Original Research Article

Evaluation of triple test score in palpable breast lump

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Abstract: The Objective is to perform and evaluate Triple Test Score (TTS) in patients with palpable breast lump in comparison with gold standard histopathology (HPE) and to develop a standard protocol for management of breast lump especially when discordant results are obtained from triple assessment. The Study was conducted on 100 patients presenting with breast lump to the department of General Surgery at R.L. Jalappa Hospital & Research Centre, Kolar, during the period from JANUARY 2012 to AUGUST 2014. It was a prospective study. Women presenting for evaluation of palpable breast lump underwent assessment by clinical examination, mammography and FNAC and got the Triple Test Scoring done. All patients who underwent complete TTS at our institution were entered into the study. All patients were subjected to necessary surgery, post TTS and followed up with histopathology of the specimen. A structured proforma was used to collect relevant information from each patient selected. In our study the mean age of the patients was found to be 46.12 ± 11.48 years, most of the patients were in the age group of 35-45 years (60%). Positive family history was found in 17%. Patients on an average took 6 months to seek medical help after recognition of the breast lump. Most common location of breast lump was upper outer quadrant (39%). Out of 9 cases with suspicious interpretation in clinical diagnosis: 5 were diagnosed to be benign and 4 were diagnosed as malignant. Two cases which were diagnosed clinically as benign turned out to be malignant on HPE. Out of 5 cases with suspicious interpretation in FNAC: 2 were diagnosed to be benign and 3 were diagnosed as malignant. One case which was diagnosed as benign turned out to be malignant on HPE. Out of 6 cases with suspicious interpretation in mammography all were diagnosed as malignant. Three cases which were diagnosed as benign turned out to be malignant on HPE. All the cases diagnosed as malignant with TTS were proved malignant by HPE, all cases diagnosed as benign were proved benign on HPE, one case with TTS of 5 required a further test in form of biopsy for confirmation, and it turned out to be benign. The study clearly demonstrates the superiority of TTS over other components of triple assessment or all of them put together. A TTS of $</=4$ is consistent with a benign lesion; a TTS of $>/= 6$ indicates malignancy. Only in patients in whom TTS score is 5, biopsy is recommended to obtain a definitive diagnosis. Thus a standard protocol can be developed, for the management of breast lump even with discordant results obtained via triple test assessment, which can be followed universally, thus empowering surgeon to go ahead in managing breast lump effectively and confidently.
Keywords: Triple Test Score, Triple Assessment, Breast lump

INTRODUCTION

Breast lump is a very sensitive issue and cause of great worry and anxiety to the patient, so a reliable, preferably non-invasive investigation and prompt diagnosis is required. Breast lump should be managed effectively and confidently with a proper protocol plan, ensuring early and best possible treatment for every patient [1].

Triple test assessment was a major breakthrough in this direction, which streamlined the management of palpable breast lump. When all the components of triple test assessment which are Clinical Examination, FNAC, Mammography point to one possibility (are concordant) then the diagnosis is almost certain and management can be confidently planned in such a situation [2]. But if there is discordancy among the components of triple test, then what should be the next step in the management plan is the question to be answered. This is where triple test score shows us the path.

By bringing in the scoring system for the triple test, management of palpable lump of breast will become more streamlined, providing a platform for managing discordant results, confidently and effectively. Scoring systems when introduced into management of any disease have always resulted in better management protocol, be it Alvarado scores for acute appendicitis, Ransons scoring in pancreatits etc. Similarly implementation of triple test scoring in palpable breast lump is the next step in formulating a better protocol plan.

TTS provides diagnostic effectiveness at substantially lower cost than traditional management. Cost savings are mainly due to decreased open biopsy [3].

In TTS lumps with score 4 points or lower are benign and managed accordingly, lump with score 6 points or higher are malignant and should undergo definitive therapy. Only those lumps that score 5 points require biopsy for confirmation of diagnosis. Thus large number of unnecessary biopsies can be avoided, saving the patient from undue anxiety, uncertainty, undue delay in receiving the appropriate treatment, financial burden, double surgeries.

MATERIALS AND METHODS
SOURCE OF DATA
Study conducted on 100 patients presenting with breast lump to the department of surgery in R.L. Jalappa Hospital & Research Centre, Kolar, during the period from January 2012 to August 2014.

Inclusion Criteria:
Patient aged $\geq$ 35 years, presenting with palpable breast lump.

Exclusion Criteria:
Obvious malignant lesions (fungation, ulceration).

METHOD OF COLLECTION OF DATA:
It being prospective study, women presenting for evaluation of palpable breast lump to the department of surgery at R.L. Jalappa hospital and Research centre underwent assessment by clinical examination, mammography and FNAC and Triple Test Scoring was done.

- All patients who underwent a complete TTS at our institution were entered into the study.
- All patients were subjected to necessary surgery, post TTS and followed up with histopathology of the specimen.
- A structured proforma was used to collect relevant information from each patient selected.
- Each component of the triple assessment was compared with the gold standard histopathology, so also TTS was compared with histopathology and findings were analyzed.
- All of patient details and relevant information was entered into the proforma.

RESULTS:
In our study the mean age of the patients was found to be 46.12 ± 11.48 years, most of the patients were in the age group of 35-45 years (60%). Positive family history was found in 17%. Patients on an average took 6 months to seek medical help after recognition of the breast lump. Most common location of breast lump was upper outer quadrant (39%). Among the 100 cases which had histo-pathologic correlation 56 were benign disease and 44 malignant.

Table 1: Results derived from various modalities used in breast lump analysis

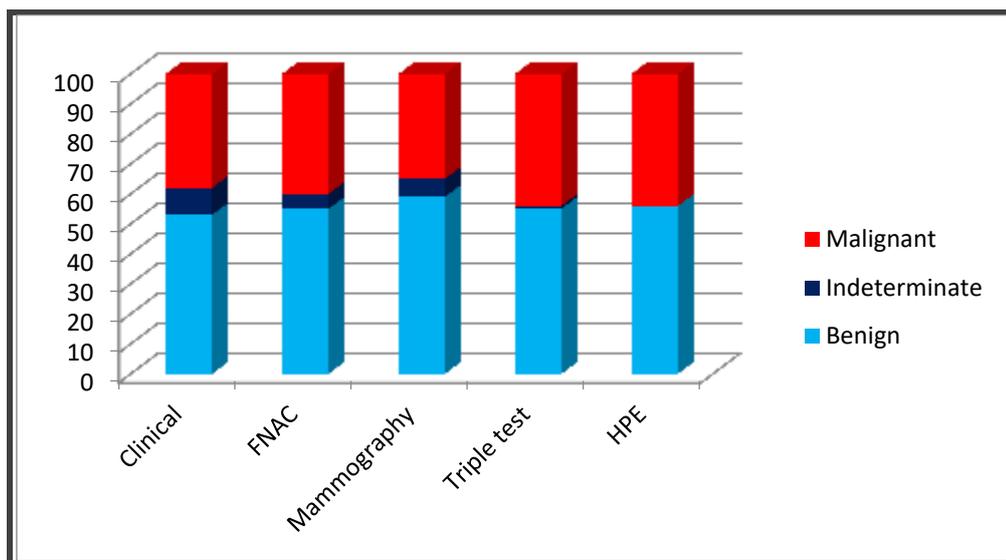| Diagnosis	Clinical	FNAC	Mammography	Triple test	HPE
Benign	53	55	59	55	56
Indeterminate	9	5	6	1	0
Malignant	38	40	35	44	44
Total	100	100	100	100	100

Fig 1: Results Derived From Various Modalities Used In Breast Lump Analysis

Table 2: Comparison of all the components used in breast lump analysis

Investigation	Sensitivity	Specificity	Positive	Negative	
	(%)	(%)	Predictive	Predictive	Accuracy
			Value (%)	Value (%)	(%)
Clinical	95	100	100	96.23	97.80
FNAC	97.56	100	100	98.18	98.94
Mammography	92.11	100	100	94.92	96.80
TTS	100	100	100	100	100

Table 3: Kappa agreement between HPE and all diagnostic modalities

DIAGNOSTIC	Kappa value	p value
Clinical examination	0.795	<0.01
FNAC	0.884	<0.01
Mammography	0.758	<0.01
Triple test	0.903	<0.01

DISCUSSION

Prospective analysis of TTS on 100 patients and confirming the results with histopathological finding showed TTS to be highly sensitive and specific. In the present study 100 patients with age ranging from 35 years to 90 years with a mean age of 46.12 ± 11.48 years who presented with complaint of breast lump were evaluated. The mean age here was considerably less than that seen in the western population (57 years) and comparable to study done at Nepal (48 years) [1]. 60% of the patients belonged to age group between 35-45yrs. Benign diseases (56%) were more common than malignant (44%). Fibrodenoma (42%) being the most common benign lesion and Infiltrating ductal carcinoma (43%) being the most common malignant lesion. Most of the patients aged above 55 years with breast lump were diagnosed with a malignant lesion reinforcing the fact that age is an important risk factor in carcinoma breast. The lesion was found to be present commonly in upper outer quadrant (39%). Women on an average sought medical help with a delay of 6 months after realizing the presence of breast lump, thus delaying the treatment which in cases of malignancy carry bad prognosis, thus emphasizing the need of better education of the mass at large.

In our study, clinical diagnosis (physical examination) showed a sensitivity of 95%, a specificity of 100% and positive predictive value of 100%, negative predictive value of 96.23 with an overall accuracy of 97.80% (Table 2). Other studies showed that clinical examination could diagnose accurately only 70% of cases of carcinoma. Egan recorded an accuracy of 65% detection by physical examination [4]. Our study showed an accuracy of 97.80% by clinical examination. This relatively high accuracy in detecting malignancy by clinical examination is due to the fact that our patients rarely present early in the course of the

disease. Breast lump in our patients on an average was about 4x3centimeters on presentation. Out of 9 cases with suspicious interpretation in clinical diagnosis: 5 were diagnosed to be benign and 4 were diagnosed as malignant. Two cases which were diagnosed clinically as benign turned out to be malignant on HPE (Table 1).

In examining the triple test elements individually, we noted that FNAC is typically more accurate than physical examination or mammography (Table 2). This agrees with the study of Morris *et al.;* and Vetto *et al.;* [3]. In our study, the sensitivity of FNAC was 97.56%, the positive predictive value was 100%, specificity was 100%, and the negative predictive value was 98.18% with no false positives, but 1 false negative (Table 1). These results are in accordance with those of Morris *et al.;* Vetto *et al.;* reported a sensitivity of 96% for FNAC, with a specificity of 100%, and a positive predictive value of 100% [3]. Rubin and Joy concluded that FNAC is the first reliable diagnostic step in detection of breast carcinoma. They reported a positive predictive value of 100%, a specificity of 100%, a sensitivity of 87%, and a negative predictive value of 89%.

The widespread use of mammography has helped in better management of breast lump. In our study, the accuracy of mammography was 96.80%, the sensitivity 92.11%, the specificity 100%. The positive predictive value was found to be 100% (Table 2). There were 3 false positives and 6 cases were inconclusive (Table 1). In a Dutch study of breast cancer screening, Romback [6] found that if mammography alone has been used the sensitivity of breast cancer diagnosis would have been 95%. Rodes *et al.;* [7] reported that mammography was the sole detection modality in 56% of cases. When combined with physical examination, an additional 30% were detected, while physical examination alone detected 14% of cases.

In our study, the best results was got by TTS, it showed sensitivity of 100%, the positive predictive value was 100%, specificity was 100%, and the negative predictive value was 100% almost in perfect alignment with that of histopathology(Table 2). In one case where the TTS was 5 an additional test in the form of biopsy was required.

Clinical examination remains indispensable for detection of different breast lesions. Mammography remains the method of choice in radiology of the breast. FNAC has proved to be a very effective diagnostic aid. It is an easy technique, safe and very acceptable to patients. TTS outweighs all of these components and also helps us proceed further even in difficult scenarios of discordant results with triple assessment, thus reducing the fall back on the option of open biopsy which carries with it a number of disadvantages.

The use of the triple test score has proved itself to be a reliable tool for the accurate diagnosis of palpable breast lump. Triple test score when implemented streamlines the management of breast lump, more so when triple assessment can't come to a definitive diagnosis and thus biopsy which usually is resorted to in such a scenario can be avoided, saving the patient from anxiety, repeated operative procedure, financial burden, undue delay in treatment and also providing the surgeon a platform to base his further management.

CONCLUSION

Triple test score can be safely used as an accurate and least invasive diagnostic test and based on its interpretation, definitive treatment can be initiated which would reduce the need for unnecessary biopsies. The strength of TTS seems to lie in its ability to reliably predict benign lumps and thus avoid major surgeries. Given the increased incidence of malignant lumps in elderly females and the tendency to hide asymptomatic lumps, we need more awareness programs targeting this age group.

When patient presents to us with breast lump, it has been the usual practice to do a thorough clinical assessment, reaching a provisional diagnosis, which is then confirmed by using FNAC. With triple assessment gaining popularity mammography too was included into the scheme of breast lump evaluation for more apt diagnosis thus leading to better management of the patient.

When all the components of triple assessment are concordant, that is agree on common grounds the diagnosis is easily reached and patient is managed accordingly. When the components are discordant, that is differ in their interpretation of the breast lump, what would be the next step forward is the area which needs more light to be shed upon. It is precisely in this area where triple test score can be the answer to this dilemma. TTS being non-invasive and economical, with certain diagnosis in most of the cases (except in score of 5) can be relied upon as an effective test for further management of the patient.

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