

## Triple Assessment of Breast – Gold Standard in Mass Screening for Breast Cancer Diagnosis

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**Abstract: Background:** In Breast cancer there is paradigm shift towards its prevention and early detection. Self breast examination and clinical breast examination plays an important role in early detection. Currently a combination of three tests, i.e. clinical examination, radiological imaging (mammography, ultrasonography) and pathology called as triple assessment test is used as Gold standard in diagnosing all palpable breast lumps. Together they give sensitivity of 99%. The triple assessment is taken as positive if any of the three components is positive and negative only if all of its components are negative for malignancy.

**Materials And Methods** This study was conducted in the Department of Surgery, Rama Medical College Kanpur over a period of 4 years from March 2009 to Feb.2013. A total of 400 patients with a breast lump were selected irrespective of age. A detailed history, thorough clinical examination, radiological imaging and fine-needle aspiration cytology (FNAC) were used as diagnostic tools for screening of the patients. The aim of this study was to evaluate accuracy of triple assessment in the early detection of breast carcinoma.

**Results** The sensitivity and specificity of all the modalities used in triple assessment when combined together was 100% and 99.3%, respectively. The concordance for the triple assessment was 99.3%, positive predictive value was 93.3%, negative predictive value was 100%, sensitivity was 100% and specificity was 99.3%. p value was significant (0.000).

**Conclusion** 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 99.3%.

**Keywords:** Clinical examination, Carcinoma, Fine-needle aspiration cytology, Mammography, Ultrasonography,

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### I. Introduction

Patients presents with a number of complaints like mastalgia, nipple discharge, cystic lesions and more commonly a lump. A lump in the breast is of great concern to the patients and is also a challenge to the diagnostic acumen and judgments of the surgeon.

Presence of a lump or space occupying lesion in the breast raise suspicion of being benign or malignant. However, differential diagnosis of breast lesion includes traumatic fat necrosis, acute and chronic breast abscess, fibroadenosis, breast cysts, etc. though they are non neo-plastic but any lump in breast have a psychological impact on the patient. Of these malignant breast disease is the most dreaded one, feared not only by the patients but also by the surgeons as well. Breast cancer cases have been recorded in medical writings for more than 5,000 years. In documents from the ancient times, they appear with perhaps greater frequency than any other form of cancer. The first written evidence suggestive of breast cancer is from ancient Egypt and is found in the Edwin Smith Surgical papyrus, dating back from 3000 to 2500 BC [1, 2]. A lump in the breast is experienced by the patient with the phobia of cancer. The disease poses a threat to the woman's sense of bodily integrity and her conceptions of body image and sexuality. The aim of our study was to study the role of triple assessment in the diagnosis of breast cancer and its sensitivity and specificity of triple assessment with regards to histopathology.

### II. Materials and methods

This study was conducted in the Department of Surgery, Rama Medical College Hospital , Kanpur over a period of 4 years from March 2009 to Feb. 2013 attending the surgical OPD of RMCH Hospital, Kanpur .Women with a breast lump or suspicious change in the breast texture were included in the study. A detailed patient's history, focused clinical examination and radiological imaging(mammography, HDUSG) 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).A total of 400 patients with a breast lump were selected irrespective of age. Informed consent was taken for physical examination and investigations giving due respect to maintain the patients privacy and keep her comfortable.

1.1 Mammography The standard examination for women undergoing mammography consists of a lateral oblique and a craniocaudal view of each breast. The lateral oblique view is usually combined with tube angled at 45 degrees to the horizontal, tube angulations from 30 to 60 degrees may be needed depending on the build of the woman. The criteria for the adequate positioning of the woman for this view, the nipple should be seen in profile, the anterior surface of pectoralis major should be visible, the breast should be lifted sufficiently and compression applies so that the breast tissue is spread evenly between the compression plate and the film holder. The craniocaudal projection demonstrates the sub-areolar, medial and lateral portions of the breast. As reported by various radiologist the mammographic findings are different in malignant and benign breast disorder. Irregular borders, micro-calcifications, speculated density, loss of architecture and skin retraction suggests malignant disorder, while as well circumscribed mass with regular borders is suggestive of benign disorders.

1.2 High definition Ultrasonography Breast (HDUSG) was performed using high frequency transducer of 7–12 MHz HD/-1500 ATL. The patient was placed in a supine or oblique position, with ipsilateral arm above the head. The breast was scanned in either a transverse or sagittal or radial and antiradial planes. The retro-areolar area was evaluated by angling the transducer in multiple planes to avoid the shadowy artifact produced by the nipple.

1.3 Fine-needle aspiration cytology (FNAC) in patients of the breast lumps was done with 22 gauge needle, mounted on a 20 ml syringe. The mass was immobilized between the index and middle finger of the non-dominant hand. The needle was inserted into the breast lump and the piston of the syringe was retracted to create suction. Needle was moved back and forth inside mass using rapid excursion. The material was expelled onto a glass slide, fixed by air drying and stained with Giemsa, haematoxylin and eosin. Slides were examined by the pathologist and the cytological diagnosis of the breast masses were given.

### III. Results And Observations:

This study was conducted in the Department of Surgery, Rama Medical College Kanpur over a period of 4 years from March 2009 to Feb 2013 attending the surgical OPD of our hospital and various observations were made. Most of our patients were in the age group of 30–39 years, constituting 41.5% of the studied cases. Table 1

Age (year)	n	%
<20	30	7.5
20–29	98	24.5
30–39	166	41.5
40–49	62	15.5
≥50	44	11.0
Rural	300	75
Urban	100	25

Patients <20 years constituted only 7.5% of total cases. Three hundred and forty four (86%) patients were having age of menarche >12 years. 56(14%) patients had age of menarche more than 12 years. Three hundred fifty four (88.5%) patients were premenopausal and 46 (11.5%) patients were postmenopausal. 36 of post-menopausal patients had age of menopause <50 years and rest of postmenopausal women had menopause >50 years. Of the studied patients 278 (69.5%) were married and the rest were unmarried. Of the married patients 262 (94.2%) were multiparous and 16 (5.8%) were nulliparous. Breast swelling alone was the most common presenting symptom, seen in 386 (96.5%) patients. Table 2 depicts various presentations.

Clinical feature	No. of patients	Percentage
Swelling (lump)	386	96.5
Swelling and pain	12	3.0
Swelling and retraction	2	0.5
Retracted nipple	6	1.5
Nipple discharge	6	1.5
Redness of skin	4	1.0
Swelling	6	1.5
Puckering with nodules	2	0.5
Palpable axillary lymph nodes	12	3.0
Family history of carcinoma breast	10	2.5

Right side of the breast was the most common side involved (58.5%). Bilateral disease was present in only 3 (1.5%) patients. Upper and outer quadrant was the most common quadrant involved in the studied patients (48%), whereas central zone of breast was least involved (11%) in the studied patients. All the 400 patients were subjected to HD-USG of the breast. Out of 400 patients, 242 (60.5%) patients had fibroadenoma, 12 (3%) had well defined solid masses, 8 (2%) had solid mass with irregular margins with fibroadenosis in 94 (23.5%) patients. Rests of patients were diagnosed as galactocele, breast abscess, lactational change and breast cyst (Table 3)

USG impression	n	%
Fibroadenoma	242	60.5
Fibroadenosis	94	23.5
Galactocele	4	1.0
Breast abscess	34	8.5
Lactational changes	2	0.5
Solid mass	12	3.0
Solid mass with irregular margins	8	2.0
Loss of normal architecture	2	0.5
Cyst	2	0.5
Total	400	100

Only married females (278) were subjected to mammography. Mammographic findings were well circumscribed mass with regular margins in 252 (90.6%) patients, density lesion with micro-calcification in 6 (2.2%) cases, density lesion with irregular margins and spiculations in 14 (5.0%) cases and density lesion with micro-calcification, irregular margins and spiculation in 6 (2.2%) patients. All the 400 patients were taken for FNAC. Fibroadenoma was the most common FNAC diagnosis seen in 238 (59.5%) patients. Fibroadenosis was seen in 100 (25%) cases with galactocele in 4 patients, breast abscess in 36 patients and ductal cell carcinoma of breast in 22 (5.5%) patients (Table 4).

FNAC	n	%
Fibroadenoma	238	59.5
Fibroadenosis	100	25
Galactocele	4	1.0
Breast abscess	36	9.0
Ductal carcinoma of breast	22	5.5
Total	400	100

Result of triple assessment were in favour of benign diagnosis in 272 patients while as malignant diagnosis was made in 28(7%) patients. Histopathology diagnosed fibroadenoma in 226 (75.3%) cases, breast abscess in 30 (10%) cases, infiltrating ductal cell carcinoma in 30 (10%) cases and fibroadenosis in 12 (4%). Inflammatory changes were seen in 2 (0.7%) case. Only 12 (3%) patients proved hormone receptor Positive.

Physical examination when compared with histopathology had a concordance of 97.3%, positive predictive value of 80%, negative predictive value of 99.3%, sensitivity of 92.3% and specificity of 97.8%. p value was significant (0.000). Mammography when compared with histopathology had a concordance of 98.1%,

positive predictive value of 86.7%, negative predictive value of 100%, specificity of 97.9% and sensitivity of 100%. p value was significant (0.000) “Fig. 1”.

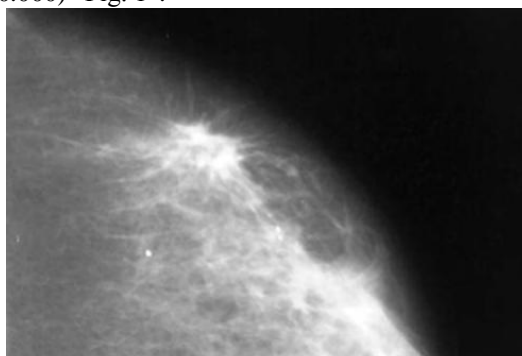


Fig. 1 Mammogram showing malignancy

Ultrasonography when compared with histopathology had a concordance of 96.7%, positive predictive value of 66.7%, negative predictive value of 100%, sensitivity of 100% and specificity 96.4%. p value was significant (0.00) “Fig2”.



Fig. 2 USG of breast showing malignancy

FNAC results when compared with histopathology results showed a concordance of 97.3%, positive predictive value of 73.3%, negative predictive value of 100%, sensitivity of 100% and specificity 97.1%. p value was significant (0.000) “Fig. 3”.

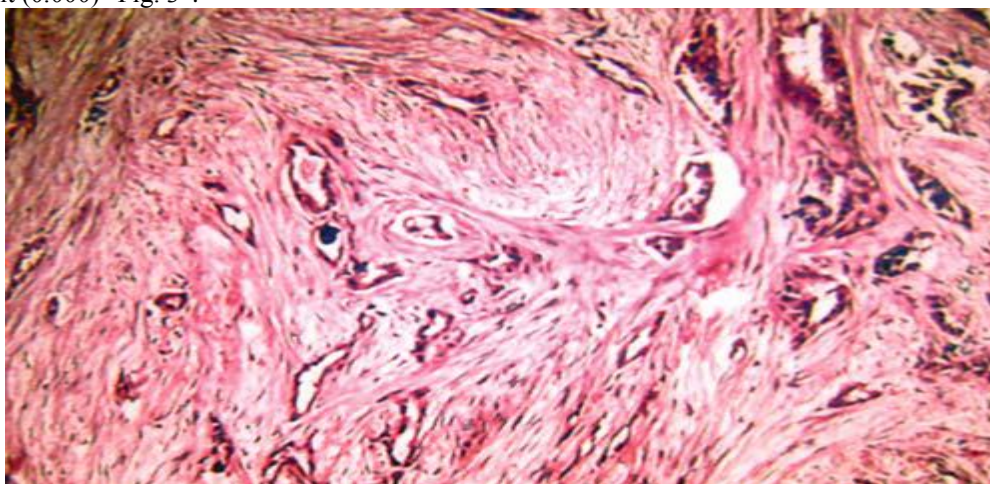


Fig. 3 A photo micrograph showing duct cell carcinoma of breast

The sensitivity and specificity of all the modalities used in triple assessment when combined together was 100% and 99.3%, respectively. The concordance for the triple assessment was 99.3%, positive predictive value was 93.3%, negative predictive value was 100%, sensitivity was 100% and specificity was 99.3% “Table 5”.

Table 5.Results of triple assessment							
Modality of triple assessment	Histopathology	No. of patients	No. of physical examination	Concordance value	Positive predictive value	Negative predictive value	p value
<b>Physical Exam</b>							
Malignant (+)	24 (92.3%)	2 (7.7%)	26	97.3	80%	99.3%	0.000 significant
Benign (-)	6 (2.2%)	268 (97.8%)	274				
<b>Total</b>	<b>30</b>	<b>270</b>	<b>300</b>				
<b>Mammography</b>							
Malignant (+)	26 (92.3%)	0 (7.7%)	26	98.1	86.7%	100%	0.000 significant
Benign (-)	4 (2.2%)	184 (97.9%)	188				
<b>Total</b>	<b>30</b>	<b>184</b>	<b>214</b>				
<b>Ultrasonography</b>							
Malignant (+)	20 (92.3%)	0 (7.7%)	20	96.7	66.7%	100%	0.000 significant
Benign (-)	10 (3.6%)	270 (96.4%)	280				
<b>Total</b>	<b>30</b>	<b>270</b>	<b>300</b>				
<b>FNAC</b>							
Malignant (+)	22 (100%)	0 (7.7%)	22	97.3	73.3%	100%	0.000 significant
Benign (-)	8 (2.9%)	270 (97.1%)	278				
<b>Total</b>	<b>30</b>	<b>270</b>	<b>300</b>				

#### IV. Discussion

The study entitled “triple assessment in the diagnosis of breast cancer” was a prospective study conducted in the Department of Surgery, Rama Medical college and Hospital on OPD basis. A total 400 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 4 years from March 2009 to Feb.2013. Currently a combination of three tests, i.e. clinical examination, radiological imaging (mammography, USG) and FNAC (pathology) together called as triple assessment is used to accurately diagnose all palpable breast lumps. The triple assessment is taken positive if any of the three components is positive for malignancy and negative only if all of its components are negative for malignancy. Physical examination was in favour of malignant disease in 26 patients. However histopathology confirmed malignancy in 24 patients only and 2 patient proved to be benign. Similarly benign diagnosis was made on physical examination in 274 patients. However histopathology confirmed benign diagnosis in 268 patients only with the remaining 6 patients being diagnosed as malignant. Thus histopathology confirmed malignant breast disease in 30 patients. Yang et al. (1996) found a sensitivity, specificity and positive predictive value for clinical examination as 88%, 92%, 67%, respectively [3].

Ultrasonography was in favour of malignant diagnosis in 20 patients, all of which turned out to be malignant on histopathology. Out of 280 cases diagnosed as benign on ultrasound, 10 turned out to be on histopathology. Thus the concordance for histopathology was 96.7%, sensitivity was 100% and specificity was 96.4%. Positive predictive value was 66.7% and negative predictive value was 100%. ‘P’ value was significant (0.000).

When we compare these results with the available literature we found that our result correlated with other studies. Pande et al. (2003) found that sensitivity specificity, positive predictive value and negative predictive value for USG was 95%, 94.10%, 95.50%, 93.75%, respectively [4]. Yang et al. (1996) found that sensitivity, specificity and positive predictive value for USG was 97%, and 85%, respectively [3].

Concordance for mammography was 98.1%, sensitivity was 100% and specificity was 97.9%. Positive predictive value was 86.7%, negative predictive value was 100% and 'p' value was significant (0.000).

Our results were in agreement with the results of other studies. Shetty et al. (2003) sensitivity for a combined mammographic and sonographic assessment were 100%; the specificity was 80.1% [5].

Martelli et al. (1990) found that sensitivity of mammography was 73%. Kaufman et al. (1994) found that sensitivity and specificity of mammography was 89% and 73%, respectively [6, 7]. Steinberg et al. (1996) found that mammography had a sensitivity and specificity of 85.3% and 70.6%, respectively [8].

Yang et al. (1996) found that the sensitivity of mammography was 92%, specificity was 94% and positive predictive value of 84% [3].

FNAC was in favour of malignant diagnosis in 11 patients. Histopathology was in agreement with FNAC results in all 11 patients. FNAC was in favour of benign diagnosis in 139 patients. However histopathology was in favour of benign diagnosis in 135 patients with 4 patients proving to be malignant on histopathology.

Concordance for FNAC was 97.3, sensitivity was 100% and specificity was 97.1%. Positive predictive value for FNAC was 86.7% and negative predictive value was 100%. 'p' value was significant (0.000).

Our results were in correlation with the results of other studies.

Martelli et al. (1990) found that FNAC had a sensitivity of 68% and specificity of 97%. Kaufman et al. (1994) found that sensitivity and specificity of FNAC was 93% and 97%, respectively [6, 7].

Steinberg et al. (1996) found that concordance for FNAC was 83.0%, Specificity was 99.5% and sensitivity was 49.0% [8]. Positive predictive value was 98%.

Reinikainen et al. (1999) found that sensitivity of FNAC was 92% and specificity was 83% while overall accuracy was 88% [9].

Ariga et al. (2002) found that FNAC had a sensitivity of 99%, positive predictive value of 99%, specificity 99%, respectively [10].

Mohammed et al. (2005) found that fine needle aspiration biopsy (FNAB) had a positive predictive value of 100%, sensitivity of 90.6% and specificity of 100% [11].

When triple assessment was compared with the results of histopathology we found that concordance for triple test was 99.3%, specificity was 100% and sensitivity was 99.3%.

Positive predictive value was 93.3%, negative predictive value was 100% and 'p' value was significant (0.000).

Our result compares favourably with the available literature. Martelli et al. (1990) found that sensitivity of triple assessment was 95% and positive predictive value was 100%. Kaufman et al. (1994) found that sensitivity of triple assessment was 100% and negative predictive value was 100% [6, 7]. Steinberg et al. (1996) found that concordance for triple test was 98.8%, specificity was 100% and sensitivity was 95.5% [8].

Ahmad et al. (2007) found that the sensitivity of triple test was 100% and specificity was 100% [12].

## V. Conclusion

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 99.3%. 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 when clinical examination, mammography, USG and FNAC were all negative for malignancy in a patient with a breast lump, the patient can be safely observed, obviating the need for histology (surgical biopsies). Triple assessment did not require hospitalisation, but was performed on OPD basis, without any complications. The modalities used are either non-invasive or minimally invasive. Recent advances in imaging and cytopathology have made the diagnosis of breast cancer easy and accurate. We found that sensitivity of triple assessment with regard to histopathology was 100, specificity was 99.3% and concordance was 99.3%.

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