

Original Research Article

Diagnostic evaluation of triple test in detection of breast lesions

Sanjay R. Gaikwad¹, Mahesh C. Talpallikar^{1*}, Jyoti K. Tapadia², Anand S. Gajakos²

¹Department of General Surgery, ²Department of Radiology, Ashwini Rural Medical College, Hospital & Research Centre, Kumbhari, Solapur, Maharashtra, India

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***Correspondence:**

Dr. Mahesh C. Talpallikar,

E-mail: mahesh139@rediffmail.com

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ABSTRACT

Background: Detection of malignant lesion leads to early initiation of definitive treatment or its exclusion saves the patient from unnecessary medication and psychological trauma. It is difficult to establish the nature of the lesion merely on the clinical examination. So “triple” test is suggested, which is a mixture of clinical examination, mammography and FNAC.

Methods: The results of clinical examination, mammography and FNAC were compared with those of histopathological examination. The concordant results of the “triple test” were compared with those of the histopathological examination. Sensitivity, specificity, positive and negative predictive values were calculated for each of these tests and for “triple test”.

Results: The sensitivity, specificity, positive predictive value and negative predictive value of clinical examination in this study were 74.36%, 88.70%, 69.05% and 91.07%. The same parameters of mammography were 92.31%, 93.91%, 83.72% and 97.30%. For FNAC, the same values were 92.31%, 93.04%, 81.82% and 97.27%. The triple test was concordant in 115 lesions, while results of 39 lesions were discordant in triple test. Out of 115 concordant results, 27 results were malignant on all the three tests while 88 results were benign on all the three tests. All the concordant results of triple test were similar to the results of histopathology examination.

Conclusions: The triple test can diagnose malignant breast lesion with 100 % accuracy, at least in concordant results.

Keywords: Breast lesions, FNAC, Mammography, Triple test

INTRODUCTION

Majority of the breast pathologies initially present as a lump. It is important to establish a definitive diagnose of the lump, as it can be a malignant lesion. Detection of malignant lesion leads to early initiation of definitive treatment or its exclusion saves the patient from unnecessary medication and psychological trauma. It is difficult to establish the nature of the lesion merely on the clinical examination. If only clinical examination is done, the chances of accurate detection of the nature of the lump are only 70%.¹ To increase the accuracy of the diagnosis, physical examination must be supported by laboratory and radiological investigations. There are

many techniques available, which can help in establishing the definitive diagnosis. Three of these tests are commonly used, mammography, ultrasonography and fine needle aspiration cytology (FNAC). However, the diagnostic accuracy of these tests, individually, is reported to be 82%, 82%, 78% respectively.²⁻⁴ However if these tests are combined then the accuracy can be significantly increased, almost reaching to 100%. The combination of clinical examination, mammography and fine needle aspiration cytology (FNAC) is referred as “triple test”, and its diagnostic accuracy is reported to be almost 100%.⁵⁻⁸

Another combination of tests, clinical examination, ultrasonography and FNAC / core biopsy is known as

“modified triple test”, and its diagnostic accuracy is also as high as 100%.^{9,10} However all these studies were conducted in urban population and majority are conducted in developed country.

The diagnostic performance of “triple test” has not been tested in rural Indian population. So, the study was planned to evaluate the diagnostic accuracy of clinical examination, mammography and fine needle aspiration cytology (FNAC) individually and as a “triple test”.

METHODS

The present hospital-based study was conducted in the department of General Surgery, Ashiwini Rural Medical College, Hospital and Research Centre, Solapur. Inclusion and exclusion criteria for the study subjects were as follows.

Inclusion criteria

- Women, above the age of 30 years, presenting with a palpable lump in breast.
- Women, who are ready to participate in the study and give consent for all the diagnostic tests under “triple test” and biopsy for histopathological examination.

Exclusion criteria

- Pregnant women
- Women presenting with breast abscess
- Lumps with ulcerations, necrosis or other major skin lesions involving breast area.

Included women were initially clinically examined and then mammography as well as FNAC was done. During the mammography standard views - Cranio-caudal (CC) and medio-lateral oblique (MLO) views were taken for all the subjects. Additional views were also taken wherever necessary.

Each of the result was classified into any one of these three categories, benign, malignant and suspicious. All suspicious results were finally included in the category of malignant lesions.

The results of clinical examination, mammography and FNAC were compared with those of histopathological examination. “Triple test” was considered as concordant, only if all the three results were same, as malignant or benign. If any of these three results were different than the other two, then “triple test” was considered as discordant.

The concordant results of the “triple test” were compared with those of the histopathological examination. Sensitivity, specificity, positive and negative predictive values were calculated for each of these tests and for “triple test”.

Kappa statistics, a measure for inter-rater agreement (here, agreement between gold standard and the test) was calculated for each of these tests.¹¹

RESULTS

Total of 154 women with same number of breast lesions were included in the study. Table 1 shows the age-wise distribution of the patients. The mean age of the patients was 43.53±7.38. Maximum patients were in the age group of 40 -44 followed by 45-49.

Table 1: Age wise distribution of the patients presenting with breast lesions.

Age Group	Number	Percentage
30 - 34	13	8.44
35 - 39	15	9.74
40 - 44	39	25.32
45 - 49	37	24.03
50 - 54	35	22.73
> 55	15	9.74

Table 2: Comparison of clinical examination and histopathology results.

		Histopathology results		
		Malignant	Benign	Total
Clinical examination	Malignant	29	13	42
	Benign	10	102	112
	Total	39	115	154

Histopathological examination of 154 lesions confirmed that 115 lesions were benign and remaining 39 lesions were malignant. However, clinical examination detected 42 lesions as malignant, which included 13 false positive results and remaining 29 were true positives. Table 2 shows the comparison of the clinical examination and histopathological examination. The sensitivity, specificity, positive predictive value and negative predictive value of clinical examination in this study were 74.36%, 88.70%, 69.05% and 91.07%. The overall accuracy of clinical examination was found to be 85.06%. The kappa coefficient for agreement between clinical examination and golden test was 0.615±0.073.

Table 3: Comparison of mammography results and histopathology results.

		Histopathology results		
		Categories	Malignant	Benign
Mammography	Malignant	36	7	43
	Benign	3	108	111
	Total	39	115	154

Table 3 shows the comparison of the results of mammography and gold standard. Mammography detected 43 lesions as malignant, which included 7 false positive results. The sensitivity, specificity, positive predictive value and negative predictive value of mammography were 92.31%, 93.91%, 83.72% and 97.30%. The overall accuracy of clinical examination was found to be 93.51%. The kappa coefficient for

agreement between clinical examination and golden test was 0.834±0.051.

Table 4: Comparison of FNAC results and histopathology results.

		Histopathology results			
		Categories	Malignant	Benign	Total
FNAC	Malignant		36	8	44
	Benign		3	107	110
	Total		39	115	154

Table 4 shows the comparison of the results of FNAC and gold standard. FNAC detected 44 lesions as malignant, which included 8 false positive results. The sensitivity, specificity, positive predictive value and negative predictive value of FNAC were 92.31%, 93.04%, 81.82% and 97.27%. The overall accuracy of clinical examination was found to be 92.86 %. The kappa coefficient for agreement between clinical examination and golden test was 0.819±0.052.

Table 5: Comparison of concordant triple test results and histopathology results.

		Histopathology results			
		Categories	Malignant	Benign	Total
Triple test	Malignant		27	0	27
	Benign		0	88	88
	Total		27	88	115

The triple test was concordant in 115 lesions, while results of 39 lesions were discordant in triple test. Out of 115 concordant results, 27 results were malignant on all the three tests while 88 results were benign on all the three tests. All the concordant results of triple test were similar to the results of histopathology examination. Thus sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy of triple test, for concordant results, were 100%.

DISCUSSION

The triple test is the evaluation of palpable breast masses by physical examination, mammography, and fine-needle aspiration (FNA) in women.¹² The present study was planned to evaluate the diagnostic efficacy of “triple test” in detection of malignant breast lesions. The study has showed that the sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy of “triple test” for concordant results were found to be 100 %. Previous studies conducted in different settings have also reported the same results of the triple test.^{5,13-15}

In the present study, sensitivity and specificity of diagnostic clinical examination was found to be 74.36% and 88.70% which is in accordance with the most of published series.^{5,16} For mammography, sensitivity and specificity of diagnostic was found to be 92.31% and

93.91% which is similar findings of the most of published studies.^{5,17,18} And for FNAC, sensitivity and specificity of diagnostic was found to be 92.31% and 93.04% which is in agreement with previous studies.^{5,13,19}

However, the study has revealed that the concordant results were possible in only 115 out of 154 lesions, i. e. in 74.68% lesions. So, the results of the triple test could be interpreted in only 74.68% of lesions. Remaining 25.32% lesions gave discordant results, so no interpretation could be drawn in these lesions. Almost similar findings were obtained study done by Kharkwal et al.⁵

CONCLUSION

Nevertheless, the study proved that the triple test is a useful diagnostic tool which can be used in almost three fourth of the breast lesions, for the accurate identification of malignant lesion.

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