

**EVALUATION OF TRIPLE ASSESSMENT FOR DIAGNOSIS OF BREAST CANCER IN A TERTIARY CENTRE**Kanwar Singh Goel<sup>1</sup>, Sapna Goel<sup>2</sup><sup>1</sup>Associate Professor, Department of General Surgery, SGT Medical College, SGT University, Budhera, Gurugram, Haryana.<sup>2</sup>Senior Resident, Department of Pathology, SHKM Government Medical College, Nalhar, Mewat, Haryana.**ABSTRACT****BACKGROUND**

Breast is a specialised accessory (modified sweat gland) of skin capable of milk secretion. Breast diseases may present with lump, nipple discharge or retraction, mastalgia etc. Benign lesion of breast commonly encountered are fibroadenosis, fibroadenoma, cyst, lactational breast abscess, non-lactational breast abscess etc. Malignant diseases of breast may present with a painless lump, mostly in the upper and outer quadrant of the breast. Pain is present only in about 10 percent cases. Nipple discharge is uncommon, but may be the only symptom. There may be enlargement, shrinkage or asymmetry of the affected breast. Sometimes the patient presents with metastatic symptoms like backache, chest pain, jaundice etc. Of all the diseases of breast the malignant diseases are the most dreaded, feared not only by the patients but also by the surgeons as well. If a lump is present in the breast, the woman feels threatened. Cancer phobia haunts her. She feels a sense of dissociation. In such cases, it is our duty to find out whether the lump is benign or malignant with as much certainty as possible. Triple assessment is the clinical assessment- history including age and examination; radiological imaging US/ mammography (after 40 years); cytological or histological analysis FNAC/core biopsy- pathology. Triple assessment is taken as positive if any of the three component is positive and negative only if all of its components are negative for malignancy. In view of this, we studied 180 cases of breast lump for evaluation by triple assessment to diagnose cancer.

The aim of the study is evaluation of triple assessment for diagnosis of breast cancer in a tertiary centre.

**MATERIALS AND METHODS**

The study was performed in Surgery Department in SGT Medical College, SGT University, Budhera, Gurugram, Haryana, over a period of 2 years 3 months from December 2015 to March 2018. A total of 180 patients were studied. A detailed history was taken. Focused clinical examination was done. USG, mammography and FNAC were performed. The results were evaluated.

**RESULTS**

The sensitivity and specificity of triple assessment when combined together was 100% and 99.3%, respectively. 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 was found to be very useful in evaluating patients of breast lumps with an overall accuracy of 99.3%.

**KEY WORDS**

Triple Assessment, Clinical Examination, Mammography, Ultrasonography, Fine-Needle Aspiration Cytology, Carcinoma.

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**BACKGROUND**

Breast is a specialised accessory (Modified sweat gland) gland of skin capable of milk secretion.<sup>1</sup> Breast diseases may present with lump, nipple discharge or retraction, mastalgia etc. Benign lesion of breast commonly encountered are fibroadenosis, fibroadenoma, cyst, lactational breast abscess, non-lactational breast abscess etc. A malignant breast disease may present as lump in the breast, which is hard and painless (most common). At least tumour should become 1 cm to be clinically palpable. Nipple discharge is the second common presentation. Ulceration and fungation, axillary lymph node enlargement, supraclavicular lymph node enlargement, chest

pain and haemoptysis, bone pain, tenderness and pathological fracture, pleural effusion, ascites, liver secondaries, secondary ovarian tumour are other presentations. Pain in the lump occurs in 10% cases. Various risk factors for carcinoma breast have been considered (Table 1). Breast cancer cases have been reported in ancient Egypt and found in Edwin Smith surgical Papyrus from 3000 to 2500 BC.<sup>2,3</sup> Of all the disease of breast the malignant diseases is the most dreaded one, feared not only by the patients but also by the surgeons as well. If a lump is present in the breast, the woman feels threatened. Cancer phobia haunts her. She feels a sense of dissociation. In such cases it is our duty to find out whether the lump is benign or malignant with as much certainty as possible. Triple assessment i.e. clinical assessment- history including (age) and examination; radiological imaging US/ mammography (after 40 years); cytological or histological analysis FNAC/ core biopsy- pathology. 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.

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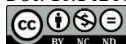
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**Aims and Objectives**

To evaluate triple assessment for diagnosis of breast cancer in a tertiary centre.

**MATERIALS AND METHODS****Study Site**

The study was performed in Surgery Department in SGT Medical College, SGT University, Budhera, Gurugram, Haryana, over a period of 2 years 3 months from December 2015 to March 2018.

**Study Design**

Prospective observational study.

**Selection of Subjects (Cases)**

A total of 180 patients were studied. Informed consent was taken for physical examination and investigations giving due respect to maintain the patient's privacy and keep them comfortable.

**Data Collection**

A detailed history about swelling (duration, rate of growth, any rapid growth), any swelling in opposite breast and axilla, details of pain, ulcer if any, nipple discharge, chest pain, cough, haemoptysis, h/o loss of weight, appetite, any pain in abdomen, back and limbs taken. Detailed past family, personal and treatment history taken. Focused clinical examination done. Ultrasonography was performed in supine or oblique position with ipsilateral arm above the head. The breast was scanned in transverse or sagittal or radial and anti-radial planes. USG is the better imaging modality to detect breast lesion in premenopausal women where mammography may not detect small lesion.<sup>4</sup> Ultrasonography can detect the mass as solid or cystic. It is cheap and easily available. There is no radiation. But ultrasonography cannot detect small lesion less than 1 cm in diameter. The sensitivity, specificity, PPV and NPV of USG in detecting carcinoma breast is 55.6%, 97.7%, 83.3% and 91.5% respectively.<sup>5</sup> Irregular margins, irregular internal echoes, irregular posterior shadowing, non-compressibility, ratio between antero-posterior to width (lateral/ horizontal) dimensions more than 1 are features of carcinoma.<sup>6</sup> Mammography was done using craniocaudal and mediolateral views. The sensitivity, specificity, Positive predictive value (PPV) and Negative Predictive value (NPV) of mammography in detecting carcinoma breast is 77.8%, 97.7%, 87.5% and 95.6% respectively.<sup>5</sup> The characteristics of malignant lesion in mammography may be architectural distortion of breast tissue, duct dilation, dense stellate soft tissue mass with irregular margin and spiky projection, microcalcification (in early patients few microcalcification may be normal), stippled calcification, increased thickness of skin due to lymphoedema and nipple retraction may be seen. Fine-needle aspiration cytology was done with 23-gauge needle and 20 mL syringe. The lump was held firmly between fingers and thumb. Needle was passed into lump and with negative pressure continuous aspiration was done until adequate material came out through the needle. Needle with syringe was removed without negative pressure. Material was collected on a slide. Minimum 6 aspirations were done. Smear was prepared using 100% alcohol. Cytology was studied after staining with Giemsa and Papanicolaou stains. FNAC is least

painful, can be done on an OPD basis, reliable and cheaper. Malignant deposits will not occur along FNAC track.

**Ethical Considerations**

The study was started after taking approval from Institutional Ethics Committee for Research on Human Subjects. Throughout the study, ethical considerations were followed strictly. Confidentiality was ensured. The patients were enrolled after written informed consent was obtained from patient and care taker of patient in their local language (mother tongue). Patient and care taker of patient were informed about the nature and purpose of the study. Before entry into the study, the investigator explained to the subjects about the aims and objectives of the study. Patient or caregiver were informed that their participation was voluntary and that they could withdraw consent to participate at any time. They were informed that choosing not to participate would not affect their care and the subjects would receive the proper treatment of his/her disease. The subjects or legally acceptable representative were given sufficient time to read the informed consent form and the opportunity to ask questions. If the subject or relative were unable to read or write informed consent, then investigator read and explained all written information. After this explanation and before entry to the study, consent was appropriately recorded by means of the subject's signature or thumb impression. Subjects who did not give consent to participate were not included in the study. In summary following ethical considerations were observed-

1. Before starting the study, approval for this study was obtained from the Institutional Ethics Committee for research on human subjects.
2. Written informed consent was obtained from each subject interviewed after asking them to go through the subject information sheet printed in Hindi language (in which subjects were well versed) and a verbal explanation by the interviewer.
3. Confidentiality of the information provided was maintained.

**Statistical Methods in Methodology**

The data were collected, and entries were made, and analysis was carried out using statistical SPSS version 23 software. Analysis was studied using Chi-square test. Sensitivity, specificity, NPV and PPV were also carried out in each category of the assessment criteria like clinical assessment, ultrasonography, mammography and FNAC. Sensitivity is considered as proportion of persons with the diseases who test positive in the screen. Specificity is the proportion of persons who do not have the disease that test negative in the screening test. The PPV is the proportion of persons who test positive that actually have the diseases. NPV is the proportion testing negative that do not have the disease. Statistically significant p-value of less than 0.05 was considered statistically significant. P-value less than 0.01 was considered as statistically very significant and p-value of less than 0.001 was considered as statistically extremely significant.

**RESULTS**

The study was performed in Surgery Department in SGT Medical College, SGT University, Budhera, Gurugram, Haryana, over a period of 2 years 3 months from December 2015 to March 2018. A total of 180 patients were studied. A

detailed history was taken, focused clinical examination done, USG, mammography and FNAC were performed. The results were evaluated. Our maximum patients were in the age group of 30 to 39 followed by age group 20 to 29. Constituting 41.0% and 24.3% respectively (Table 2). 80% patients were from rural area and 20% from urban area (Table 2). One hundred and sixty one (88.9%) were premenopausal and 19 (10.1%) were postmenopausal (Table 3). Out of total patients 126 (70%) were married and 54 (30%) were unmarried (Table 3). Breast swelling was most common presenting feature in 173 (96.0%) patients. Swelling and pain was in 5(2.8%) patients. Swelling and retraction was in 1 (0.6%) patient. Retracted nipple was found in 2 (1.1%) patients. Nipple discharge was there in 2 (1.1%) patients. Erythema of skin was in 3 (1.7%) patients. Puckering was present in 2(1.1%) patients. Palpable axillary lymph nodes were present in 5 (2.8%) patients. There was family history of carcinoma breast in 4 (2.1%) patients (Table 4). Right side breast was involved in maximum patients (106 patients, 58.9%) (Table 5). Upper and outer quadrant was most commonly involved (86 patients, 48.0%) (Table 5). All the patients underwent ultrasonography. Fibroadenoma was present in maximum patients (116 patients, 64.4%). Fibroadenosis was in 29 patients, galactocele 2 patients, breast abscess 20 patients, lactation changes in 1 patient and cyst was present in 2 patients. Solid mass finding was in 5 (2.8%) patients. Solid mass with irregular margin were present in 4 (2.2%) patients. Loss of normal architecture were found in 1 (0.6%) patient (Table 6). Mammography done only in married patients revealed well-circumscribed mass with regular margins in 113 (90.0%) patients. Density lesion with microcalcification was found in 3 (2.3%) patients. Density with irregular margins and speculation was found in 7 (5.4%) patients. Density lesion with microcalcification, irregular margins and spiculation was found in 3 (2.3%) patients (Table 7). FNAC was done in all patients. Fibroadenoma was found in maximum number of patients (114, 63.2%). Duct carcinoma was found in 11 (6.1%) patients (Table 8). On histopathology fibroadenoma was found in 108 (72.0%) patients, fibroadenosis was found in 5 (3.3%) patients, breast abscess was found in 21 (14.0%) patients, inflammatory changes was found in 1 (0.7%) patient and infiltrating ductal carcinoma of breast were found in 15 (10.0%) patients (Table 9). There was a concordance of 97.3%, PPV of 80%, NPV of 99.3%, 92.3% sensitivity and 97.8% specificity on physical examination. There was a significant P-value of 0.0000. In case of mammography corresponding values were 98.1%, 86.7%, 100%, 97.9% and 100% respectively for concordance, PPV, NPV, sensitivity and specificity respectively. Again, there was a significant p-value (0.000). So far as USG is concerned the values were 96.7%, 66.7%, 100%, 100% and 97.1% respectively for concordance, PPV, NPV, sensitivity and specificity respectively. There was again a significant p-value of 0.000. On FNAC, the results were like this. Concordance 97.3%, PPV 73.3%, NPV 100%, sensitivity 100% and specificity 97.1% with a significant p-value of 0.000. The results of all the above modalities were on comparison with histopathology examination. The final results for triple assessment were like this. Concordance 99.3%, PPV 93.3%, NPV 100%, sensitivity 100% and specificity 99.3% and a significant p-value of 0.000%.

Slight-to-Moderate Risk	Moderate-to-High Risk	Very High Risk
Florid hyperplasia	Age > 60 years	Therapeutic radiation
Solid duct papilloma	LCIS	Family history of breast cancer in two 1 <sup>st</sup> degree relatives
Obesity, alcohol, HRT	History of DCIS	Family history of breast and ovarian cancer
Nulliparity	Cancer on one side breast	Mutation of tumour suppressor genes BRCA1/BRCA2
Early menarche, late menopause		

**Table 1. Showing Risk Factors Classification**

Age (Year)	No. of Patients	Percentage
<20	15	8.1
20-29	44	24.3
30-39	73	41.0
40-49	30	16.6
>50	18	10.0
Rural	135	80.0
Urban	45	20.0

**Table 2. Showing Age and Demographic Distribution of the Study Cases (No. of Patients- 180)**

Age (Year) of Menarche		No. of Patients	Percentage
Menstruation status	Pre-menopausal	161	88.9
	Post-menopausal	19	10.1
Marital status	Married	126	70.0
	Unmarried	54	30.0

**Table 3. Showing Menstrual Profile and Marital Status of Patient**

Clinical Feature	No. of Patients	Percentage
Presence of lump	173	96.0
Lump along with retraction	5	2.8
Lump with pain	1	0.6
Retraction of nipple	2	1.1
Presence of discharge from nipple	2	1.1
Erythema of skin	3	1.7
Presence of puckering	2	1.1
Presence of axillary lymph nodes	5	2.8
Presence of history of carcinoma breast in family	4	2.1

**Table 4. Showing Clinical Feature of Patients (No. of Patients= 180)**

Characteristics	No. of Patients	Percentage	
Side involved	Left	72	40.0
	Right	106	58.9
	Bilateral	2	1.1
Quadrant	Central	19	10.6
	Upper outer	86	48.0
	Upper inner	33	18.0
	Lower outer	21	11.2
	Lower inner	21	11.2

**Table 5. Showing Side and Quadrants of the Affected Breast in the Studied Patients**

USG Impression	No. of Patients	Percentage
Fibroadenoma	116	64.4
Fibroadenosis	29	16.0
Galactocele	2	1.1
Breast abscess	20	11.2
Lactational changes	1	0.6
Solid mass	5	2.8
Solid mass with irregular margins	4	2.2
Loss of normal architecture	1	0.6
Cyst	2	1.1
<b>Total</b>	<b>180</b>	<b>100</b>

*Table 6. Showing Ultrasonographic Impression of the Breast Lumps in the Patients (No. of Patients= 180)*

Findings	No. of Patients	Percentage
Well circumscribed mass with regular margins	135	91.3
Density lesion with microcalcification	3	2.0
Density lesion with irregular margins and spiculation	7	4.7
Density lesion with microcalcification, irregular margins and spiculation	3	2.0
<b>Total</b>	<b>148</b>	<b>100</b>

*Table 7. Showing Mammographic Findings in Patients*

FNAC	No. of Patients	Percentage
Fibroadenoma	114	63.2
Fibroadenosis	30	16.6
Galactocele	2	1.1
Breast abscess	23	13.0
Ductal carcinoma	11	6.1
<b>Total</b>	<b>180</b>	<b>100</b>

*Table 8. Showing Results of FNAC in the Studied Patients*

Findings	No. of Patients	Percentage
Fibroadenoma	108	72.0
Fibroadenosis	5	3.3
Breast abscess	21	14.0
Infiltrating ductal carcinoma of breast	15	10.0
Inflammatory changes	1	0.7

*Table 9. Showing Results of Histopathology in the Studied Patients (No. of Patients= 150)*

Modality of Triple Assessment		Histopathology		No. of Patients	Positive Predictive Value	Negative Predictive Value
		Malignant	Benign			
Physical examination	Malignant (+)	12 (92.3%)	1 (7.7%)	13	80%	99.3%
	Benign (-)	3 (2.2%)	134	137		
<b>Total</b>		<b>15</b>	<b>135</b>	<b>150</b>		

*Table 10. Showing Results of Physical Examinations in Triple Assessment*

Modality of Triple Assessment		Histopathology		No. of Patients	Positive Predictive Value	Negative Predictive Value
		Malignant	Benign			
Mammography	Malignant	13 (100%)	0	13	86.7%	100%
	Benign	2 (2.1%)	92 (97.9)	94		
<b>Total</b>		<b>15</b>	<b>92</b>	<b>107</b>		

*Table 11. Showing Results of Mammography in Triple Assessment*

Modality of Triple Assessment		Histopathology		No. of Patients	Positive Predictive Value	Negative Predictive Value
		Malignant	Benign			
USG	Malignant	10 (100%)	0	10	66.7%	100%
	Benign	5 (3.6%)	135 (96.4)	140		
<b>Total</b>		<b>15</b>	<b>135</b>	<b>150</b>		

*Table 12. Showing Results of USG in Triple Assessment*

Modality of Triple Assessment		Histopathology		No. of Patients	Positive Predictive Value	Negative Predictive Value
		Malignant	Benign			
FNAC	Malignant	11 (100%)	0	11	73.3%	100%
	Benign	4 (2.9%)	135 (97.1)	139		
<b>Total</b>		<b>15</b>	<b>135</b>	<b>150</b>		

*Table 13. Showing Results of FNAC in Triple Assessment*

## DISCUSSION

This study of evaluation of triple assessment for diagnosis of breast cancer in a tertiary centre was performed in Surgery Department in SGT Medical College, SGT University, Budhera, Gurugram, Haryana, over a period of 2 years 3 months from December 2015 to March 2018. A total of 180 patients were studied. A combination of three tests (Triple assessment) i.e. clinical assessment- history including (age) and examination; radiological imaging US/ mammography (after 40 years); cytological or histological analysis FNAC/ core biopsy-pathology. 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.

As per physical examination, malignant disease was in favour of 13 patients. Histopathology revealed malignancy in 12 patients. Benign disease was considered in 137 patients on physical examination. On histopathology, benign disease was confirmed in 134 patients and the remaining 3 patients diagnosed as malignant (Table 10). Our results were similar to Yang et al (1996).<sup>7</sup> The results of mammography revealed positive predictive value of 86.7% and negative predictive value of 100% with significant p-value of 0.000. The results are comparable with Shetty et al (2003).<sup>8</sup> Marteli et al (1990)<sup>9</sup> also gave similar results. Kaufman et al (1994)<sup>10</sup> found the sensitivity of mammography as 89.0% and specificity as 73.0%. The results of Steinberg et al (1996)<sup>11</sup> and Yang et al (1996)<sup>7</sup> were also similar. Ultrasonography was in favour of malignancy in 10 patients, who were all found to be malignant on histopathology. On ultrasonography 140 cases were diagnosed as benign, of which 5 were malignant on histopathology. Thus, the sensitivity was 100%, specificity was 96.4%, positive predictive value was 66.7% and negative predictive value was 100%. 'P' value was significant (0.000). Our results were comparable to Pande et al (2003)<sup>12</sup> and Yang et al (1996).<sup>6</sup>

In 11 patients, FNAC revealed malignancy. All these patients were malignant as per histopathology also; however, 4 patients who were told benign by FNAC were actually found to be malignant as per histopathology. Sensitivity of FNAC was 100%, specificity was 97.1%, positive predictive value was 86.7% and negative predictive value was 100%. 'P' value was significant (0.000). Our results of FNAC were similar to Marteli et al (1990),<sup>9</sup> Kaufman et al (1994),<sup>10</sup> Steinberg et al (1996),<sup>11</sup> Reinikainen et al (1990)<sup>13</sup> and Ariga et al (2002).<sup>14</sup> The results of Mohammad et al (2005)<sup>15</sup> of FNAC were 100% for positive predictive value, 90.6% for sensitivity and 100% for specificity. Thus, we have in triple assessment the concordance of 99.3%, specificity of 100%, sensitivity of 99.3%, positive predictive value of 99.3%, negative predictive value of 100% and a significant p-value (0.000).

## CONCLUSION

We have found that in diagnosis of breast cancer in our tertiary centre, the triple assessment was found to be very useful in evaluating patients of breast lumps with an overall accuracy of 99.3%. When clinical examination, mammography, USG and FNAC are all negative for malignancy in a patient with breast lump, the patient is unlikely to have malignancy and need for histology can be obviated and patient can be safely observed.

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Farquharson; SRB's Manual of Surgery 5<sup>th</sup> Edition by Sriram Bhat M; Bedside Clinics in Surgery, 3<sup>rd</sup> Edition by Makhan Lal Saha.

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