



Original Research Paper

Diagnostic Approach to Palpable Breast Lump by Modified Triple Test Score- A Prospective Study

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Abstract

Introduction: Breast carcinoma is one of the common causes of cancer related deaths in women and along with colorectal and lung cancers is responsible for approximately 40% of cancer related deaths in women. The single most important prognostic factor in determining the outcome of treatment in these patients is the stage in which it is detected. The early detection of carcinoma breast is associated with excellent prognostic outcome. Triple test consisting of physical examination; mammogram and fine needle aspiration cytology is one of the most sensitive test for early detection of carcinoma breast and is found to have a considerably high sensitivity in detection of carcinoma breast as compared to any single test such as mammography or fine needle aspiration cytology. The modified triple test which substitutes mammography by ultrasound examination is also found to be highly sensitive in early detection of breast carcinoma we conducted this study to assess the accuracy of modified triple test score i.e. clinical examination, ultrasonography and fine needle aspiration cytology in breast lump by comparing with histopathology.

Materials and Methods: 50 women with palpable breast lump attending surgical outpatient and inpatient who underwent surgery for the same were included in the study on the basis of a predefined inclusion and exclusion criteria. Clinical examination of all the patients in respect to size of breast lump, site, consistency, tenderness, mobility and fixity to underlying structures was assessed in all the cases. Ultrasonography of both breast and axillae and Fine needle aspiration cytology of breast lump was done in all the cases. The accuracy of modified triple test was assessed by comparing the histopathology of the breast lump. SSPE 16.0 software was used for statistical analysis and *p* value less than '0.05' was taken as statistically significant.

Results: Out of 50 studied cases 15 turned out to be malignant on histopathology, 14 patients had intra ductal carcinoma (no special type) and 1 had mucinous carcinoma. 35 were benign lesions on histopathology, 26 had fibro adenoma, 5 had fibrocystic disease and 2 had mammary hamartoma. Out of 50 patients, 34 had MTTs score of 3 or 4 points all of which were proved benign on histopathology report. 15 patients had MTTs score of 6 and above and all were malignant on HPR, out of which 14 were intraductal carcinoma. Only 1 patient had a score of 5 and it was proved to be benign.

Conclusion: Modified triple test score assessment is highly sensitive and specific in diagnosing breast lumps as well as differentiating benign from malignant breast pathologies.

Keywords: Modified Triple Test, Clinical Examination, Fine Needle Aspiration Cytology, Ultrasonography.

Introduction

Patient with breast problems make up a major part of the patient load at a general surgical OPD clinic. Breasts are the most important feature of female anatomy and an integral part of the reproductive system. Majority of breast lumps prove to be benign, but the probability of the diagnosis of cancer is never zero. Breast cancer is the commonest cancer in American women and third most common in Indian women and its incidence has been increasing over the past decade. So careful evaluation, exact diagnosis and definite treatment is mandatory in any breast mass¹.

Despite centuries of theoretical meanderings and scientific research, cancer of breast remains one of the most dreaded of human disease². The breast being a paired organ further increases its exposure to the disease. Open surgical biopsy has been the gold standard a reference standard method of evaluating a suspicious breast lesion³. However, surgical excision or biopsy of mass can be painful, expensive and frequently unnecessary in young age groups, which have very low rates of malignancy⁴. The dilemma still remains that the dogmatic statement "every palpable mass in breast must be excised" should be replaced by recommendation that "every palpable mass in breast must be assessed and clarified" thus avoiding a number of unnecessary scars, stress, workload and expenditure⁵.

Introduction of FNAC changed the entire outlook to the matter the combination of clinical examination, mammography and tissue diagnosis came to be called upon as the triple test for assessment of breast lumps and has become the gold standard in the work up of the same. There is strong evidence for the value of using the triple assessment to estimate the probability of malignancy and guide the evaluation of palpable breast lump⁶. Each component of the triple test assigns score number 1 when it appears benign, number 2 when it appears suspicious and number 3 when it appears malignant and the sum of the scores is called the triple test score (TTS). When

the triple assessment is performed adequately and produces concordant results(all benign or all malignant) or scores are above 6 (malignant) or under 4 (benign) the diagnostic accuracy approaches 100%. However 40 % of cases are non-concordant and lumps with score 5 require open biopsy⁷.

When the components of the triplet test all point to benignity, the patient may be confidently followed up without the necessity of biopsy and adoption of these guidelines may safely reduce the number of open breast biopsies by about 50-60%⁸. Due to reduced sensitivity and specificity of lesion detection by mammography in young women under 40 and the non-availability of mammography machine at many tertiary centers and the usefulness of ultrasonography, researchers combined ultrasonography instead of mammography to the scoring system and the modified triple test score (MTTS) was introduced which is an integration of clinical breast examination, Fine needle aspiration cytology and ultrasonography⁹.

Breast ultrasound has now become available at higher resolutions and is proving to be highly useful adjunct to mammography esp. in females < 40yrs. Although the role of fine needle aspiration cytology and clinical examination has been unanimous, the role of ultrasonography, instead of mammography, has been emphasized recently. The wide acceptance of ultrasound as a diagnostic modality has been documented extensively in literature. Incorporation of ultrasound in the triple assessment of palpable breast masses can result in a reduction of total costs for the diagnosis and treatment of breast cancer¹⁰.

A simple, noninvasive but reliable test can make a huge difference in the management of patients especially the rural population where the patients do not have the luxury of complex tests and investigations. Hence this study was taken up in our institute.

Materials and Methods

All patients attending the surgery outpatient department and or admitted in surgery ward with palpable breast lump undergoing surgery were included in this study on the basis of a predefined inclusion and exclusion criteria.

All the cases were initially evaluated in the outpatient department. Patients with palpable breast lump were included after informed consent. Detailed history was taken as per the proforma. A detailed history and Clinical examination of breast in respect to lump for size, site, consistency, tenderness, mobility, fixity to breast tissue/skin/deeper structures was done. Ultrasound of both breasts and axilla was done using the sonographic unit as a scanner, equipped with a side or end firing, T shaped, linear array, 7.5 MHz transducer. Finally fine needle aspiration cytology of breast lump was done in all the cases. Both dry and wet smears were prepared. The smears thus prepared were stained with Leishman Giemsa stain (dry) while the wet fixed smears were stained by Papanicolaou and Haematoxylin Eosin stains using standard procedure.

An individual score was appointed based on the findings in respective test. Accordingly, a completely benign finding was given a score point of 1, a suspicious finding was given a score of 2 points and a malignant finding was given a score of 3 points.

Table 1: Scores on the basis of Benign, suspicious and malignant features

Findings	Score
Completely Benign	1
Suspicious	2
Malignant	3

Respective scores were combined to calculate modified triple test score (MTTS) for each patient. A combined score of 6 and above was considered as malignancy. A combined score of 5 was considered as equivocal. A combined score of 4 or less was considered as benign.

Table 2: Components of MTTS score

	Findings	Score
Scoring On Physical Examination	Soft / firm, Freely Mobile Lump	1
	Lump with Doubtful fixity to skin / breast tissue, Not freely Mobile	2
	Hard Definite fixity to the skin / breast tissue Immobile lump	3
Scoring On USG Examination	Round oval, ellipsoidal Hyper / Hypo echoic Lump with thin echogenic pseudo capsule Width / AP diameter ratio of ≥ 1.4 Gentle bi / trilobulation W/O any malignant finding	1
	Iso / mildly hypo echogenic Normal / enhanced sound transmission Homo / heterogeneous texture	2
	Poorly defined / irregular Lump Mixed / marked hypo echogenicity Width / AP diameter ratio ≤ 1.4 Spiculation, angular margins, calcification, shadowing, duct. extension, brand pattern / microlobulation	3
Scoring On FNAC	Lump with Benign report	1
	Suspicious for malignant cells	2
	Positive for malignant cells	3

All the patients will be subjected to excisional biopsy/appropriate surgery with consent for the purpose of the study. All the findings were carefully recorded as per the proforma. After documentation of information as per the data, important results were obtained by correlating the findings of physical examination, breast USG and FNAC to HPR as standard. The sensitivity, specificity, positive predictive value and negative predictive value was calculated. SSPE 16 was used for statistical analysis.

Results

The analysis of age groups of the studied cases showed that the most common age group was 26-35 years (26%) followed by 36-45 years (22%) and 15-25 years (22%).

Table 3: Age groups of the studied cases

Age	No Of Patients	Percentage
15-25 yrs	11	22%
26-35 yrs	13	26%
36-45 yrs	11	22%
46-55 yrs	4	8%
56-65 yrs	8	16%
66 yrs onwards	3	6%
Total	50	100%

The distribution of the lesion on the basis of side showed that 26 (52%) patients had lesion on left side whereas 24 (48%) patients had lesion on right side.

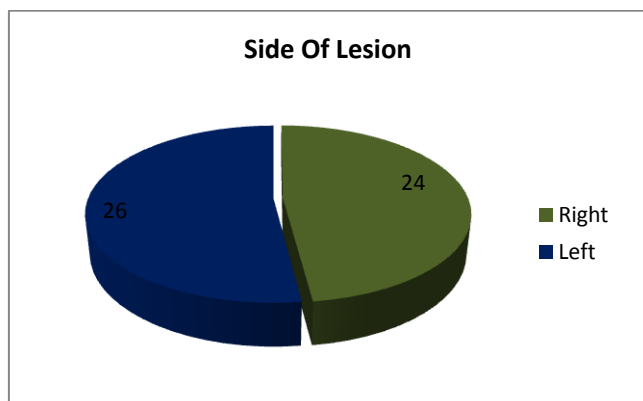


Figure 1: Side of the lesion in studied cases

The duration of lump showed that majority of the patients had signs and symptoms since less than 6 months (68%) followed by 7-12 months (22%). 3 (6%) patients had signs and symptoms since more than 2 years.

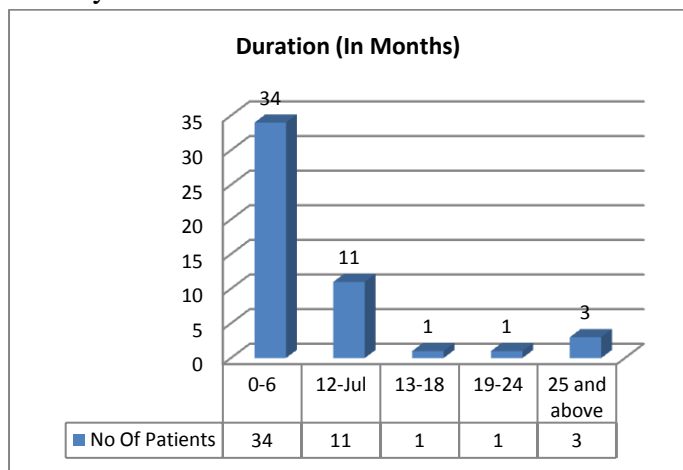


Figure 2: Duration of breast lump in studied cases.

The most common site of lesion was found to be upper outer quadrant which was seen in 24 (48%) patients followed by upper inner quadrant (18%).

Least commonly affected quadrant was found to be lower outer quadrant which was seen in 6 (12%) patients.

Table 4: Site of the lump in the studied cases

Quadrant	No Of Patients	Percentage
Upper Inner	9	18 %
Upper Outer	24	48 %
Lower Inner	6	12 %
Lower Outer	4	8%
Central	7	14 %
Total	50	100%

The analysis of histopathology reports showed that out of 50 studied cases 35 (70%) patients had benign and 15 (30%) patients had malignant lesions. Out of 35 patients having benign lesions the common lesion was found to be fibroadenoma which was seen in 26 (52%) cases. The other common benign lesions were found to be fibrocystic disease (10%) and mammary hamartoma (4%). 15 (30%) patients were found to be having malignant lesions out of which 14 (28%) had intraductal carcinoma and 1 (2%) patient had mucinous carcinoma.

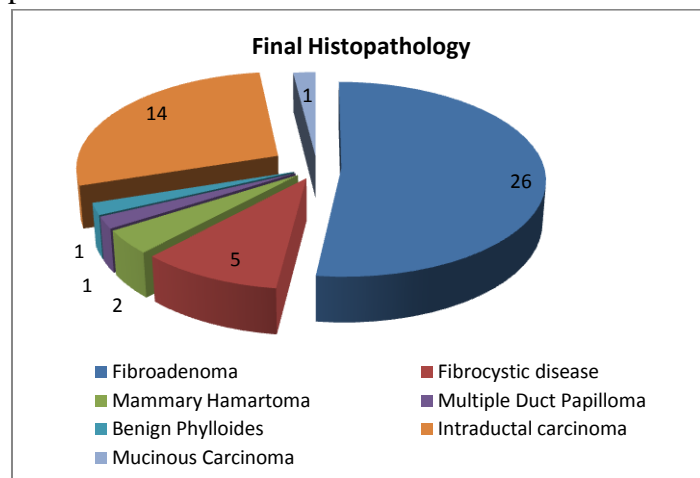


Figure 3: Histopathology Reports of the studied cases

The analysis of clinical score and its correlation with final HPR reports showed that 13 patients with malignant diseases had clinical score of 3 whereas amongst 37 patients with clinical score of 1, 35 patients had benign pathology on histopathology whereas 2 patients were found to have malignant pathology. The sensitivity, specificity, positive predictive value and negative predictive value was found to be 100 %, 86.67%, 94.59% and 100 %. The diagnostic accuracy was found to be 96%.

Table 5: Correlation of clinical examination scores with Final HPR

Clinical Examination		HPR		Total
Score		Benign	Malignant	
1		35	2	37
2		0	0	0
3		0	13	13
Total		35	15	50
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
100 %	86.67%	94.59%	100 %	96%

The analysis of Ultrasonography and its correlation with final HPR reports showed that 13 patients with malignant diseases had USG score of 3 whereas amongst 33 patients with clinical score of 1 all had benign pathology. Out of 4 patients with USG score of 2 benign and malignant pathology was found in 2 patients each on histopathology. The sensitivity, specificity, positive predictive value and negative predictive value was found to be 94.29% %, 86.67%, 94.29% and 86.67% The diagnostic accuracy was found to be 92%.

Table 6: Correlation of Ultrasound scores with Final HPR

USG		HPR		Total
Score		Benign	Malignant	
1		33	0	33
2		2	2	04
3		0	13	13
Total		35	15	50
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
94.29%	86.67%	94.29%	86.67 %	92 %

The analysis of FNAC and its correlation with final HPR reports showed that 13 patients with malignant diseases had FNAC score of 3 whereas amongst 33 patients with clinical score of 1 all had benign pathology. Out of 4 patients with FNAC score of 2 benign and malignant pathology was found in 2 patients each on histopathology. The sensitivity, specificity, positive predictive value and negative predictive value was found to be 94.29% %, 86.67%, 94.29% and 86.67% The diagnostic accuracy was found to be 92%.

Table 7: Correlation of FNAC scores with Final HPR

FNAC		HPR		Total
Score		Benign	Malignant	
1		33	0	33
2		2	2	04
3		0	13	13
Total		35	15	50
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
94.29%	86.67%	94.29%	86.67 %	92 %

On clinical examination out of 50 patients 13 were suspected to be malignant and it was found that in 33 patients 37 patients may be having benign pathology. Whereas on USG and FNAC 33 patients were suspected to be benign and 13 patients were suspected be having malignant pathology. In 4 patients the lesion was suspicious on USG and FNAC. Final Histopathology examination found 35 malignant and 15 benign lesions.

Table 8: Correlation of components of MTS with HPR

	Clinical	USG	FNAC	HPR
Benign	37	33	33	35
Suspicious	-	4	4	-
Malignant	13	13	13	15
Total	50	50	50	50

The combined consideration clinical examination, ultrasound and FNAC showed that out of 50 patients 34 were found to be benign and be benign and 16 were considered to be malignant whereas on the basis of histopathology 15 patients turned out to be having malignant lesions. The combined sensitivity, specificity, positive predictive and negative predictive value was found to be 97.14%, 100 %, 100 % and 93, 75% respectively. The overall diagnostic accuracy of MTTs was found to be 98%.

Table 9: Correlation of MTS Scores with HPR

		HPR		Total
		Benign	Malignant	
MTTS				
Benign		34	0	34
Malignant		1	15	16
Total		35	15	50
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
97.14%	100 %	100 %	93.75 %	98 %

MTTS score of up to 4 was found in 34 patients and in all these patients lesion was found to be benign whereas 1 patient had MTTS score of 5 and was found to be having benign lesion. 15 patients who had MTTS score of 6 or above were found to be having malignant lesions.

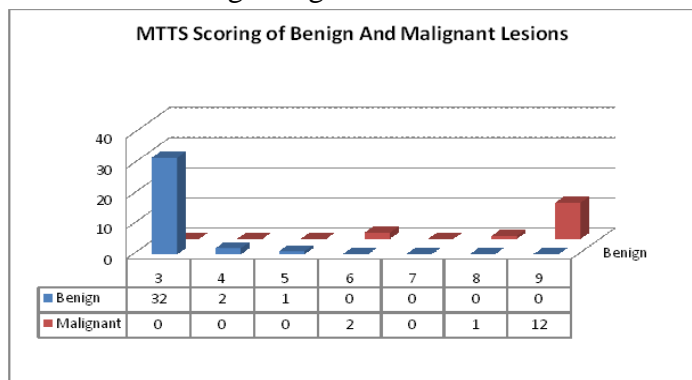


Figure 4: Correlation of MTTS score with the final Histopathology reports.

Discussion

Breast cancer continues to be the third most common cancer in Indian women and the most common cancer in American women and its incidence is increasing day by day. The greatest risk is for women over the age of 40 years and the incidence increases up to the age of 70 years^{11,12}. Although some women are known to be at higher risk, 75% women who develop breast cancer have no known risk factors other than increasing age. Annually, over 100,000 cases of breast cancer are diagnosed in India leading to increased health care burden¹³. This rising trend has been observed across all regions of India and in all age groups but more so in the young (< 45 years)¹⁴. In general, breast cancer has been reported to be occurring a decade earlier in Indian patients compared to their western counterparts. More than 80% of Indian patients are younger than 60 years of age. The average age of breast cancer patients has been reported to be 50–53 years as per National Cancer Registry Program¹⁵. The majority of breast cancer patients in western countries are postmenopausal and in their 6th and 7th decades. The best hope for improving survival is early detection and treatment and thus reduces the mortality. For evaluation of women with

symptomatic breast, a careful history and physical examination of the breast play an important role along with imaging techniques like mammography and breast ultrasonography to locate the appropriate site for the biopsy and thus to come to a final diagnosis and to detect early breast cancers¹⁶.

In our study out of 50 studied cases 15 were malignant and 35 were benign. Hence, malignancy was found in 30% cases. In a study of 50 cases Chaudhari R et al¹⁷ found the malignancy rate to be 46%. In other similar studies Kachewar SS et al¹⁸ and Kumari N et al¹⁹ found the malignant breast disease to be present in 31% and 41.66% respectively.

Considering the side of the breast involved, our study involved maximum number of cases on left side of breast compared to Masooda Jan and others study which showed maximum number of cases involving right side of breast²⁰.

Among the 50 patients, 48% patients presented with a lump in the upper outer quadrant of breast, followed by 8% in the lower outer quadrant and the remaining 44% in other quadrants and central region of breast. Similar observations were reported in other studies where the majority of breast lumps were found in the upper outer quadrant²¹. The relative higher occurrence of lumps in the upper outer quadrant of breast could be due to presence of much of the epithelial tissue of breast in this quadrant²².

In our study, sensitivity of MTTS was high (97.14%) compared to Ghafouri et al study (63.6%)²³. Combination of all the three modalities i.e. clinical examination, USG and FNAC increases the probability that the diagnosis is correct in about 100%. In our study, there were 32 patients having a score of 3 s/o benign and were proved to be benign on final HPR. 2 patients had a score of 4 s/o benign and also proved benign on final hpr report. 12 patients scored 9 highly s/o malignancy and turned out malignant on final HPR. 1 patient scored 8 and proved malignant on hpr. We did not have patients scoring 7. 2 patients scored 6 s/o suspicious lump, both were proved

malignant on hpr.1 patient scored also s/o suspicious lump but proved benign on hpr. The studies conducted by Mansoor I et al²⁴ and Wai CJ²⁵ et al showed MTTs to be highly sensitive in differentiating benign from malignant breast lesions.

Conclusion

Modified triple test score (MTTS) is a highly sensitive and can be relied upon for evaluation of palpable breast lumps. It is a better diagnostic tool as compared to FNAC alone. Scores 3 and 4 are benign and could be followed up unless abnormal changes occur during this period of time. Scores 6, 7, 8 and 9 are malignant and operation is mandatory. Score of 5 due to possible malignant nature, excisional biopsy seems more appropriate. This approach avoids open biopsy in the majority of cases while capturing all malignancies.

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