

Original Research Article

Modified triple assessment in the diagnosis of breast lump in Saurashtra region of Gujarat

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ABSTRACT

Background: Breast lump is a common complaint of women presenting to surgeons. Most of them are benign, careful evaluation, exact diagnosis and definitive treatment is mandatory to rule out cancer. The diagnosis of breast cancer is suggested on clinical examination. Currently a combination of three tests, i.e. clinical examination, radiological imaging (mammography, ultrasonography) and pathology called as triple assessment test is used to accurately diagnose all palpable breast lumps. Together they give sensitivity of 100%. The triple assessment is taken as positive if any of the three components, two are positive or positive report of FNAC and negative only if all of its components are negative for malignancy.

Methods: This study was conducted in the Department of Surgery, P.D.U Medical College, Rajkot, Gujarat over a period of 2 years. A total of 100 patients with a breast lump were selected more than 15 years of age. A detailed history, focused clinical examination, radiological imaging and FNAC were used as diagnostic tools for screening of the patients. The aim of this study was to evaluate accuracy of modified triple assessment in the preoperative diagnosis of patients with breast carcinoma.

Results: Results shows sensitivity and specificity of all the modalities used in triple assessment when combined together was 100% and 99.3%, respectively. Positive predictive value was 93.3%, negative predictive value was 100%, p-value was highly significant ($p < 0.0001$). We conclude that modified triple assessment is a very useful diagnostic tool to evaluate patients with breast lumps and an overall accuracy of 98%.

Conclusions: Thus, triple assessment is an easily available, cost effective, least invasive, rapid and patient compliant diagnostic tool for diagnosis of breast lump.

Keywords: Modified triple assessment, Clinical examination, Mammography, Ultrasonography, Fine-needle aspiration

INTRODUCTION

Patients with breast problems make up a major part of the patient load at a general surgical out-patients clinical. With the increasing public and professional awareness each year large number of young women are being referred to general surgeons with palpable breast lump. Breast problems can present themselves in number of ways like breast pain, nipple discharge, cystic lesions and more commonly a lump. Majority of them prove to be benign,

but probability of the diagnosis of cancer not be excluded. So careful evaluation, exact diagnosis and definite treatment is mandatory in any type of breast lump. Until a few years ago, it was generally believed that breast tumour should be excised and histologically examined to determine its nature with certainty because the preoperative physical assessment alone was associated with too much uncertainty. Eventually, with the advent of mammography, a radiological tool became available to the surgeons to make a pre-operative diagnosis of the breast

with a reasonable degree of accuracy. However, it was the introduction of Fine needle aspiration cytology (FNAC) that changed the entire outlook to the matter. The combination of physical examination mammography and FNAC came to be called upon as the "triple test" for assessment of breast lumps and has now become the gold standard in the work-up of the same. According to National Institute for Health and Clinical Excellence (NICE) guidelines, for patients with symptoms that could be caused by breast cancer, diagnosis is made by Modified triple assessment. The combination of physical examination, sono mammography and FNAC came to be called upon as the "Modified Triple Test". The aim of our study was to the role of modified triple assessment in diagnosis of breast lump and sensitivity and specificity of modified triple assessment with regards to histopathology. Chandak NS et al in their study they have taken 50 patients in the age range of 11 to 70 years, with a mean of 38.54 years.¹ Khoda L et al in their study a total of 50 female patients with clinically palpable breast lump(s) attending the surgical Outpatient department (OPD) were included for their study. The age range was 18-56 years and the mean age was 32 years.²

Objectives

To review sensitivity and specificity of modified triple assessment in diagnosis of breast lump. To assess the diagnostic accuracy of modified triple test in diagnosis of breast lump. To correlate the modified triple assessment test with histopathology findings in patients with palpable breast lump. To reduce the number of open biopsies for definitive diagnosis of breast lump. To provide an easily available, cost effective, least invasive, rapid and patient compliant diagnostic tool for breast lump. To study the effectiveness of the test to differentiate benign lesion from malignant breast lesion.

METHODS

Randomly selected 100 female patients with breast lump attending surgery OPD PDUMCH and admitted in female surgical ward surgical unit during the study period in PDUMCH. This study was conducted in the Department of Surgery, P.D.U Medical College, Rajkot, Gujarat attending the surgical OPD of P.D.U Hospital, Rajkot. Women with a breast lump or suspicious change in the breast texture was included in the study. A detailed patient's history, focused clinical examination and radiological imaging (mammography, ultrasonography (USG)) and fine-needle aspiration cytology (FNAC) were used as diagnostic tools for screening of the patients for a possible malignant disease at its inception (early stage).

Study design

It was a hospital based cross sectional analytic, clinical study.

Study location

Study was placed at PDU Medical College and Hospital, Rajkot, Gujarat, India.

Study duration

Study duration was 2 years (September 2017 to August 2019).

Sample size

100 patients with breast lump, age more than 15 years.

Subject and selection method

Randomly selected 100 female patients with breast lump attending surgery OPD PDUMCH and admitted in female surgical ward surgical unit during the study period in PDUMCH.

Inclusion criteria

Female patients with palpable breast lump/lumps above 15 years of age attending surgery OPD and admitted in female surgical ward in PDUMCH.

Exclusion criteria

Exclusion criteria was as follows: male patients and female patients with advanced breast cancer that makes diagnosis obvious were excluded from the study, patient not willing for FNAC, lactating mother, radiation given to the breast, acute inflammatory conditions of the breast and obvious advanced malignancy of breast.

Procedure methodology

This cross sectional study has included female patients selected randomly, having a breast lump/lumps in, who attended the surgery OPD or were admitted in female surgical ward of general surgery with having complaint of breast lump/lumps were assessed thoroughly as per modified triple assessment comprised of clinical breast examination, sono mammography of bilateral breast with bilateral axilla and FNAC of lump after detailed explanation about the purpose of study, to the all enrolled patients in this study, in their own language and valid consent has been obtained with assurance of confidentiality and only shared for academic purpose.

Statistical analysis

The modified triple test (MTT) was scored as concordant if the elements had either all malignant or all benign results. It was non-concordant if the elements had neither all malignant nor all benign results. The test results were analyzed separately in concordant and non-concordant cases. The sensitivity, specificity and accuracy were calculated by the following formula, where TP indicates

true positive; TN, true negative; FP, false positive; and FN, false negative: sensitivity = $TP / (TP+FN)$ specificity = $TN / (TN+FP)$ accuracy = $TP+TN / (TP+FP+TN+FN)$. In non-concordant cases, results of each components of triple test were analyzed separately and then in combination and then above said parameters were calculated. In non-concordant cases, triple test was scored as benign or malignant, depending upon the result of either of the two elements amongst three components.

RESULTS

This study was conducted in the general surgery department, P.D.U Medical College and Hospital, Rajkot, Gujarat over a period of 2 year from September 2017 to August 2019. In present study as we can observe that most common age group in this series is 36 to 45 years of age. Mean age is 36.45 ± 13.20 years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. All patients presented with palpable breast lump as their most common symptoms and we observe that lump in axilla along with breast lump are 12 patients as additional symptoms followed by with pain over the breast are 8 patients and with nipple discharge are 4 patients out of 100 patients. In present study the breast lump was present more on right side 56 patients as compared to left side 44 patients with right to left ratio is 1.27. We found that 62 patients were most commonly involved upper outer quadrant and lower inner quadrant was least commonly involved in just 4 patients of cases in breast lump in this series.

Table 1: Mammographic findings (n=68)

Findings	No. of patients (%)
Well circumscribed mass with regular margins	55 (80.88)
Density lesion with microcalcification	04 (5.8)
Density lesion with irregular margins and spiculation	02 (2.9)
Density lesion with microcalcification, irregular margins and spiculation	07 (10.29)
Total	68 (100)

Table 2: USG impression (n=100)

Findings	No. of patients (%)
Fibroadenoma	43
Fibro adenosis	18
Galactocele	2
Traumatic fat necrosis	4
Phyllodes	6
Ductal cell carcinoma	20
Lobular cell carcinoma	7
Total	100

As from present study we can observed that most common size of lump was in range of >2 cm to 5 cm in diameter in clinical breast examination are 63 patients and in 17 patients, size of lump is more than 5 cm in diameter. Most of the patients who went under clinical breast examination yield that mostly the patients with lump in firm consistency 67 patients, one of them had soft and other 32 patients had hard in consistency.

Table 3: FNAC findings (n=100)

Findings	No. of patients (%)
Fibroadenoma	63
Fibroadenosis	20
Galactocele	5
Solid mass	4
Solid mass with irregular margins	2
Cyst	6
Total	100

DISCUSSION

The study entitled “modified triple assessment in the diagnosis of breast lump” was a prospective study conducted in the Department of Surgery, P.D.U Medical College and Hospital, Rajkot. A total 100 patients with breast lump were included in the study to determine the number of patients having breast cancer. This study was carried out over a period of 2 years from September 2017 to August 2019. Currently a combination of three tests, i.e. clinical examination, radiological imaging (mammography, USG) and FNAC (pathology) together called as modified triple assessment is used to accurately diagnose all palpable breast lumps. The triple assessment is taken positive if any two out of the three components is positive for malignancy or positive component of FNAC and negative only if all of its components are negative for malignancy. Clinical examination was in favor of malignant disease in 24 patients, however histopathology also confirmed malignancy in 24 patients. Similarly, benign diagnosis was made on clinical examination in 76 patients, however histopathology confirmed benign diagnosis in 69 patients only with the remaining 7 patients being diagnosed as malignant. Thus, histopathology confirmed malignant breast disease in 31 patients. Had found sensitivity 77.41%, specificity 100%, positive predictive value 100%, negative predictive value 90.78%, p-value was significant ($p < 0.0001$). Yang et al found a sensitivity, specificity and positive predictive value for clinical examination as 88%, 92%, 67%, respectively.³

Bhavinder et al they conducted a prospective study to evaluate the diagnostic efficacy of clinical examination, ultrasonography and FNAC individually and in combination for the diagnosis of palpable breast lump in 50 patients. Clinical assessment when compared with histopathology had a sensitivity of 99%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 80%.⁴ Sonomammography was in

favor of malignant diagnosis in 28 patients, all of which turned out to be malignant on histopathology. Out of 100 patients, 72 cases diagnosed as benign on sonomammography, 3 turned out to be malignant on

histopathology. Thus, the sensitivity was 90.32% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 95.83%. P value was significant (0.000).

Table 4: Findings of different modalities of modified triple assessment

Clinical	Sonomammography	FNAC	Triple test Benign or malignant	Histology	
				B	M
B	B	B	64-B	64	00
B	B	M	02-M	00	02
B	M	B	01-B	01	00
B	M	M	09-M	01	08
M	B	B	02-B	02	00
M	B	M	04-M	00	04
M	M	B	03-M	01	02
M	M	M	15-M	00	15

Table 5: Modified triple assessment.

Modality of triple assessment		Histopathology		No. of patients	Sensitivity	Specificity	PPV	NPV
		Malignant	Benign					
Clinical Examination	Malignant	24	00	24	77.41	100	100	90.78
	Benign	7	69	76				
Total		31	69	100				
Sonomammography	Malignant	28	00	28	90.32	100	100	95.83
	Benign	3	69	72				
Total		31	69	100				
FNAC	Malignant	30	00	30	96.77	100	100	98.57
	Benign	1	69	70				
Total		31	69	100				
Modified triple assessment test	Malignant	31	2	33	100	97.10	93.93	100
	Benign	00	67	67				
Total		31	69	100				

When we compare these results with the available literature, Shetty et al sensitivity for a combined mammographic and sonographic assessment were 100%, the specificity was 80.1%.⁵ FNAC was in favor of malignant diagnosis in 30 patients. Histopathology was in agreement with FNAC results in all 30 patients. FNAC was in favor of benign diagnosis in 70 patients. However, histopathology was in favor of benign diagnosis in 69 patients with 1 patient proving to be malignant on histopathology. Had found sensitivity was 96.77% and specificity was 100%, positive predictive value for FNAC was 100% and negative predictive value was 98.57%. P value was significant (0.000). Our results were in correlation with the results of other studies. Mohammed et al found that fine needle aspiration biopsy (FNAB) had a positive predictive value of 100%, sensitivity of 90.6% and specificity of 100%.⁶ Ronak Chaudhari et al in their prospective study all 50 patients went under FNAC, that finally correlated with histopathological diagnosis had found sensitivity and specificity were 100% and 96.77%

respectively and positive predictive value 95.00%.⁷ When modified triple assessment result was compared with the results of histopathology, we found that specificity was 97.10% and sensitivity was 100%, positive predictive value was 93.93%, negative predictive value was 100% and p value was significant (0.000). Our result compared to favorably with the available literature. Kaufman et al found that sensitivity of triple assessment was 100% and negative predictive value was 100%.⁸ Ahmad et al found that the sensitivity of triple test was 100% and specificity was 100%.⁹ Lingaraju et al observational cross-sectional study conducted in Mandya Institute of Medical Sciences from March 2015 to March 2016. 80 female patients below 35 years presented to OPD with palpable breast lumps are assessed by triple modified assessment. The result of triple assessment was in favor of benign diagnosis in 41 (51.25%) patients while as the malignant diagnosis was made in 14 (17.5%) patients. Histopathology diagnosed fibroadenoma in 41 (51.25%) cases, breast abscess in 7

(8.75%) cases, infiltrating ductal cell carcinoma in 14 (17.5%) cases, and fibro adenosis in 6 (7.5%).¹⁰

CONCLUSION

Modified triple assessment is a very useful diagnostic tool to evaluate patients with breast lumps and to detect patients with breast cancers with an overall accuracy of 98%. Modified triple assessment was useful in diagnosing breast cancers at an earlier stage, with most of breast cancers detected at stage I or stage II (T1 or T2, N0 or N1, M0). It was found that triple assessment did not require hospitalization, but was performed on OPD basis, without any complications. The modalities used are either non-invasive or minimally invasive. We found that sensitivity of triple assessment with regard to histopathology was 100%, specificity was 97.10%. Thus, Modified Triple Assessment is an easily available, cost effective, least invasive, rapid and patient compliant diagnostic tool for diagnosis of breast lump. Limitations are it is limited in pregnancy, younger female (<35 years), patient with breast implant, advance breast carcinoma, co-ordination between pathologist and radiologist is difficult sometimes.

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