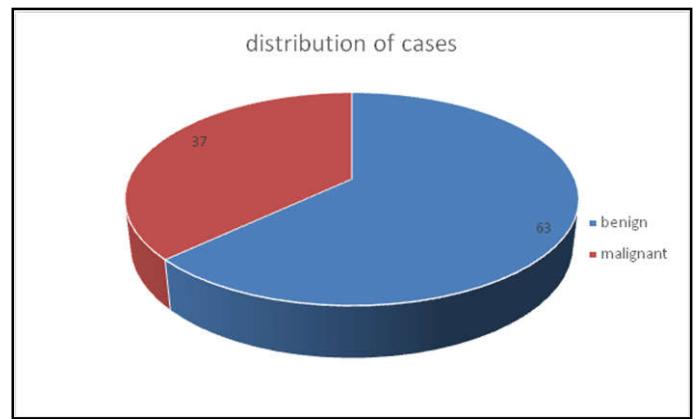


Fig. 1. Distribution of cases

Our study shows benign lesions were more common in premenopausal group and malignant lesions were more common in postmenopausal group. Only 3 patients included in our study were nulliparous (2-benign, 1-malignant) and rest of the 97 were multiparous. This study shows that both benign and malignant lumps were more common in left breast as shown in fig 2.

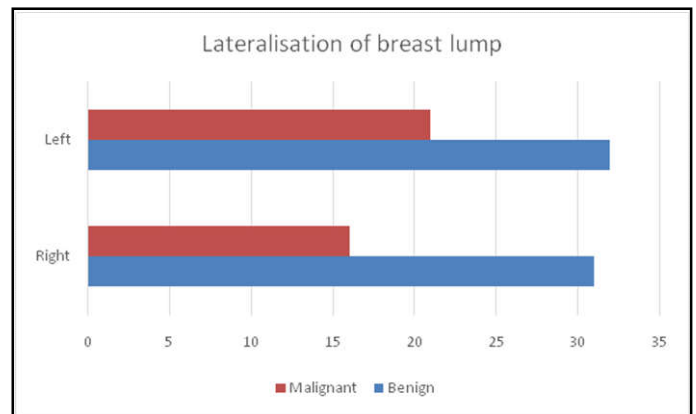


Fig. 2. Lateralisation of breast lump

Table 3. Lump size

	<1cm	1-2cm	2-3cm	3-4cm
Benign	1	6	19	37
Malignant	0	4	11	22

Table 3 shows that 59 females had breast lump of size 3-4cm, of which 22 were found malignant. Both benign and malignant lumps were most commonly found in upper outer quadrant as shown in Fig 3.

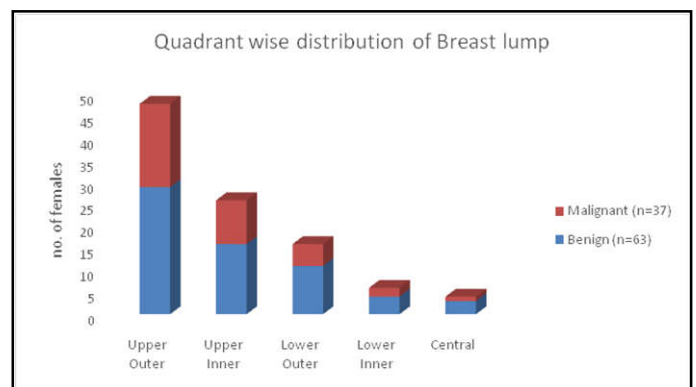


Fig. 3. Quadrant wise distribution of breast lump

Table 4. Sensitivity and specificity of Physical examination, Mammography, FNAC and Triple Test

no. of cases Diagnosis	Physical Examination (PE)	Mammography (MM)	Fine Needle Aspiration Cytology (FNAC)	Triple Test (TT)
TP	35	36	36	36
FP	06	04	01	01
TN	57	59	62	62
FN	02	01	01	01
Sensitivity	94.59%	97.29%	97.29%	97.29%
Specificity	90.47%	93.65%	98.41%	98.41%

Table 4 shows that combined sensitivity of triple test in this study was 97.29% and specificity was 98.41%.

Table 5. Evaluation of Triple Test Score

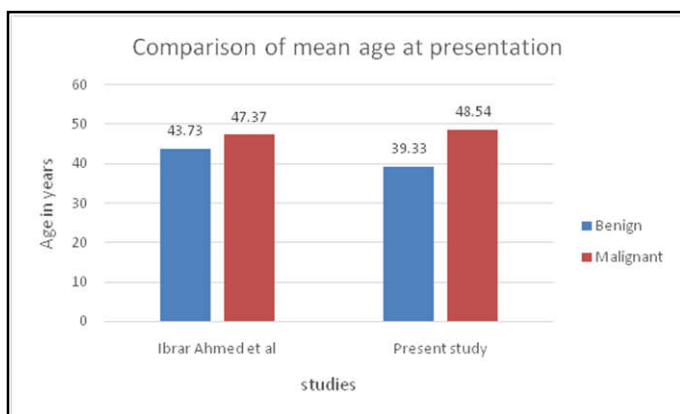
No. of cases	PE	MM	FNAC	TTS	HPE
51	B	B	B	3	B
31	M	M	M	9	M
05	S	B	B	4	B
04	B	S	B	4	B
01	S	B	S	5	B
02	B	B	S	4	B
01	B	B	M	5	M
03	M	M	S	8	M
01	M	M	B	7	M
01	B	S	M	6	M

(B- benign; S- suspicious; M- malignant; HPE- histopathological examination)

Table 5 shows calculation of triple test score by various components. It shows that TTS with score more than 6 were malignant on final biopsy reports and so was a concordant malignant. TTS with score of less than or equal to 3 were benign on final biopsy specimen- concordant benign. TTS score of 5 required confirmatory biopsy for diagnosis. Table 6 shows that sensitivity and specificity of triple test score is 100% and accuracy of the test was 100%. So it can be used as an ideal tool for diagnosing breast lumps.

Table 6. Accuracy of triple test and its components

	PE	MM	FNAC	TT	TTS
Sensitivity	94.59	97.29	97.29	97.29	100
Specificity	90.47	93.65	95.23	98.41	100
PPV	85.36	90.00	92.30	97.29	100
NPV	96.61	98.33	98.36	98.41	100
Accuracy	92	95	96	98	100
Error	08	05	04	02	00
Kappa	0.832	0.894	0.915	0.957	1



Ibrar Ahmed et al⁽⁵⁾

Fig. 4. Comparison of mean age of presentation

DISCUSSION

This study shows mean age of presentation of females with benign breast lump was 39.33 yrs and for malignant lump was 48.54 yrs as shown in Fig 4.

Table 7. Comparison of sensitivity and specificity of physical examination(PE), Mammography(MM) and FNAC

	Sensitivity			Specificity		
	PE	MM	FNAC	PE	MM	FNAC
Mokri M et al ⁽⁶⁾	87%	93.5%	89%	86%	79%	90%
Katherine T et al ⁽⁷⁾	87%	91%	92%	80%	78%	96%
Arden Morris et al ⁽⁸⁾	92%	96%	96%	66.7%	66.7%	100%
Mande N et al ⁽⁹⁾	99.3%	73.1%	73.9%	68.2%	98.5%	98.5%
Our study	94.59%	97.29%	97.29%	87.30%	93.65%	95.23%

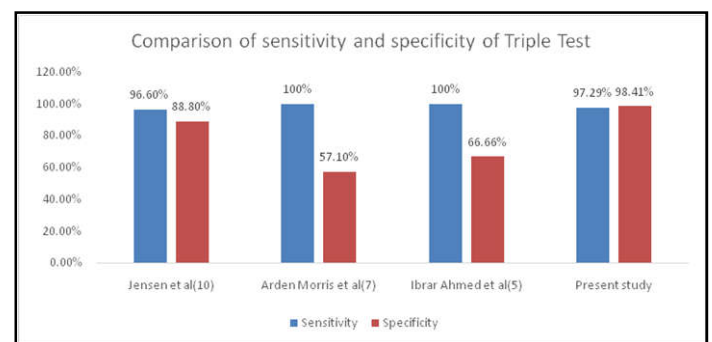


Fig. 5. Comparison of sensitivity and specificity of triple test

Sensitivity and specificity of triple test in present study was 97.29% and 98.41% respectively as shown in Fig 5.

Table 8. Comparison of sensitivity and specificity of Triple Test Score

	Sensitivity	Specificity
Mokri M et al ⁽⁶⁾	98%	100
Katherine T et al ⁽⁷⁾	100	100
Arden Morris et al ⁽⁸⁾	100	100
Mande N et al ⁽⁹⁾	100	100
Present study	100	100

Thus it is clear that when the triple test is concordant it has high diagnostic accuracy approaching 100% and can be considered as 'standard diagnostic method' to evaluate palpable breast lump. Definitive treatment can be started if the triple test is concordant for benign or malignant.

Conclusion

Triple assessment is a powerful clinical tool that permits rapid, minimally invasive and accurate diagnosis of breast malignancies. Triple assessment did not require hospitalization and was performed on OPD basis, without any complications. We found that sensitivity and Specificity of Triple Test Score with regard to histopathology was 100% in our study. The management of disease of breast is a multidisciplinary endeavour dependent on skill and expertise of clinical specialists. The study also highlights the fact that CBE is quite effective as a screening tool for carcinoma breast and is still relevant as an investigation, specially in developing countries, where cost of the treatment is an issue.

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Conflict of interest – none to be declared.

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