

A Study for Evaluation of Modified Triple Test for the Assessment of Palpable Breast Lumps

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Abstract: Breast lump is one of the most common presentations in Surgical OPD with malignancy reported as nearly 25% of all cancer in women. The conventional triple test was replaced with Modified Triple Test that included clinical examination, ultrasonography and Trucut biopsy. The objective of the study was to evaluate the efficacy of Modified triple test for the assessment of palpable breast lumps. **Aim:** The aim of this study was to assess the result of the modified triple test for palpable breast masses that aim at adding the value of ultrasound and core needle biopsy as compared to the original triple test. **Material and Methods:** Total of 100 patients presenting with breast lump were assessed for Modified triple test. The patients were subjected to detailed clinical history and examination, Ultrasonography and trucut biopsy. The results were correlated with histopathology as the reference standard. The results of Triple test were compared with those of Modified Triple test. **Results:** A total of 100 cases with the mean age at presentation as 49.6 ± 2.11 years were included in the study. 56% patients presented with right sided lesion. Upper outer quadrant was the most commonly involved site (42%). 77% presented with painless lump. The most common lump size observed was 4 - 6cm (59%) with 51% having a hard lump, 59% showing restricted mobility. Ultrasound was statistically insignificant whereas Trucut biopsy showed significant correlation when compared to histopathology. The overall sensitivity, specificity, positive predictive and negative predictive value of Modified Triple test as compared to Triple test was 100%, 98%, 97.7%, and 100% each respectively. **Conclusion:** Modified triple test was observed to be comparable with the triple test in accurately diagnosing clinically palpable breast lumps. It is a reliable and reproducible modality.

Keywords: Modified triple test, breast lump, mammography, FNAC, Trucut biopsy

1. Introduction

Breast cancer is the most frequent cancer among women, with an estimated 2.3 million new cases diagnosed worldwide in 2020, representing about 25% of all cancers in women.¹ In Western Europe approximately one in nine women are likely to develop breast cancer, accounting for 3–5% of all deaths in women.² In resource - poor countries 1 in 28 women develop breast cancer in her lifetime and for every 2 women diagnosed with breast cancer there is one death reported.^{3, 4} The risk factors predisposing to develop breast cancer include increasing age, positive family history, lobular pattern, early menarche, late menopause, later age at first full - term pregnancy and, nulliparity.⁵⁻⁷

In India, breast cancer is diagnosed in advanced stages possibly due to lack of awareness and preventive measures. Therefore, the main motto of breast cancer control is early detection so as to enhance the outcome and survival of the patients.

A systematic approach in the evaluating of breast masses should start with symptoms, clinical examination, and detailed clinical history, followed by Triple Assessment, which includes: clinical examination, imaging (usually mammography, ultrasonography, or both) and tissue diagnosis (Fine Needle Aspiration Cytology (FNAC), core needle/Trucut biopsy or both).^{3, 8} Use of triple test provides strong evidence in estimating the probability of malignancy and deciding further line of management of palpable breast lumps.^{4, 9, 10}

Due to the low sensitivity and specificity of mammography in detecting lesions in young women under the age of 40 as well as lack of proper equipment, ultrasonography is now incorporated in the modification to the triple test along with

FNAC replacing Trucut biopsy now termed as Modified Triple Test.

The aim of our study was to assess the result of the modified triple test for palpable breast masses that aim at adding the value of ultrasound and core needle biopsy as compared to the original triple test.

2. Materials and Methods

We have prospectively analysed 100 women presenting with a palpable breast lump in the Out Patient Department of General Surgery, of a tertiary care teaching Hospital in Western Uttar Pradesh, in a one-and-a-half-year duration based on certain predefined inclusion and exclusion criteria after obtaining clearance from the Institutional ethical committee. All females aged 18 years or more with a palpable breast lump and those giving a proper consent were included in the present study. Male patients with a breast lump, were excluded from the present study. All females with advanced or previously diagnosed breast cancer, history of surgery for malignancy in the same or opposite breast and those not willing to provide consent were excluded out from the study. Patients aged below 40 years were not subjected to mammography.

The selected patients were subjected to all the 3 components of modified triple test. The initial evaluation included focused history to assess the various risk factors and a thorough examination to assess for size, site, consistency, tenderness, mobility and fixation of the lump to the overlying and skin, surrounding muscles, chest wall and axillary region. The clinical evaluation was followed by radiological imaging including Ultrasonography and mammography of breast and axilla. Ultrasonography reports

classified the lesion as solid or cystic and Hypoechoic or hyperechoic or of mixed echogenicity.

Mammography detected the lesion for microcalcifications. Patients were then subjected to the third component of Modified Triple Test, the tissue diagnosis as FNAC and Trucut Biopsy from the lump. FNAC reports were labelled as benign, suspicious for malignancy or malignant.

Trucut biopsy report classified the lesion as benign, malignant and inconclusive. For inconclusive reports, a repeat attempt at trucut biopsy was made. The result of the final histopathological examination was considered as the reference standard.

Appropriate statistical tests were applied to evaluate the correlation and association of components of modified triple test with the final histopathological examination. The sensitivity, specificity, positive predictive value and negative predictive values of modified triple test were calculated.

3. Observation and Results

Table I: Correlation of Mammography and FNAC with Histopathology

Histopathology	Mammography			Total	Phi Test	P Value	FNAC				Total	Phi Test	P Value
	Benign	Malignant	Na				Benign	Malignant	Na	Suspicious			
Benign	34	0	12	46	.893*	.000**	40	0	0	6	46	0.914	.000**
Malignant	1	47	6	54			0	39	2	13	54		
Total	35	47	18	100			40	39	2	19	100		

(*Phi Test > 0 Significant, **P-value < 0.05 Significant)

Table II: Correlation of Ultrasound with Histopathology

USG	HPE (Benign)	HPE (Malignant)	Total	Phi Test	P Value
Cystic	20	33	53	-.176*	.108*
Solid	26	21	47		
Hyperechoic	39	0	39	.890#	.000##
Hypoechoic	7	20	27		
Mixed	0	34	34		

(*Phi Test < 0 NOT Significant, **P-value > 0.05 NOT Significant)

Table III: Correlation of Trucut Biopsy with Histopathology

Trucut	HPE (Benign)	HPE (Malignant)	Total	Phi Test	P Value
Benign	43	0	43	.985**	.000**
Inconclusive	3	1	4		
Malignant	0	51	51		
Na	0	2	2		
Total	46	54	100		

(*Phi Test > 0 Significant, **P-value < 0.05 Significant)

Table IV: Results of Different Studies on Modified Triple Test

Study	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
Malviya et al ⁵	100%	92.01%	53.16%	100%
Khoda et al ⁸	100%	100%	100%	100%
Vaithyanathan et al ⁹	100%	82%	76.90%	100%
Sumithra et al ¹⁴	97.36%	100%	100%	98.40%
Present Study	100%	98%	97.70%	100%

A total of 100 patients were included in the study. Of which 45 patients presented in the 5th decade of life. The mean age at presentation was 49.6 ± years. In our study 45% of the patients presented within 6 to 12 months from the first detection of lump. 56% of the patients presented with lump right on the side. Upper outer quadrant was the most commonly involved with in 42% patients followed by in only 3 cases (3%). The order of quadrant involvement noted upper outer quadrant > lower outer quadrant > upper inner quadrant > Central > lower inner quadrant. Associated symptoms at presentation included nipple discharge in 39% and pain in 23% and patients. Majority of the patients presented with a painless lump (77%) and without nipple discharge (61%).

On clinical examination, the most common size of lump was observed to be 4 - 6 cm (59%) followed by < 3cm in 30% patients. Eleven patients had a lump size of >6cm. 59 patients (59%) had a lump with restricted mobility, 30% with freely mobile lump and six patients had a hard and fixed lump.

Mammography accurately detected 34 of (73.9%) benign lesions and 47 of 54 (87.0%) malignant cases. Among 18% patients who did not undergo mammography, 12 were observed to have benign pathology followed by 6 malignant lesions. Correlation of mammography with histopathology was statistically significant with p - value < 0.05 and phi test value > 0 as depicted in **Table I**.

FNAC accurately detected 40 of 46 (87.0%) benign cases followed by 39 of 54 (72.2%) malignant lesions. Two patients refused for FNAC. A total of 19 patients were reported to have suspicious findings. Thirteen of these 19 suspicious cases turned out to be malignant and 06 as benign. Correlation of FNAC with histopathology was statistically significant with a p value of < 0.05 and phi test value > 0 (**Table I**).

Ultrasound reported the lesions as solid or cystic and hyperechoic, hypoechoic or mixed echogenicity. The initial indications of USG in differentiating a solid from cystic lesion may be non - beneficial for correct diagnosis. The present study showed no association between the character of the lesion and diagnosis as calculated by not significant Phi test and p values (**Table III**). Thirty - nine of 46 (84.8%) benign cases were reported as hyperechoic. Of the 54 malignant lesions, 20 (37.0%) were hypoechoic and 34 showed mixed echogenicity. Echogenicity could not be used as a single - feature so as to rule out malignancy except when they were hyperechoic (**Table II**).

Trucut Biopsy accurately detected 43 of 46 (93.5%) benign cases followed by 51 of 54 (94.4%) malignant lesions. Of

the 4 inconclusive reports, 3 were benign and 1 was found to be malignant on histopathology. Two patients did not undergo Trucut biopsy. Correlation of trucut biopsy with histopathology was statistically significant with a p - value <0.05 & phi test >0 (**Table III**).

Modified triple test showed comparative results to Triple test with a sensitivity, specificity, positive predictive value and negative predictive value of 100%, 98%, 97.7%, and 100% each respectively. The results of different studies on modified triple test have been shown in (**Table IV**).

4. Discussion

The present study on the efficacy of modified triple for diagnosing breast lumps was conducted to assess the risk factors and presentation in patients with carcinoma breast. In our study 45% patients presented with symptom of lump within 6 - 12 months and in the 5th decade of life with the mean age of 49.6 ± 2.14 years. The studies carried by Batta *et al*, Sumithra *et al*, observed that mean age at presentation was 38.24 and 40.61 years respectively.^{11, 12} Sumithra *et al* reported the symptom duration to be 4 - 9 months.¹²

In our study 56% patients presented with right sided breast lesion with upper outer quadrant involved in 42%. Sumithra *et al* also observed right side to be more involved than the left side with upper outer quadrant to be more commonly affected. Batta *et al* reported left side lesions to be more common on the.^{11, 12}

Nipple discharge and pain were the observed associated symptoms in 39% and 23% patients respectively. Sumithra *et al* reported 50% patients having pain and 22% having nipple discharge respectively.¹² Our observations were consistent those published by Batta *et al* and Khoda *et al*.^{8, 11}

It was observed that the mean size of lump at presentation was 4.6cm with only 5% patients having a lump of more than 10cm. Our observations were consistent with those of other studies by Sumithra *et al* and Batta *et al*, as less than 5cm was the most common lump size at presentation.^{11, 12}

On clinical examination 51% patients had a hard lump followed by 30% with soft lump and 19% with firm consistency on palpation. Similar observations were reported by Khoda *et al*, Sumithra *et al*.^{8, 11} 59% patients presented with a restricted mobility followed by 30% cases with a mobile lump and 6% having a fixed lump. On axillary lymph node showed enlargement in 51% patients. The previous studies have reported that axillary lymph node involvement favoured malignancy.¹³ In our study we observed that axilla can be involved in both benign as well as the malignant pathologies. Majority of the literature shows that axillary lymph node positivity has prognostic value in cases of carcinoma breast.¹⁷

In the evaluation of triple test, 34 of 46 (73.9%) benign cases and 47 of 54 (87.0%) malignant cases on histopathology were successfully identified by mammography. Eighteen (18%) patients did not undergo mammography owing to their age being less than 40 years.

These findings were consistent with the observations made by Rinait *et al* and Khoda *et al*.^{8, 14}

On correlating FNAC findings with the histopathology reports, FNAC could accurately detect 40 of 46 (87.0%) benign cases and 39 of 54 (72.2%) malignant cases. Of the 19 suspicious reports on FNAC, 13 (38.4%) were found to be malignant and 6 (31.6%) were benign on histopathology. Two patients did not undergo FNAC. Publications by Khoda *et al* and Vaithianathan *et al* reported that FNAC could accurately detect most of the lesions with higher especially in benign lesions.^{8, 9}

In the evaluation of Modified triple test, ultrasonography findings primarily reported breast lump as solid or cystic and in terms of echogenicity of the lesion. Of the 46 benign lesions on histopathology, 20 (43.5%) were cystic and 26 (56.5%) solid whereas in terms of echogenicity, 39 were described as hyperechoic and 7 (15.2%) as hypoechoic. Out of the 54 malignant reports in histopathology, ultrasonography described 33 (61.1%) and 21 (38.9%) as cystic and solid and, 20 (37.0%) and 34 (63.0%) as hypoechoic and mixed echogenicity respectively. The early sign on ultrasonography that distinguish solid lesions from cystic lesions may not be helpful in making the correct diagnosis.^{15, 16} The observations made by Khoda *et al* and Vaithianathan *et al*, were in terms of benign and malignant reports on ultrasonography were slightly different from our findings.^{8, 9} However, our study reports were consistent with observations made by Rinait *et al*.¹⁴

Forty - three of 46 (93.5%) benign cases and 51 of 54 (94.4%) malignant cases on histopathology were accurately detected on trucut biopsy. Of the 4 inconclusive reports, 3 were benign and 1 turned out to be malignant on biopsy report.

Modified triple test, was found to be 100% sensitive and 98% specific in assessing a palpable breast lump in our study. The positive and negative predictive values of modified triple test were 97.7% and 100% respectively. All the 3 components of the modified triple test compliment each other to accurately diagnose a palpable breast lump when combined. The observations made in our study are comparable and consistent with other published studies on modified triple test.^{10 - 17}

With the aim to accurately diagnose a palpable breast lump by clinical examination, radiological investigations and histopathological confirmation, modified triple test provides an attempt to reach the accurate diagnosis early so that appropriate treatment plan can be initiated. Early diagnosis prompts favorable prognosis.

5. Conclusion

It is concluded that the painless lumps, firm to hard in consistency, restricted mobility, fixation to the chest wall or underlying muscles or breast parenchyma or overlying skin and axillary lymph node involvement were features suggestive of malignancy. Ultrasonography cannot be used as a single radiological modality in the evaluation of these palpable breast lumps. Trucut Biopsy can replace FNAC as

it is more accurate in detecting histologically. The diagnostic accuracy of combined physical breast examination breast, ultrasonography and Trucut biopsy is comparable to that of histopathology. Modified triple test showed better comparative results to Triple Test with a high sensitivity, specificity, positive predictive value and negative predictive values. It is reliable, reproducible and accurate modality for the early diagnosis of a palpable breast lump to initiate early management.

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Legend to Tables

Table I: Correlation of Mammography and FNAC with Histopathology

Table II: Correlation of Ultrasound with histopathology

Table III: Correlation of Trucut biopsy with histopathology

Table IV: Results of different studies on modified triple test