



Diagnostic accuracy of triple assessment in palpable breast lump

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Abstract

Background: Breast diseases constitute a heterogeneous group of lesions including developmental abnormalities, inflammatory lesions, epithelial and stromal proliferations, and neoplasms. With the use of clinical examination, mammography and fine needle aspiration cytology (FNAC), the diagnosis of a benign breast disease can be accomplished without surgery in the majority of patients. Combined use of these diagnostic procedures (Triple assessment) gives nearly the same degree of accuracy as excisional biopsy in patients with palpable breast diseases. Currently a combination of three tests, i.e. clinical examination, radiological imaging (mammography, ultrasonography) and pathology called as triple assessment test is used to accurately diagnose all palpable breast lumps¹. The Triple Test Score (TTS) was developed to help physicians interpret discordant triple test results. A three-point scale is used to score each component of the triple test (1 = benign, 2 = suspicious, 3 = malignant). A TTS of 3 or 4 is consistent with a benign lesion; a TTS of 6 or more indicates possible malignancy that may require surgical intervention. Excisional biopsy is recommended in patients with a TTS of 5 to obtain a definitive diagnosis².

Materials and methods: The study was conducted for diagnostic accuracy of triple assessment in palpable breast lump in 50 patients. The components of the Triple Assessment are: Clinical examination (C/E), Mammography/ultrasonograph and Fine Needle Aspiration Cytology (FNAC). The diagnostic accuracy of triple assessment was reached by comparing the results of this test with gold standard i.e. histopathological findings.

Results : The TT was concordant in 46 cases (92%). In 17 of these lesions (34%), the results of TT were interpreted as benign and subsequently were proved to be benign pathologies histologically with NPV and Specificity of 100%. Similarly, in 29 cases (58%) the results of all elements of TT were interpreted as malignant, which proved to be malignant lesions on histopathological examination and the sensitivity and PPV were 100%. TT elements were non concordant in 4 cases (8%), 3 of these cases were proved to have malignant masses and the remaining 1 case was proved to be benign on subsequent histopathological examination. In all the non concordant cases, where at least one of the elements was considered benign, FNAC was the most accurate with 0 false negative and 0 false positive results.

Conclusion: The TT has proved to be accurate, reliable diagnostic approach for evaluation of breast masses, achieved (100%) accuracy rate when all elements were concordant or when all elements were either suspicious or malignant. The study shows that when TT is concordant, final treatment may be ensued without open biopsy. In non-concordant

cases, FNAC stands as single most important investigation. However due to its false negative results, other components of triple test need to be employed to enhance its efficacy and diagnostic yield.

Keywords: palpable breast lump, triple assessment, triple test score

Introduction

Breast diseases, with its uncertain cause, have captured the attention of surgeons throughout the ages. Breast lump is a very sensitive issue for the patient so a reliable, non invasive and prompt diagnosis helps to lessen the associated anxiety and leads to early definitive treatment.³ The tools for clinical diagnosis i.e. history, clinical breast examination, FNAC, and diagnostic mammography provide valuable information and play important supplemental roles in ascertaining the presence of breast cancer.⁴

For patients who present to clinicians with palpable breast lesions, the triple test: (physical examination, mammography and fine-needle aspiration cytology) can be employed to provide accurate diagnosis⁵. The diagnostic value of aspiration cytology and the overall diagnostic quality of the so-called triple test (aspiration cytology, mammography and physical examination) helps in the evaluation of palpable breast masses. The triple test score (TTS) reliably guides evaluation and treatment of palpable breast masses.⁶

Jane M et al found that the sensitivity and specificity of all the modalities used in triple assessment when combined together was 100% and 99.3%, respectively. The concordance for the triple assessment was 99.3%, positive predictive value was 93.3%, negative predictive value was 100%, sensitivity was 100% and specificity was 99.3%. p value was significant (0.000).⁷

Hider P et al in their study included 232 studies, of which 33 focused on evaluating diagnostic tools for identifying breast cancer (5 on fine-needle aspiration, 6 on the triple test, 6 on core biopsy and 7 on scintigraphic imaging). They concluded that triple testing with mammography, fine-needle aspiration and clinical examination is more accurate than any of the tests alone.⁸

Materials and Methods

The prospective cross sectional study was done in the Department of Surgery at Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar. After approval from hospital ethics committee, a prior written consent was taken from all the patients. The inclusion criteria were all female patients presenting in the Surgical OPD with a clinically palpable breast lump. These patients were subjected to triple assessment i.e. Step 1: Clinical assessment; Step 2: Mammography for patients aged more than 30 years and sonomammography for patients less than 30 years old; Step 3: FNAC. The findings of these were graded by a scoring system as follows: Clinical examination:

- 1: Benign lump
- 2: Suspicious lump
- 3: Malignant lump

Ultrasonography(>30years)
& Sonomammography(<30years) :

- 1: Benign lump
- 2: Suspicious lump
- 3: Malignant lump

FNAC:

- 1: Benign lump
- 2: Suspicious lump
- 3: Malignant lump

This grading was further used to group the patients into benign, suspicious or malignant breast lumps. This final result was compared and co-related with the histopathological findings, and hence the diagnostic accuracy of triple assessment was assessed.

Results

Incidence of various lesions in relation to the histopathology reports

In the present study, malignant breast disorders 32 (64% of the cases) accounted for majority of breast lumps in which, infiltrating ductal carcinoma had the lead with 29 (90%) cases

followed by 2 cases of invasive lobular carcinoma (6.25%) and mucinous carcinoma of 1 case (3.12%) only. Most common benign lesion was fibroadenoma constituting 7 cases (14%) followed by 5 cases (10%) of fibrocystic disease and then by 2 cases (4%) of fibroadenosis. Only 1 case (2%) each of inflammatory, intraductal papilloma, sclerosing adenosis and duct ectasia were found.

Table 1 Incidence of various lesions in relation to the histopathology reports

Types of lesions	No. of cases	Percentage (%)
Fibroadenoma	7	14
Fibroadenosis	2	4
Fibrocystic disease	5	10
Inflammatory	1	2
Intraductal papilloma	1	2
Sclerosing adenosis	1	2
Duct ectasia	1	2
Infiltrating ductal carcinoma (IDC)	29	58
Invasive lobular carcinoma	2	4
Mucinous carcinoma	1	2
Total	50	100

Results of triple tests for (50) palpable breast lesions and histopathology confirmation

The TT was concordant in 46 cases (92%). In 17 of these lesions (34%), the results of TT were interpreted as benign and subsequently were proved to be benign pathologies histologically with NPV and Specificity of 100%. Similarly, in 29 cases (58%) the results of all elements of TT were interpreted as malignant, which proved to be malignant lesions on histopathological examination and the sensitivity and PPV were

100% TT elements were non concordant in 4 cases (8%), 3 of these cases were proved to have malignant masses and the remaining 1 case was proved to be benign on subsequent histopathological. In all the non concordant cases, where at least one of the elements was considered benign, FNAC was the most accurate with 0 false negative and 0 false positive results. The detailed description of grading, triple test score and final diagnosis on histopathology of all concordant and non concordant cases is given in table 10.

Table 2 Results of triple tests for palpable breast lesions and histopathology confirmation

TT Results		No. of lesions	Histopathology results		Total	
			Benign	Malignant	NO.	%
Concordant	BENIGN	17	17	0	17	34
	MALIGNANT	29	0	29	29	58
Non concordant	SUSPICIOUS	4	1	3	4	8
Total			18	32	50	100

True Positive – 32
 False positive – 0
 True Negative – 18
 False Negative – 0
 Sensitivity – 100 %
 Specificity – 100 %
 Positive Predictive Value – 100 %
 Negative Predictive Value – 100 %
 Accuracy – 100%

Table 3 Triple test score of concordant and non concordant cases

No. of cases	Clinical examination	Imaging	FNAC	TTS	Histopathology
17	1	1	1	3	Benign
29	3	3	3	9	Malignant
1	1	2	3	6	IDC
1	1	2	3	6	IDC
1	1	2	1	4	FA
1	1	2	3	6	IDC

Analysis of triple test and its components

FNAC was found to be the most accurate element of triple assessment in which sensitivity, specificity, positive predictive value, negative predictive value and accuracy were found to be 100%. The sensitivity of clinical breast

examination and imaging were found to be 90.6% and 96.9% respectively and negative predictive value was 85.71% and 94.4% respectively. Both clinical breast examination and imaging had the specificity and positive predictive value of 100% each.

Table 4 Analysis of triple test score (TTS) and its components for 50 cases of palpable breast lumps

Measure	CBE	Imaging	FNAC	TTS
Sensitivity	90.62	96.97	100	100
Specificity	100	100	100	100
PPV	100	100	100	100
NPV	85.71	94.44	100	100
Accuracy	94	98	100	100



Figure 1 showing PEAU'D ORANGE



Figure 2 showing NIPPLE RETRACTION



Figure 3 showing BREAST LUMP AND NIPPLE DEVIATION

Discussion

The main objective of the present study was to become conversant with percentage of various types of breast disorders including both benign and malignant on the basis of clinical breast examination, imaging technology and fine needle aspiration cytology.

A total of 50 female patients presenting to the surgery department with breast lump were studied by all the three components of triple test. All the cases underwent lumpectomy/ quadrantectomy/ mastectomy for histopathological confirmation of diagnosis. The TT components (clinical breast examination, imaging technology, fine needle aspiration cytology) were categorized as benign, suspicious and malignant. Each component is designated as benign, suspicious and malignant and rated as 1, 2 and 3 respectively. TTS is the sum of these scores with a minimum score of 3 (3-4; concordant benign) and a maximum score of 9 (6-7; concordant malignant), 5 having intermediate risk needing further evaluation before any definitive treatment.

TT was considered concordant when all three elements indicated benign or all three elements indicated malignant. The findings were correlated as triple assessment and compared with histopathology reports.

In the present study, malignant breast disorders 32 (64% of the cases) accounted for majority of breast lumps in which, infiltrating ductal carcinoma had the lead with 29 (90%) of total malignant cases followed by lobular carcinoma 2 (6.25%) and mucinous carcinoma of 1 case (3.12%) only.

These findings are similar to the study of Khokher S et al in which infiltrating ductal carcinoma was found in 91% of the total malignant cases followed by lobular carcinoma and then by mucinous carcinoma.⁹

Also in the study of Saleem KN, IDC was the most common malignant pathology and constituted (76%) of all malignant masses followed by lobular carcinoma which formed

(12%). For benign masses, fibroadenoma was the predominant lesion, formed (28%) of all benign masses followed by fibrocystic disease (22.8%).¹⁰

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TT elements were non concordant in 4 cases (8), 3 of these cases were proved to have malignant masses and the remaining 1 case was proved to be benign on subsequent histopathological. In all the non concordant cases, where at least one of the elements was considered benign, FNAC was the most accurate with 0 false negative and 0 false positive results.

More or less similar results were seen in the study of Jan M et al in which the concordance for the triple assessment was 99.3%, positive predictive value was 93.3%, negative predictive value was 100%, sensitivity was 100% and specificity was 99.3%.⁷

Also in the study of Nigam M et al the concordance for the triple assessment was 99.3%, positive predictive value was 93.3%, negative predictive value was 100%, sensitivity was 100% and specificity was 99.3%.

The sensitivity, specificity, positive predictive value, negative predictive value was found to be 100% in the study of Chalaya PL et al.¹¹

Also Saleem KN¹⁰ found FNAC to be the most reliable element of TT in cases where the elements of TT were non concordant.

Another study was done by Veto J et al in which all 21 cases where the triple test was concordant (elements had either all malignant or benign results), open biopsy was confirmatory (negative predictive value and sensitivity both 100%). Fine-needle aspiration was the most reliable element of the triple test in cases where the elements of the

test were non-concordant (negative predictive value and sensitivity of 95% and 96%, respectively), followed by mammogram and then by physical examination.¹²

In the study of Nigam et al the sensitivity and specificity of all the modalities used in triple assessment when combined together was 100% and 99.3%, respectively. The concordance for the triple assessment was 99.3%, positive predictive value was 93.3%, negative predictive value was 100%, sensitivity was 100% and specificity was 99.3%. p value was significant (0.000).¹³

Sharma P et al in their study found that out of clinical breast examination, mammography and/or ultrasonography, and fine needle aspiration cytology, diagnostic accuracy of the latter was highest (100%). The Triple Test Score had a diagnostic accuracy of 98.33% and sensitivity, specificity, positive predictive value and negative predictive value of 100% each. The Triple Test was correlated with biopsy reports and yielded comparable diagnostic accuracy.¹⁴

Lingaraju N in their study found that 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 99.3%. When the lumps are palpable clinically and of size more than 2 cm fine-needle aspiration cytology itself has a sensitivity of 100%. The triple assessment did not require hospitalization, can be performed on OPD basis, without any complications and it is the gold standard diagnostic tool for the palpable breast lumps in early detection of malignancy avoiding biopsies.¹⁵

Conclusion

The TT has proved to be accurate, reliable diagnostic approach for evaluation of breast masses, achieved (100%) accuracy rate when all elements were concordant or when all elements were either suspicious or malignant. The study shows that when TT is concordant, final treatment may be ensued without open biopsy. In non-concordant cases, FNAC stands as single most important investigation. However due to its false

negative results, other components of triple test need to be employed to enhance its efficacy and diagnostic yield.

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