e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2023; 15(10); 141-145

Original Research Article

A Hospital-Based Study Assessing Efficacy of Modified Triple Assessment in the Diagnosis of Breast Lump: An Observational Study

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Received: 10-06-2023 Revised: 21-07-2023 / Accepted: 10-08-2023
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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to assess sensitivity and specificity of modified triple assessment in diagnosis of breast lump.

Methods: The present study was conducted in the Department of General Surgery for the period of 2 years and randomly selected 100 female patients with breast lump attending surgery OPD and admitted in female surgical ward surgical unit during the study period.

Results: Mean age was 35.45 ± 12.78 years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. In present study the breast lump was present more on right side 56 patients as compared to left side 44. As from present study we observed that most common size of lump was in range of >2 cm to 5 cm in diameter in clinical breast examination are 68 patients and in 32 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 65 patients, 1 of them had soft and other 34 patients had hard in consistency. 80% patients had well circumscribed mass with regular margins followed by Density lesion with microcalcification, irregularmargins and speculation (10%). In the study, 43% patients had Fibroadenoma, 21% patients had Ductal cell carcinoma and 15% patients had Fibro adenosis. In FNAC, 64% patients had Fibroadenoma, 21% patients had Fibroadenosis and 4% patients had cyst. The sensitivity was 90.62% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 96.74%. P value was significant (0.000).

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.

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

Introduction

The first written evidence of breast cancer dates back from 3000 to 2500 BC from ancient Egypt in the Edwin Smith Papyrus. [1,2] There is an increasing incidence of breast cancer; it was reported to have caused over a quarter (28%) of all the deaths in the UK in 2017. [3] It is imperative to develop new approaches for the early detection of cancer to improve survival and to decrease the burden on health care professionals. [4]

In the spectrum of symptoms related to breast disease, a breast lump is the most commonly presented symptom. It may either be a manifestation of benign pathologies, such as fat necrosis, fibroadenoma, acute or chronic breast abscess, or a sinister carcinoma breast. [5] Distinguishing between benign and malignant breast lesions solely by a clinical/physical examination is subjective and clinician dependent and carries a risk of uncertainty and error. Core biopsy is considered to be a reliable test used in the detection of breast cancer, however, it requires time and expertise and can be a painful experience. Most hospitals in the UK run “Rapid Access” breast

cancer screening clinics offering triple assessment. [6]

Breast ultrasound (US) is a very important adjunct to mammography (MMG) in patients with equivocal findings. It is now widely accepted as a diagnostic modality for breast lesions. Using modern high resolution probes majority of carcinomas of size less than 1 cm can be identified. Potential advantages of breast US are non-invasiveness, easy availability, lower cost and good accuracy rate for diagnosing breast masses. [7,8] Bassett et al found that MMG was not useful in assessing breast lesions in women less than 35 years due to denser breast tissue. On the contrary, US was helpful in avoiding unnecessary breast biopsies and was recommended as the initial examination in younger women. [9] Triple assessment, as the name indicates, includes three modalities, physical examination, imaging (mammography and/or ultrasound), and biopsy (FNAC and core biopsy). These modalities, when used individually for breast cancer screening and diagnosis, will render less reliable results as compared to when used in combination.

The accurate diagnosis and appropriate management of breast lumps is associated with anxiety and stress, both for the patients and the caring physician. The steps in establishing a diagnosis include clinical examination, mammogram and needle biopsy. The individual components of this triple assessment are not reliable on their own in reaching a diagnosis but when combined, the diagnostic accuracy is nearly 100% and the triple test has been proposed as the gold standard for the diagnosis of breast lumps. [10-12] Patients with breast problems make up a major part of the patient load at a general surgical out-patient's 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.

The aim of the present study was to assess sensitivity and specificity of modified triple assessment in diagnosis of breast lump.

Materials and Methods

The present study was conducted in the Department of General Surgery, JLNMCH, Bhagalpur, Bihar, India for the period of 2 years and randomly selected 100 female patients with breast lump attending surgery OPD and admitted in female surgical ward surgical unit during the study period.

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).

Subject and selection method

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

Inclusion Criteria

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

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 nonconcordant 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

Table 1: Patient details

Variables	N%
Mean age	35.45 ± 12.78 years
Side affected	
Right	56 (56)
Left	44 (44)
Size of lump	
>2 cm-5 cm	68 (68)
>5 cm	32 (32)
Consistency of breast lump	
Firm	65 (65)
Hard	1 (1)
Soft	34 (34)

Mean age was 35.45 ± 12.78 years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. In present study the breast lump was present more on right side 56 patients as compared to left side 44. As from present study we observed that most common size of lump was in range of >2 cm to 5 cm in diameter in clinical breast examination are 68 patients and in 32 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 65 patients, 1 of them had soft and other 34 patients had hard in consistency.

Table 2: Mammographic findings (n=60)

Findings	No. of patients (%)
Well circumscribed masswith regular margins	48 (80)
Density lesion withmicrocalcification	4 (6.66)
Density lesion with irregularmargins and spiculation	2 (3.34)
Density lesion with microcalcification, irregularmargins and spiculation	6 (10)
Total	60 (100)

80% patients had well circumscribed masswith regular margins followed by Density lesion with microcalcification, irregularmargins and speculation (10%).

Table 3: USG impression

Findings	No. of patients (%)
Fibroadenoma	43 (43)
Fibro adenosis	15 (15)
Galactocele	3 (3)
Traumatic fat necrosis	5 (5)
Phyllodes	6 (6)
Ductal cell carcinoma	21 (21)
Lobular cell carcinoma	7 (7)
Total	100

In the study, 43% patients had Fibroadenoma, 21% patients had Ductal cell carcinoma and 15% patients had Fibro adenosis.

Table 4: FNAC findings

Findings	No. of patients (%)
Fibroadenoma	64 (64)
Fibroadenosis	21 (21)
Galactocele	5 (5)
Solid mass	4 (4)
Solid mass with irregularmargins	2 (2)
Cyst	4 (4)
Total	100

In FNAC, 64% patients had Fibroadenoma, 21% patients had Fibroadenosis and 4% patients had cyst.

Table 5: Modified triple assessment

Modality of triple assessment	Histopathology	No. of	Sensiti	Specifi	PP	NPV

		Malignant	Benign	patients	vity	city	V	
Clinical	Malignant	25	00	25				
Examination	Benign	5	70	75	78.32	100	100	90.78
Total		30	70	100				
	Malignant	28	00	28				
	Benign	2	70	72	90.62	100	100	96.74
Total		30	70	100				
	Malignant	29	00	29				
	Benign	1	70	71	96.84	100	100	98.62
Total		30	70	100				
Modified triple	Malignant	30	2	32				
assessment test	Benign	00	68	68	100	97.10	3	100
Total		30	70	100				

The sensitivity was 90.62% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 96.74%. P value was significant (0.000).

Discussion

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. [13]

Mean age was 35.45 ± 12.78 years. Youngest patient was of 16 years of age and oldest patient was 70 years of age. In present study the breast lump was present more on right side 56 patients as compared to left side 44. As from present study we observed that most common size of lump was in range of >2 cm to 5 cm in diameter in clinical breast examination are 68 patients and in 32 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 65 patients, 1 of them had soft and other 34 patients had hard in consistency. 80% patients had well circumscribed mass with regular margins followed by Density lesion with microcalcification, irregular margins and speculation (10%). Yang et al found a sensitivity, specificity and positive predictive value for clinical examination as 88%, 92%, 67%, respectively. [14]

In the study, 43% patients had Fibroadenoma, 21% patients had Ductal cell carcinoma and 15% patients had Fibro adenosis. In FNAC, 65% patients had Fibroadenoma, 20% patients had Fibroadenosis and 6% patients had cyst. In FNAC, 65% patients had Fibroadenoma, 20% patients had Fibroadenosis and 6% patients had cyst. A study conducted by Lod Khoda et al. reveals the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of the physical examination were 66.6%, 100%,100%, 90%, and 91.6%, respectively. Various other studies also show the sensitivity of physical examination ranging from 21% to as high as 100% and the specificity from 50% to 97.8%. [15] Pande et al. in 2003 found the sensitivity, specificity, positive predictive value, and negative predictive value for ultrasound was 95%, 94.10%, 95.50%, and 93.75%, respectively. [16] Shetty et al sensitivity for a combined mammographic and sonographic assessment were 100%, the specificity was 80.1%. [17] The sensitivity was 90.62% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 96.74%. P value was significant (0.000).

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 noninvasive or minimally invasive. The sensitivity was 90.42% and specificity was 100%, positive predictive value was 100%, and negative predictive value was 95.75%. P value was significant (0.000).Thus, Modified Triple Assessment is an easily available, cost effective, least invasive, rapid and patient compliant diagnostic tool for diagnosis of breast lump.

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