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ORIGINAL RESEARCH

A STUDY OF THE MODIFIED TRIPLE TEST IN EVALUATION OF BREAST LUMP

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ABSTRACT

Introduction: Though breast lumps are most common, they may be associated with morbidity and have become cause for concern to patients. Triple assessment by clinical, radiological and pathological examination is a standard approach in the evaluation of breast lumps. With the advent of USG and Core biopsy techniques, the modified Triple Test was introduced for diagnosis of breast lumps.

Aim: The aims of the study are to assess the reliability of the Modified Triple Test in making a pre-procedural diagnosis of palpable breast lumps in terms of specificity, sensitivity, negative predictive value, and positive predictive value.

Material and Methods: 50 females less than 40 years of age with complaints of a clinically palpable breast lump were included for this study. The included patients were evaluated on the basis clinical examination, imaging (USG) and FNAC and Core Biopsy. The results were then compared with histopathological examination of the lump/breast tissue excised to find out the individual reliability of each component of triple assessment and overall sensitivity and specificity of Modified Triple Assessment in relation to Histopathological Examination.

Results: There were no false positives and false negatives when the MTTS was used. It was highly significant on statistical analysis (p=0.0001). Its sensitivity, specificity, PPV, NPV, and diagnostic accuracy were all 100%.

Conclusion: The MTTS is a feasible, accurate and reliable guide with diagnostic effectiveness for treatment of palpable breast masses and is equivalent and cheaper when compared to open biopsy and can be carried out in a single visit, which saves time. There is strong evidence for the value of using the modified triple test score in evaluation of women with a palpable breast lump.

INTRODUCTION

Breast masses in young females are a common breast related problem. Some of these lumps are clinically ambiguous and majority are benign. Some benign diseases of breast can have a risk of progression to malignancy.[1] More than 1 million new cases are diagnosed

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every year.[2] Breast cancer is the second leading cause of cancer deaths among women.[3] Therefore, careful evaluation, exact diagnosis and definite treatment are mandatory in any case of breast lump.

Breast cancer is a multifactorial disease that is caused by complex interplay of genetic, hormonal and environmental factors. Many factors are associated with breast cancer in females. Implicated risk factors in breast cancer risk include age, early menarche, childbearing, altered reproductive patterns, high calorie diet, breastfeeding, oral contraceptives, late menopause, hormone replacement therapy, exogenous hormones, previous benign breast disease, breast density, diet, alcohol, smoking, and family history.[4–8] The above factors ultimately increases their exposure to estrogens and thus, increase the risk of developing breast cancer.[9] The increase in the number of cases and the net mortality might have resulted from the large population, inadequate screening programs, and lack of proper education.[10]

The diagnosis of breast cancer is simpler in advanced stages due to its classical presentation. However, diagnosis in a discrete lump is a challenge. Evaluation of any palpable breast mass starts with the triple test which includes clinical breast examination, mammography and fine needle aspiration cytology. Triple assessment is one of the best methods to diagnose and manage breast lumps.[11] It is simple, feasible, accurate, avoids unnecessary surgeries and guides the appropriate management. Histopathological examination (HPE) of excised breast lump is the gold standard test for diagnosis. Excision biopsy provides more information but results in undesirable cosmetic problems.[12]

Clinical examination is the first step in the evaluation of breast disorders. A well conducted CBE can detect at least 50% of asymptomatic cancers. The sensitivity and specificity of the breast examination are 54-96.6% and 84-94% respectively.[13,14] Several factors influence the outcome of CBE, namely, the duration, technique used, clinical experience of the examiner, the age of the patient, breast characteristics, the lump characteristics and the presence of implants in the examined breast.[13]

Mammography is a screening test for occult malignancy and detects malignant lesions in older women. It is less sensitive in women younger than 40 years because of higher breast density.[15] Although it is a sensitive technique for the diagnosis of breast cancer, it is falsely negative in 10%-20% of cancers.[16] Furthermore, the sensitivity of mammography is lower in the evaluation of dysplastic breasts due to superimposed densities with low contrast.[17]

With the advent of imaging modalities, breast ultrasonography (USG) has become an important diagnostic tool. USG is particularly useful in young women with dense breasts. Ultrasonography can also be used to guide biopsy techniques. It is unreliable in differentiating benign from malignant solid lesions, and does not reliably detect microcalcification.[17] Its major use to date has been as an adjunct to mammography in a clinically abnormal breast.

FNAC is considered an important tool in the pathological assessment of breast lumps. It is a safe, rapid, reliable and cost-effective technique for the cytopathological diagnosis of all palpable breast lesions.[18–21] and can differentiate solid and cystic masses. FNAC of breast lumps has a diagnostic accuracy of 95.5-97% for both benign and malignant masses.[19,22]

Specimens procured with core-needle biopsy allow histologic diagnosis, hormone-receptor testing, and core-biopsy can discriminate between in situ and invasive disease.

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Moreover, one does not need complete excision of the lump. However, it is costlier, traumatic, more invasive than FNAC, requires more training and experience, and usually requires imaging guidance. Core biopsy is a reliable test for the detection of breast cancer.[23]

The triple test for the assessment of breast lumps was first described in the 1970s. There is strong evidence for its value in estimating the probability of malignancy and guiding its evaluation.[24] If 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 is 100%.[11] However, 40 % of cases are non-concordant and lumps with score 5 require open biopsy.[25] When all components of the TTS diagnose the lump as benign, the patient can be followed up without the necessity of biopsy and adoption of these guidelines reduces the number of open breast biopsies by about 50-60%.[26]

Due to reduced sensitivity and specificity of mammography in young women under 40 and the non-availability of mammography machine at many tertiary centers and the usefulness of ultrasonography, Wai et al combined ultrasonography instead of mammography to the scoring system and described the modified triple test score (MTTS).[27] The modified TTS includes the use of USG and core needle biopsy when performed, and is calculated as follows: examination score, highest imaging score, and highest biopsy score. In imaging scores, BIRADS 1–3 is considered as benign, BIRADS 4 as indeterminate, and BIRADS 5 as high suspicion. Scores 0–3 are assigned in each category, with zero recorded when either the particular imaging test is not done or the biopsy technique was not used or was insufficient for diagnosis.[27] Current studies try to determine whether a benign result of the TTS or MTTS makes excision biopsy unnecessary.[28,29] These tests need to possess the same accuracy as excisional biopsy, because of the unacceptability of non-excision of a malignant tumor.

The MTTS is a relatively new scoring system to guide decision making in the management of palpable breast lumps. With this fact in mind, the current study was done in a Tertiary care hospital in the state of Punjab in North India, with the aim of studying the modified triple test, in the northern Indian population, and its effect on the management of breast lumps in the same, and to contribute to the existing pool of data about the same.

AIMS AND OBJECTIVES

The aims of the study are to assess the reliability of the Modified Triple Test in making a pre-procedural diagnosis of palpable breast lumps in terms of specificity, sensitivity, negative predictive value, and positive predictive value.

MATERIAL AND METHODS

50 females less than 40 years of age with complaints of a clinically palpable breast lump, admitted in Department of General Surgery, Govt. Medical College & Rajindra Hospital, Patiala, presenting with a palpable breast lump were included for this study. Male patients and female patients with advanced Breast Cancer that makes diagnosis obvious, and patients who did not consent or withdrew their consent were excluded from the study. The included patients were evaluated on the basis of detailed history, thorough clinical examination and necessary investigations. All patients were screened using the screening tools in modified Triple Assessment of a breast lump and excision of lump/mastectomy was done according to the cytological evaluation of lump and clinical examination. On the basis of a systematic

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clinical examination, the lumps were grouped as malignant, benign, and inconclusive. All patients underwent ultrasonography as they were less than 40 years of age. On the basis of ultrasonography findings, the lumps were categorized as benign, suspicious and malignant. After this, FNAC/CNB was performed by the surgeon/pathologist and sent for cytological/Histopathological examination. The results were then compared with histopathological examination of the lump/breast tissue excised to find out the individual reliability of each component of triple assessment and overall sensitivity and specificity of Modified Triple Assessment in relation to Histopathological Examination.

Data collected was entered into a Microsoft Excel 365 Spreadsheet. All the statistical calculations were done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows. Data was described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data were normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using Mann Whitney *U* test for non-parametric data. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test was used when the expected frequency is less than 5. Sensitivity, specificity, accuracy, PPV and NPV, PLR and NLR were calculated for Clinical Examination, Imaging, FNAC, Core Biopsy and Modified Triple Test Score for the diagnosis of breast lumps, with Histopathology as the gold standard. Receiver operator characteristics (ROC) curve was done, and criterion value was estimated depending on the specificity and sensitivity. Area under curve (AUC) was measured. A probability value (*p* value) less than 0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

All the women included in the study population were under 40 years of age. The mean age was 32.92 years, and the predominant age group was 31-40 years. Age was found to be statistically significant. (p=0.021)

The commonest ages at menarche in our study population were 13 and 14 years, seen in total 30 patients (60%). The mean age at menarche was 13.78 years, and it was found to be a statistically significant risk factor (p=0.001). History of breast feeding was present in 62% women, and it was a significant risk factor (p=0.003). 52% patients had a left sided breast lump, and the remainder had a right-sided breast lump.

On CBE, there was low suspicion in 30 patients (60%), and all were benign on histopathology, with no false negatives. 9 patients (18%) were moderately suspicious on CBE, of whom HPE showed malignancy in 2 patients (4%) and a benign lesion in 7 patients (14%). 11 patients had a highly suspicious lesion on CBE, and of these, histopathology confirmed malignancy in 9 patients (18%), and the remaining 2 were false positives. CBE was highly significant (p=0.0001) Its sensitivity, specificity, Its sensitivity and specificity, PPV, NPV and accuracy were calculated to be 81.82%, 94.87%, 81.82%, 94.87%, and 92% respectively. It had a PLR of 15.95 and NLR of 0.19.

All females underwent ultrasound imaging as the study population was less than 40 years of age. Imaging showed a benign lesion in 35 patients (70%), and all were confirmed to be benign on histopathology, with no false negatives. It showed an intermediately suspicious

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lesion in 3 patients (6%), of whom, 2 patients had a benign lesion and one was found to be malignant of histopathology. 12 patients (24%) had a highly suspicious lesion on imaging, of whom 10 were true positives and 2 were false positives. Imaging was found to be highly significant (p=0.0001). Its sensitivity, specificity, PPV, NPV and diagnostic accuracy were 90.91%, 94.87%, 83.33%, 97.37% and 94% respectively. It had a PLR and NLR of 17.73 and 0.1 respectively.

78% patients underwent FNAC, and FNAC was found to be highly significant (p=0.0001). On FNAC, 31 patients (62%) were benign, of whom all were benign on HPE and there were no false negatives. 1 patient had an Atypical lesion on FNAC, which was confirmed to be benign on HPE (2%). 7 patients (14%) had a malignant lesion on FNAC, of whom 6 (12%) were true positives and 1 (2%) was false positive. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of FNAC were calculated to be 100%, 96.97%, 85.71%, 100%, and 97.44% respectively. It had a PLR and NLR of 33 and 0 respectively.

22% patients underwent Core Biopsy. 5 patients had a benign result on core biopsy, which was confirmed by HPE (10%). Thus, there were no false negatives. 1 patient (2%) had an atypical result on core biopsy. HPE confirmed it to be benign. 5 lesions were malignant on core biopsy, and were confirmed by HPE (10%). Core biopsy results were highly significant (p=0.000). Its sensitivity, specificity, PPV, NPV and diagnostic accuracy were all 100%.

On histopathology, 78% were benign, and 22% were malignant.

The MTTS was stratified into three groups: benign (MTTS 3–4); indeterminate (MTTS 5–7); and malignant (MTTS 8–9). 72% patients in our study had MTTS of 3-4 and all were found to be benign on histopathology. 6% patients had MTTS of 5, and were indeterminate and were confirmed to be benign on histopathology. 22% had an MTTS of 8-9, and were confirmed to have malignant etiology on HPE. Thus, there were no false positives and false negatives. It was highly significant on statistical analysis (p=0.0001). Its sensitivity, specificity, PPV, NPV, and diagnostic accuracy were all 100%.

Area under the ROC Curve for MTTS was 1. Maximum specificity and sensitivity were obtained at a score of 6.5, which was lower than the cut-off for malignancy (MTTS 8). AUC of the MTTS ROC was highly significant on statistical analysis. (p=0.000)

Table 1 – Confusion Matrix for CBE vs HPE

Clinical examination	HPE		Total	Chi-square value	p-value
	Malignant	Benign			
High Suspicion	9	2	11	31.399	0.0001
Low & Moderate Suspicion	2	37	39		
Total	11	39	50		

Table 2 – Confusion matrix for Imaging vs HPE

Imaging	HPE		Total	Chi-square value	p-value
	Malignant	Benign			

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High Suspicion	10	2	12	36.402	0.0001
Low & Moderate Suspicion	1	37	38		
Total	11	39	50		

Table 3 – Confusion Matrix for FNAC and comparison with HPE

FNAC	HPE		Total	Chi-square value	p-value
	Malignant	Benign			
Malignant	6	1	7	34.107	0.0001
Benign	0	32	32		
Total	6	33	39		

Table 4 – Confusion matrix for Core biopsy vs HPE.

CORE BIOPSY	HPE		Total	Chi-square value	p-value
	Malignant	Benign			
Malignant	5	0	5	20.414	0.000
Benign and Atypical	0	6	6		
Total	5	6	11		

Table 5 – Confusion matrix for MTTS vs HPE

	HPE		Total	p-value
MTTS	Malignant	Benign		
8-9	11	0	11	0.0001
3-7	0	39	39	
Total	11	39	50	

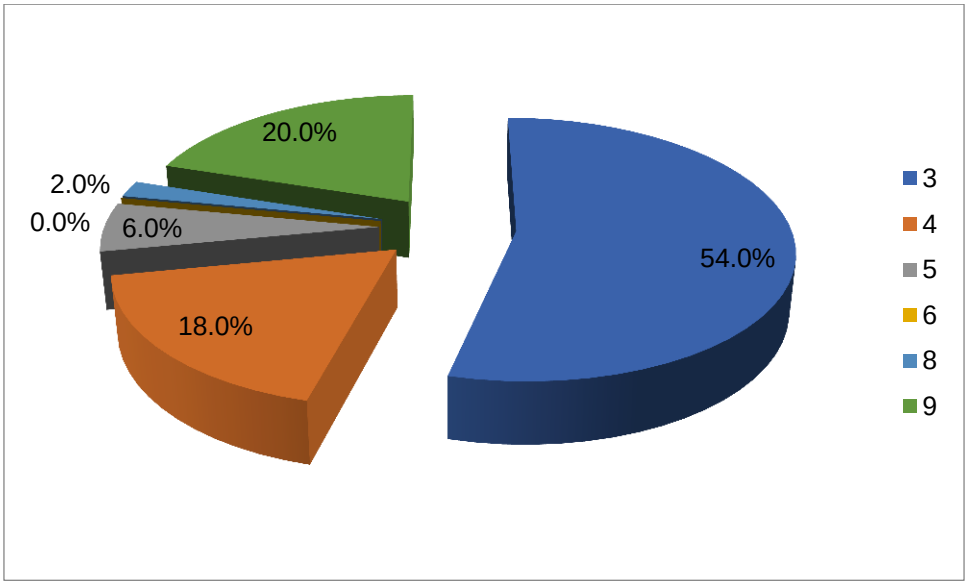

Fig 1 – Pie Chart showing distribution of MTTS score.

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Table 6 – Statistical parameters for CBE, Imaging, FNAC, Core Biopsy, and MTTS

Statistic	CBE	Imaging	FNAC	Core Biopsy	MTTS
Sensitivity	81.82%	90.91%	100.00%	100.00%	100.00%
Specificity	94.87%	94.87%	96.97%	96.97%	100.00%
Positive Likelihood Ratio	15.95	17.73	33	33	-
Negative Likelihood Ratio	0.19	0.1	0	0	0
Disease prevalence	22.00%	22.00%	15.38%	15.38%	78.00%
Positive Predictive Value	81.82%	83.33%	85.71%	85.71%	100.00%
Negative Predictive Value	94.87%	97.37%	100.00%	100.00%	100.00%
Accuracy	92.00%	94.00%	100%	100%	100.00%

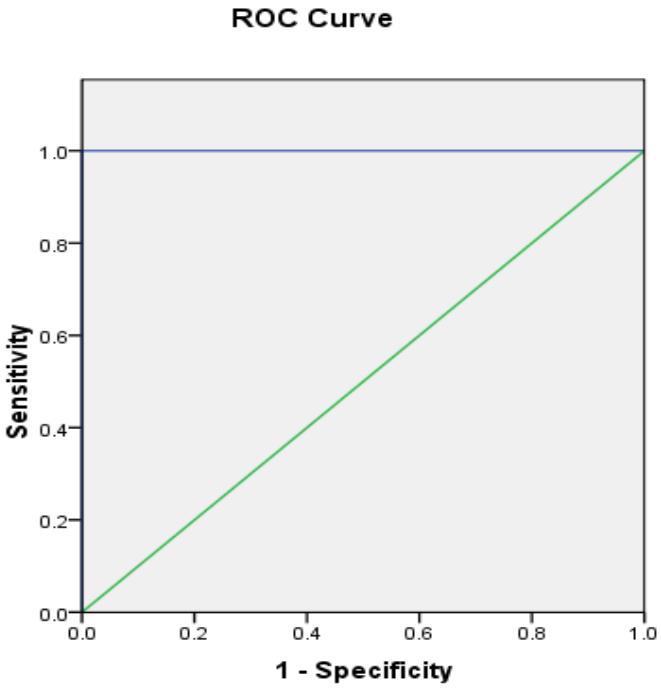

Fig 2 – ROC Curve for the MTTS

DISCUSSION

The diagnosis and management of a palpable breast mass is an area of high anxiety for many women. Definitive diagnosis can be obtained with an excisional biopsy and histopathologic examination of the breast lump. Excision of breast tumors is a common diagnostic intervention, but about 80% of the excised tumors are benign.[19] Thus, excisional biopsy cannot be recommended directly in every case of palpable breast lump, as it increases morbidity and puts patients under the stress of unnecessary breast surgery. However, it is vital to diagnose malignancy. Thus, to aid in this dilemma, the Triple assessment and later, the modified Triple Test score were introduced. The mean age was 32.92 years. Age>30 years was found to be statistically significant on comparison with HPE (p=0.021) Morris et al reported a mean age of 27 years, while our results correlated better with those of Ghafouri et al (mean age = 33.6 years).[29,30] The mean age at menarche in our study was 13.78 years. Age at menarche was found to be statistically significant on comparison with HPE. (p=0.001) The commonest age at menarche in the study by AlShamlan et al[31] was 12-13 years (57.14%), and

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the mean ages reported by Memon et al[32] (12.53 years) and Takalkar[33] (11.32 years), were slightly lower than that of our study population. Vishwakarma et al[34] reported an age of menarche <13 years to be statistically significant in their pooled meta-analysis. History of Breast-feeding was present in a total of 62%. Breastfeeding was a significant factor on comparison with HPE (p=0.003) in our series. Our results correlated well with those of Memon et al,[32] who reported a history of breast-feeding in 61.5% patients, while those of AlShamlan et al[31] were lower 45.45%. Vishwakarma et al noted absence of history of breast feeding to be a significant risk factor.[34]

52% patients had a left-sided lump, of whom 10% had malignant histopathology. AlShamlan et al[31] reported a left breast lump in 47.37% patients, while Memon et al[32] reported a left breast lump in 39% patients. Takalkar et al reported a left sided lump in 50.77%.[33] Our findings correlated well with alShamlan, who also reported that the site of the lump was not a significant risk factor.[31]

On statistical analysis, CBE was highly significant (p=0.0001) Its sensitivity, specificity, Its sensitivity and specificity, PPV, NPV and accuracy were calculated to be 81.82%, 94.87%, 81.82%, 94.87%, and 92% respectively. It had a PLR of 15.95 and NLR of 0.19. Khoda et al reported the sensitivity, specificity, PPV and NPV to be 66.6%, 100%, 100%, and 100% respectively.[35] Ngotho et al reported a sensitivity, specificity, PPV and NPV to be 100%, 92%, 60%, and 100% respectively.[36] Our sensitivity and specificity correlated well with those of Vaithinathan et al, who calculated the sensitivity, specificity, PPV to be 96.67%, 84%, and 78.4%. Ghafouri et al reported the sensitivity and specificity of CBE to be 18.2% and 99.9% respectively.[30] The lower sensitivities and specificities of CBE suggest that one cannot rely on CBE alone in the diagnosis of a palpable breast lump.

In our study, all females underwent ultrasound imaging as the study population was less than 40 years of age. Imaging was found to be highly significant (p=0.0001). Its sensitivity, specificity, PPV, NPV and diagnostic accuracy were 90.91%, 94.87%, 83.33%, 97.37% and 94% respectively. It had a PLR and NLR of 17.73 and 0.1 respectively. Ngotho et al reported the sensitivity, specificity, PPV and NPV to be 100%, 94.2%, 66.7% and 100%, respectively.[36] Again, our findings correlated well with Vaithinathan et al, who calculated the sensitivity, specificity, PPV to be 93.1%, 95.9%, and 93.1%, respectively, and our sensitivity matches that of Khoda et al (91%).[14,35] Ghafouri et al reported the sensitivity and specificity of USG to be 45.5% and 85.4% resdpectively.[30] Thus, ultrasonography has a high diagnostic sensitivity and specificity and may help direct further assessment and/or follow-up. It is often useful in patients with a suspicious breast mass at physical examination, as preoperative assessment of the axillary lymph nodes may be important in operative decision making.[27]

Majority of the patients in our study (78%) underwent FNAC as it is easier to perform, and more cost effective, as compared to core-biopsy, especially in moderate and low resource settings. The choice of whether to do an FNAC or a core biopsy was ultimately made by the surgeon. FNAC was found to be highly significant (p=0.0001). The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of FNAC were calculated to be 100%, 96.97%, 85.71%, 100%, and 97.44% respectively. It had a PLR and NLR of 33 and 0 respectively. Our findings correlate well with those of Ngotho et al, who reported the sensitivity, specificity, PPV and NPV to be 100%, 98.1%, 83.3%, and 100% respectively, and with those of Vaithinathan who reported 96.6% sensitivity and 100% specificity.[14,36] Khoda

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et al reported sensitivity, specificity, PPV and NPV to be 91.6%, 100%, 100%, and 97.4%.[35] Ghafouri et al reported the sensitivity and specificity of FNAC to be 54.5% and 95.5% respectively.[30] FNAC thus has higher specificity and sensitivity when compared to CBE and imaging, thus establishing its value in the evaluation of palpable breast lumps. Fine-needle puncture, as a part of the preoperative diagnosis of breast tumors, should thus be mandatory.

Our observations underline the importance of supplementing imaging with fine-needle puncture, but also the necessity of the physical examination to obtain maximum diagnostic accuracy. When evaluating our data, the MTTS could be stratified into three groups: benign with a MTTS of 3–4; indeterminate with a MTTS of 5–7; and malignant with a MTTS of 8–9. There were no false positives and false negatives. It was highly significant on statistical analysis (p=0.0001). Its sensitivity, specificity, PPV, NPV, and diagnostic accuracy were all 100%. Ngotho et al, Vaithinathan, and Khoda et al, all reported the sensitivity to be 100%, and Vaithinathan et al reported a low specificity of 82%,while Ngotho et al and Khoda et al reported the specificity to be 100%[14,35,36] Ghafouri et al reported the sensitivity and specificity to be 63.6% and specificity of 94.4%.[30] Thus, the MTTS is extremely good at ruling out a benign diagnosis, and is very helpful in ruling in a diagnosis of malignancy. Patients with a palpable breast mass can readily be assigned to one of three categories: benign, allowing for dismissal from further assessment or follow-up; indeterminate, which requires evaluation to confirm the presence or absence of malignancy; and malignant category, which allows definitive surgery. This approach avoids open biopsy in the majority of cases while capturing all malignancies.

CONCLUSION

In essence the MTTS is a feasible, accurate and reliable guide with diagnostic effectiveness for treatment of palpable breast masses and is equivalent and cheaper when compared to open biopsy and can be carried out in a single visit, which saves time. It has a great importance in reducing morbidities and expenses in breast mass evaluation by preventing unnecessary surgeries. Thus there is strong evidence for the value of using the modified triple test score in evaluation of women with a palpable breast lump.

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