IJPRP

Indian Journal of Pathology: Research and Practice

Volume 7 Number 7, July 2018
DOI: http://dx.doi.org/10.21088/ijprp.2278.148X.7718.11

Original Research Article

Efficacy of Triple Test Score in Evaluation of Breast Lumps: A One Year Prospective Study

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(**Received on** 23.06.2018,
Accepted on 14.07.2018)

Abstract

Introduction: The Triple test score includes triad of clinical examination, imaging studies and FNAC to arrive at a diagnosis. In TTS each component of the triple test score is rated as benign, suspicious or malignant and assigned 1,2 or 3 points respectively based on each type of examination thereby reducing the need for unnecessary surgeries. The current prospective study was carried out in our diagnostic centre with aim of evaluating the role of TTS in palpable breast masses and classifying them into benign, suspicious and malignant categories based on the TTS and advising biopsies in case of discordant results

Materials and methods: The present prospective study was conducted on 200 female patients coming to our diagnostic centre with complaints of breast lump between January to December 2017. Each parameter of the TTS was assigned a score of 1,2 or 3 based on it being benign, suspicious or malignant lesion. A BIRADs score was also assigned to each lump based on imaging studies. A score of ≤ 4 was considered to be benign and ≥ 6 was considered to be malignant with score of 5 in suspicious category.

Results: 98.7% benign lesions had TTS below 4, 6.25% suspicious lesions had a TTS of 5.63.55%malignant lesions had a TTS of ≥ 6.When these lesions were correlated with histopathology findings, the sensitivity and specificity of TTS was 94.5% and 98.17% respectively with a PPV of 97.73% and NPV of 95.54%.

Conclusion: Triple test score can be used as a reliable and non invasive diagnostic test for evaluating palpable breast masses with high degree of accuracy thus avoiding unnecessary surgeries. When the results are concordant, the diagnosis is most often final. When there are discordant results, biopsy is mandatory for confirmation.

Keywords: Breast Lumps; Triple Test `Score; Fnac; Mammography.

Introduction

Breast cancer is the most common cancer affecting females all around the world and is second leading cause of cancer related deaths next only to cervical and lung cancer [1]. It usually presents as a palpable lump or discharge from nipples [2]. The incidence of breast cancer in India is estimated to be 22.9 per 100,000 population, which is one third

that of Western countries, but unfortunately, the mortality rates due to breast cancer are higher in India [3,4]. Timely diagnosis and treatment plans are required for successful management of all cancer patients [5].

Evaluation of breast lumps by clinical assessment or self breast examination is insufficient to arrive at a diagnosis of malignancy. X-ray mammography, sonomammography and Fine needle aspiration cytology (FNAC) are helpful in such cases as it is safe, reliable and time saving outdoor procedure [6]. X ray mammography can detect small, on palpable breast lumps which can be visualized as radiodensities and calcifications. Sometimes, the surrounding radiodense tissues may obscure the lump, or there may be no calcification or desmoplastic response which can lead to a false negative diagnosis. This limitation of X-ray mammography is overcome by sonomammography which helps in distinguishing solid and cystic lesions [7].

Triple test score (TTS) was major advancement in the diagnosis of breast lumps .The TTS includes triad of clinical examination, imaging studies and FNAC to arrive at a diagnosis. The triple test score was initially described in 1975 for evaluating breast masses by physical examination, mammography and FNAC in women above 40 years of age [8]. In TTS each component of the triple test score is rated as benign, suspicious or malignant and assigned 1, 2 or 3 points respectively based on each type of examination thereby reducing the need for unnecessary surgeries. If used alone, the role of mammography and FNAC is 82% and 78% respectively [9]. Several reports and studies indicate that the triple test assessment of breast lumps increases the diagnostic accuracy to nearly 100% [10]. Moreover, they provide information about the size, extent and grade of the tumour preoperatively [11]. In those cases where the TTS is discordant, core biopsy is performed for confirmation [12]. In September 1996, National cancer institute held a conference to address FNA related issues and came to a consensus that TTS is a reliable tool in diagnosis of breast cancer [13].

The current prospective study was carried out in our diagnostic centre with the aim of evaluating the role of TTS in palpable breast masses and classifying them into benign, suspicious and malignant categories based on the TTS and advising biopsies in case of discordant results. Moreover, we compared the FNAC diagnosis with histopathological diagnosis wherever it was available.

Materials and Methods

The present prospective study was conducted on 200 female patients coming to our diagnostic centre with complaints of breast lump between January to December 2017. Females of all ages with palpable breast lumps were included in the study. Lactating females, females with nipple discharge and those with previous history of breast surgery were excluded from the study. Those patients in which only FNAC was advised without imaging studies were also excluded from the study. All the patients underwent clinical, imaging and FNAC assessment (Triple test) and a score was assigned to each group.

Each parameter of the TTS was assigned a score of 1,2 or 3 based on it being benign, suspicious or malignant lesion. A BIRADs score was also assigned to each lump based on imaging studies. The BI-RADS stands for Breast Imaging-Reporting and Data System which is accepted worldwide for risk assessment and quality assurance in mammography, ultrasound or MRI [14,15].

The lesions were classified into six categories:

- *BI-RADS 0:*
  - incomplete, further imaging or information is required, e.g. compression, magnification, special mammographic views, ultrasound
- *BI-RADS I*: negative, symmetrical and no masses, architectural disturbances or suspicious calcifications present
- *BI-RADS II*: benign findings,
- *BI-RADS III*: probably *benign*, short interval follow-up suggested
- *BI-RADS IV*: suspicious abnormality
  - further divided as
    - *BI-RADS IVa*: low level of suspicion for malignancy
    - *BI-RADS IVb*: intermediate suspicion for malignancy
    - *BI-RADS IVc*: moderate suspicion for malignancy
- *BI-RADS V*: mammographic appearance which is highly suggestive of malignancy
- *BI-RADS VI*: known biopsy proven malignancy

The reports were correlated with histopathology reports. Sensitivity, specificity, positive and negative predictive value (PPV and NPV) were

calculated for each parameter. A score of ≤ 4 was considered to be benign and ≥ 6 was considered to be malignant with score of 5 in suspicious category. Clinical examination was based on referring clinician's observations, the radiologist reviewed mammographic findings and FNAC smears were analysed by cytopathologist.

Calculations were based on the following formulae-

Sensitivity=TP/TP+FN where TP= true positive, FN= False negative

Specificity = TN/TN+FP where TN= true negative FP = false positive.

All patients were divided into different age groups such as < 20, 21-30, 31-40, 41-50, 51-60, 61-70 and 71-80 years age group.

Results

A total of 200 female patients presenting with palpable breast lumps were included in the study. Maximum number of patients (26.5%) were in 41-50 years of age group, followed by 24% in 31-40 years, 17.5% in 51-60 years, 13.5% in 21-30 years, 9.5% in 61-70, 5.5% in 71-80 years and least 3.5% below 20 years of age (Table 1).

Out of 200 cases, 99 (49.5%) were benign, 32 (16%) were in suspicious category and 69 (34.5%) were malignant (Table 2). Out of the benign lumps, 33 (16.5%) were in 31-40 years age group, 25 (12.5%) in 21-30 years age group, 22 (11%) in 41-50 years of age 12 (6%) in 51-60 years of age. In the suspicious

Table 1: Age wise distribution of patients

Age	Number	%
< 20	7	3.5%
21 - 30	27	13.5%
31 - 40	48	24.0%
41 - 50	53	26.5%
51 - 60	35	17.5%
61 - 70	19	9.5%
71 - 80	11	5.5%

Table 2: Age wise Distribution of Malignant, Suspicious & Benign Lesions

Age	Benign	%	Suspicious	%	Malignant	%
< 20	7	3.5%	0	0.00%	0	0.00%
21 - 30	25	12.5%	1	0.50%	1	0.50%
31 - 40	33	16.5%	11	5.50%	4	2.00%
41 - 50	22	11.0%	8	4.00%	23	11.50%
51 - 60	12	6.0%	3	1.50%	20	10.00%
61 - 70	0	0.0%	6	3.00%	13	6.50%
71 - 80	0	0.0%	3	1.50%	8	4.00%
Total	99	49.50%	32	16%	69	34.50%

Table 3: Age wise Distribution of Benign Lesions With Bi-rad's Category

Age	Fibroadenoma			Benign Cystic lesion			Breast abscess			Granulomatous mastitis chronic abscess			Fibroadenosis			Fat Necrosis			Galactocoel			Giant Fibroadenoma/ Phylloides Tumour			Benign epithelial lesion			Inflammation Lesion			Fibrocystic Disease			Total
	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	2	3	4	
< 20	1	1	0	0	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	6
21 - 30	1	6	0	0	0	2	1	1	0	0	0	0	4	0	0	0	0	0	2	0	0	0	0	0	1	0	0	0	0	0	2	0	0	22
31 - 40	4	4	1	0	5	0	1	6	0	0	1	0	2	1	0	0	1	0	0	0	0	0	1	1	0	2	0	0	0	0	2	4	0	36
41 - 50	2	5	0	3	4	0	3	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	1	23
51 - 60	3	0	0	2	2	0	2	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	12
Total	11	16	1	5	13	1	7	8	0	0	2	0	8	3	0	0	2	0	2	0	0	0	2	1	1	2	0	0	1	0	3	9	1	

category, 11 (5.5%) were in 31-40 years age group, followed by 8 (4%) in 41-50 years age group, 6 (3%) in 61-70 years age group. In the malignant category, maximum cases were observed in 41-50 years of age, accounting for 11.5% of all cases, followed by 10% in 51-60 years, 6.5% in 61-70 years, and 4% in 71-80 years age group. One case of malignancy was observed in 21-30 years of age group. No malignant case was detected below 20 years of age. (Table 3)

11 cases of fibroadenoma were in BIRAD category II, 16 cases in BIRAD category III and one case in category IV. Maximum benign cystic lesions were in BIRADS category III(13 cases) and 7 in category II.9 cases of fibrocystic disease were assigned BIRADs category III and two were in category II. Out of the suspicious lesions, which included 13 cases of ductal hyperplasia with atypia and three cases of IV papillary neoplasm, the BIRADS category was IV (Table 4).

In the malignant lesions BIRADS category IV was observed in two cases of lobular carcinoma, 31 cases of ductal carcinoma, one case each of DCIS and medullary carcinoma. BIRADS category V was observed in 30 cases of Duct carcinoma and two cases of Medullary carcinoma (Table 5).

98.7% benign lesions had TTS below 4, 28.9% were in suspicious category with a TTS score ≥ 6 and 6.25% suspicious lesions had a TTS of 5.63.55% malignant lesions had a TTS of ≥ 6 (Table 6).

When these lesions were correlated with histopathology findings, the sensitivity and specificity of TTS was 94.5% and 98.17% respectively with a PPV of 97.73% and NPV of 95.54% (Table 7).

Table 7: Correlation of TTS with histopathology

Histological Diagnosis	TTS 3 - 4 (n)	TTS 3-4 (%)	TTS 5 (n)	TTS 5 (%)	TTS 6 - 9 (n)	TTS 6 - 9 (%)	Total (n)	Total (%)
Benign	7	87.50%	6	100.00%	4	4.30%	17	15.89%
Malignant	1	12.50%	0	0.00%	89	95.70%	90	84.11%
Total	8		6		93		107	

Table 4: Age wise Distribution of Suspicious Lesions With Bi-rad's Category

Age	Suspicious for Malignancy			Epthelial hyperplasia with atypia-breast				Papillary Neoplasm/ Carcinoma			Total
	2	3	4	2	3	4	5	2	3	4	
21 – 30	0	0	0	0	0	1	0	0	0	0	1
31 – 40	0	0	1	0	2	4	1	0	0	2	10
41 – 50	0	0	4	0	0	4	0	0	0	1	9
51 – 60	0	1	0	0	2	0	0	0	0	0	3
61 – 70	0	0	5	0	0	1	0	0	0	0	6
71 – 80	0	0	0	0	0	3	0	0	0	0	3
Total	0	1	10	0	4	13	1	0	0	3	

Table 5: Age wise Distribution of Malignant Lesions With Bi-rad's Category

Age	Lobular Carcinoma			Mucinous Carcinoma			Ductal Carcinoma			DCIS			Medullary Carcinoma			Total
	3	4	5	3	4	5	3	4	5	3	4	5	3	4	5	
21 - 30	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1
31 - 40	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	4
41 - 50	0	0	0	0	0	0	1	12	9	0	1	0	0	0	0	23
51 - 60	0	0	0	0	0	0	0	8	11	0	0	0	0	0	1	20
61 - 70	0	2	0	1	0	0	0	4	5	0	0	0	0	1	0	13
71 - 80	0	0	0	0	0	0	0	5	2	0	0	0	0	0	1	8
Total	0	2	0	1	0	0	1	31	30	0	1	0	0	1	2	

Table 6: Triple test score in spectrum of lesions on cytology

Cytological Diagnosis	TTS 3 - 4 (n)	TTS 3-4 (%)	TTS 5 (n)	TTS 5 (%)	TTS 6 - 9 (n)	TTS 6 - 9 (%)	Total (n)	Total (%)
Benign	76	98.70%	15	93.75%	8	7.48%	99	49.50%
Suspicious	0	0.00%	1	6.25%	31	28.97%	32	16.00%
Malignant	1	1.30%	0	0.00%	68	63.55%	69	34.50%
Total	77		16		107		200	

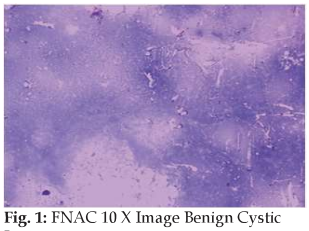

Fig. 1: FNAC 10 X Image Benign Cystic Lesion

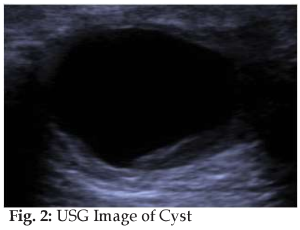

Fig. 2: USG Image of Cyst

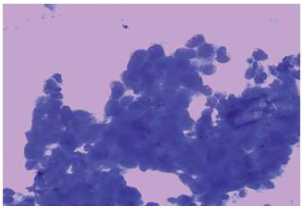

Fig. 3: FNAC 40X Image of Duct Carcinoma

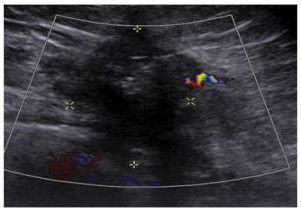

Fig. 4: USG Iamge of Duct Carcinoma

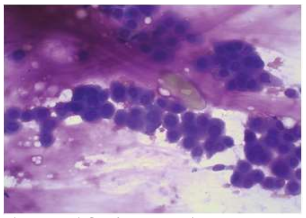

Fig. 5: FNAC 40X Image of Mucinous Carcinoma

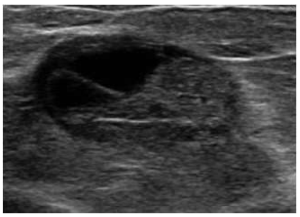

Fig. 6: USG Image of Mucinous Carcinoma

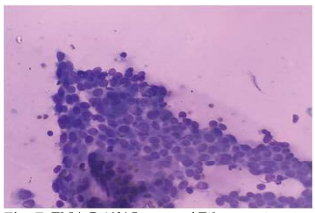

Fig. 7: FNAC 40X Image of Fibrocystic Disease

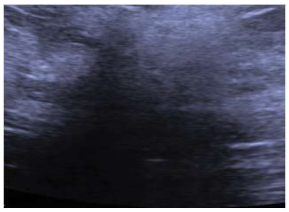

Fig. 8: USG Image of Fibrocystic Disease

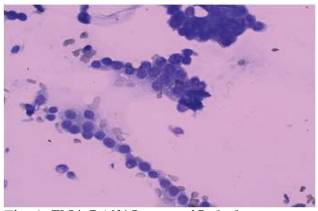

Fig. 9: FNAC 10X Image of Lobular Carcinoma

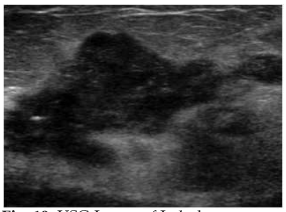

Fig. 10: USG Image of Lobular Carcinoma

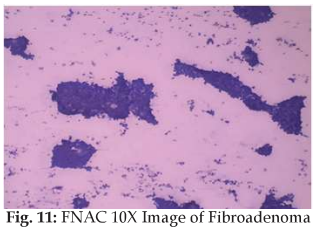

Fig. 11: FNAC 10X Image of Fibroadenoma

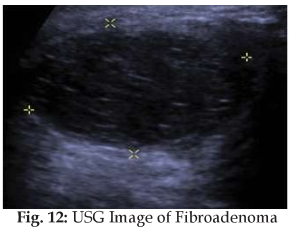

Fig. 12: USG Image of Fibroadenoma

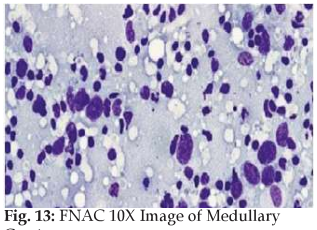

Fig. 13: FNAC 10X Image of Medullary Carcinoma

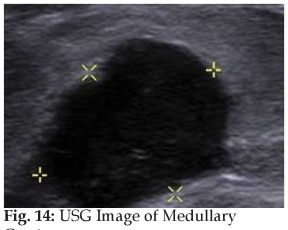

Fig. 14: USG Image of Medullary Carcinoma

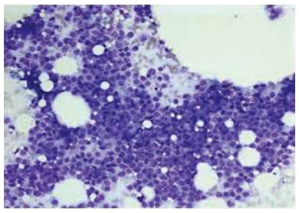

Fig. 15: FNAC 10X Image of DCIS

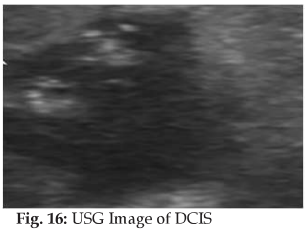

Fig. 16: USG Image of DCIS

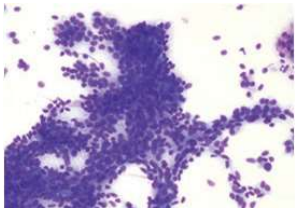

Fig. 17: FNAC 10X Image of Phyllodes Tumour

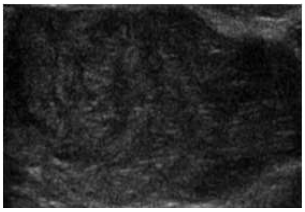

Fig. 18: USG Image of Phyllodes Tumour

Sensitivity and specificity of clinical examination alone was 100% and 87.5% respectively with a PPV of 98.3% and NPV of 100%. For only radiological assessment the sensitivity was 95.4% and specificity was 81.8% with PPV of 97.6% and NPV of 69.2% for malignant lesions. For only FNAC the sensitivity was 100% with a PPV of 98.6%. The overall sensitivity and specificity of TTS was 94.5% and 98.17% respectively with a PPV of 97.73% and NPV of 95.54%.

Discussion

The triple test score was first described by Johansen in mid 1970. Triple test score or TTS is a combination of clinical examination of the breast, radiological imaging and fine needle aspiration cytology of the breast lump to arrive at a diagnosis. It is a cost effective, non invasive technique which saves the precious time of the patient till diagnosis and is well accepted by the patients. When the three evaluations produce concordant results, the diagnostic accuracy of the breast masses is nearly 100 % [16,17,18].

In our study we observed a sensitivity of 94.5% and specificity of 98.17% with a PPV of 97.73% and NPV of 95.5%. In our study, benign breast lumps were most common accounting for 49.5% of the cases as compared to malignant masses. Fibroadenoma was the most common benign lump and duct carcinoma was the most common malignancy detected. Our study correlates with the study of Anil Kumar et al. [19]. Katherine et al in their study observed that all lesions with TTS less than 4 were benign and TTS ≥6 were confirmed to be malignant on biopsy [20]. Al Muhim et al observed a sensitivity of 82.6% and 97.3% specificity and a

PPV of 86.4% for physical examination alone [21]. Mammography alone had a sensitivity of 87.5%, specificity of 97.3% and PPV 87.5% while FNAC had 91.7% sensitivity, 100% specificity and 100% PPV. They observed that TTS was 100% accurate in diagnosis of palpable breast masses. In our study, sensitivity and specificity of clinical examination alone was 100% and 87.5% respectively with a PPV of 98.3% and NPV of 100%. For only radiological assessment the sensitivity was 95.4% and specificity was 81.8% with PPV of 97.6% and NPV of 69.2% for malignant lesions. For only FNAC the sensitivity was 100% with a PPV of 98.6% in our study.

Ahmed I et al in their study observed that 54.28% cases were benign and 45.71% cases were malignant [22]. They observed a 100% specificity and NPV for benign lesions when TTS was used.

Kachewar et al observed that TTS ≥6 had a sensitivity of 97.44% and specificity of 100% in diagnosing malignant breast lumps [23]. Due to lower sensitivity and specificity of X-ray mammography in picking up lesions in women below 40 years of age and usefulness of sonomammography in this group of patients, TTS is a better and reliable tool for picking up maximum number of breast lumps [24]. A TTS of 3 or 4 is almost always benign. A TTS of 5 should be further evaluated by core biopsy or excision of the lump for confirmation [25].

Conclusion

Triple test score can be used as a reliable and non invasive diagnostic test for evaluating palpable breast masses with high degree of accuracy thus avoiding unnecessary surgeries. When the results are concordant, the diagnosis is most often final. When there are discordant results, biopsy is mandatory for confirmation.

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