ORIGINAL RESEARCH

Evaluating the accuracy of clinical, radiographic and fnac assessment as a preoperative diagnostic tool in subjects with breast lump

Dr. Sanjay Sawant

Assistant Professor, Department of Pathology, SSPM Life Time Hospital and Medical College Padave, Shindhudurg, Maharashtra, India

Corresponding Author
Dr. Sanjay Sawant
Assistant Professor, Department of Pathology, SSPM Life Time Hospital and Medical College Padave, Shindhudurg, Maharashtra, India
Email: sumedhlab@gmail.com

ABSTRACT
Background: Despite various technical and diagnostic advances in the modern surgical era of diagnosing and managing breast lesions, the traditional triple assessment method still holds a gold standard in diagnosing breast lesions including the pathological, radiological, and clinical assessment. **Aim:** The present study was aimed at evaluating the accuracy of clinical, radiographic, and FNAC assessment as a preoperative diagnostic tool in subjects with breast lumps. **Methods:** The present clinical study assessed 200 female subjects with a mean age of 38.68±12.28 years and an age range of 10-65 years that presented with the breast lump to the institute. For all the included females, detailed history and demographics were recorded followed by comprehensive clinical assessment, radiographical evaluation, and FNAC assessment as screening and diagnostic assessment in study subjects. **Results:** The results of the present study were assessed as individual components as well as overall rate clinically and radiographically. The results obtained were compared with the results of the final histopathological assessment. It was seen that in diagnosing the malignant breast lesions, the physical examination had specificity and sensitivity of 95.31% and 90.86% respectively, whereas, radiography revealed specificity and sensitivity of 99.14% and 95.77% respectively. The sensitivity and specificity of FNAC were 95.73% and 99.14% respectively. **Conclusions:** Considering its limitations, the present study concludes that the assessment of breast lesions using the clinical, radiographical, and FNAC assessment forms a reliable criterion for assessment, diagnosis, and management of breast lesions.
Keywords: Breast lesion, breast lump, fine needle aspiration cytology, mammography, ultrasonography

INTRODUCTION

The first documented evidence of breast cancer depicts its ancient existence dating back to 3000 to 2500 BC. The written evidence is documented in the Edwin Smith Papyrus from ancient Egypt. Since its first documentation, the incidence and prevalence of breast cancer have been largely increasing globally, including in India with more than 28% of the total mortalities reported to be resulting from breast cancer in the United Kingdom following the data of 2017. With the increasing mortality rates associated with breast cancer, it is vital to develop new tools and techniques for early and prompt detection of breast cancer to improve the survival rates and reduce the disease burden on healthcare professionals.[1]

Considering the various presenting symptoms of breast cancer, the most common presenting symptom is the breast lump. The diagnosis of the breast lump can be benign pathological conditions including the sinister carcinoma breast, chronic breast abscess, acute breast abscess, fibroadenoma, and/or fat necrosis. An increase in the incidence of breast cancer globally can be attributed to an increase in the Western lifestyle, an increase in urbanization, and increased life expectancy in the developing World. Some decrease in the risk of developing breast cancer can be done with preventive strategies.[2]

However, prevention strategies cannot eliminate the high number of breast malignancies that are usually seen in middle and low-income countries like India

where the breast malignancies are usually diagnosed at very late stages. Hence, detection of breast cancer at early stages can help improve the survival rates and outcomes in breast cancer subjects which forms a key factor in controlling breast cancer.[3]

The combined use of mammography, physical examination, and FNAC (fine needle aspiration cytology) for assessing breast lesions is termed a triple test and is now used as the gold standard for breast lesion assessment. Following the guidelines of the NICE (National Institute of Health and Clinical Excellence) for the subjects presenting symptoms that are seen as secondary to breast cancer, the lesions are assessed and diagnosed using the Modified triple assessment method.[4]

Modified triple test or modified triple assessment use the combination of FNAC, sono mammography, and physical examination for assessment of the breast lesions. Assessment of breast cancer usually starts with triple test components that include the clinical assessment of the breast followed by mammography and finally the fine-needle aspiration assessment which is either done alone or combined with other factors. Open biopsy, however, presents more data than FNAC, it usually leads to undesired, cosmetic, and esthetic concerns.[5]

The results of the triple assessment are considered positive when any one of the three factors is positive and the results are taken as negative when all of the three components of the triple assessment are desired negative for the breast malignancy. The present study aimed to assess the accuracy of modified triple assessment including the clinical, radiographic, and FNAC assessment as a preoperative diagnostic tool in subjects with breast lumps.

MATERIALS AND METHODS
The present cross-sectional, descriptive clinical study was aimed to assess the accuracy of modified triple assessment including the clinical, radiographic, and FNAC assessment as a preoperative diagnostic tool in subjects with breast lump. The study was done at Department of Pathology, SSPM Life Time Hospital and Medical College Padave, Shindhudurg, Maharashtra after the clearance was given by the concerned Institutional Ethical committee. The study assessed subjects reporting to the Department of Obstetrics and Gynecology of the institute with breast lump. A written and verbal informed consent was taken from all the subjects before study participation.

The present clinical study assessed 200 female subjects with a mean age of 38.68±12.28 years and an age range of 10-65 years that presented with the breast lump to the institute. The inclusion criteria for the study were females with definitive breast lumps in either one or both breasts who were willing to participate in the study. The exclusion criteria for the study were females taking oral contraceptives, undergoing hormonal therapy, history of breast surgery, and not giving consent for study participation.

After the final inclusion of the study subjects, a detailed history was recorded for all the subjects followed by a comprehensive clinical examination. After deciding on the procedure for breast lump removal, the complications, results, benefits, risks, and techniques for lump removal were discussed with all the study subjects. All the procedures were carried out by two surgeon experts in their field. The surgical procedures done in all 200 subjects were either mastectomy, wide excision, or lumpectomy followed by histopathological assessment of the removed tissue. The obtained histopathological reports were also included in the study. The final histopathological assessment report was also compared with the individual components of the triple assessment tool.

The data gathered were assessed statistically using the SPSS software version 21.0 (IBM Corp., Armonk, NY, USA) after entering the recorded data in MS Excel 2019. The data were expressed as mean and standard deviation and the percentage and frequency for descriptive statistics. The significance level was considered at $p<0.05$.

RESULTS
The present cross-sectional, descriptive clinical study was aimed to assess the accuracy of modified triple assessment including the clinical, radiographic, and FNAC assessment as a preoperative diagnostic tool in subjects with breast lump. The present clinical study assessed 200 female subjects with a mean age of 38.68±12.28 years and an age range of 10-65 years that presented with the breast lump to the institute. The highest number of malignant lesions were seen in the females of age range 41-50 years with 56.9% (n=37) females, whereas, the majority of the benign breast lesions were seen in 32 females of 21-30 years of age. The second majority of malignant lesions were seen in the>60 years age group with 58.82% (n=10) females followed by 56.66% (n=17) in 51-60 years, 25R (n=10) in 31-40 years, and at least 3.03% (n=1) in 21-30 years age range as shown in Table 1.

Table 1: Correlation of age range with the clinical diagnosis in the study subjects

S. No	Age range	Diagnosis		Total	Malignant lesion percentage
		Benign	Malignant		
1.	<20	15	-	15	-
2.	21-30	32	1	33	3.03
3.	31-40	30	10	40	25
4.	41-50	28	37	65	56.9

5.	51-60	13	17	30	56.66
6.	>60	7	10	17	58.82
7.	Total	125	75	200	37.5

On assessing the correlation of age range with ultrasonographic diagnosis in the study subjects, it was seen that the majority of malignant breast lesions were seen in the>60 years of age range with 58.82% (n=10) females followed by 55.17% (n=16) in 51-60 years, 54.83% (n=34) lesions in 41-50 years age range, 20.93% (n=9) in 31-40 years, 2.94% (n=1) lesion in 21-30 years age range, and no malignant lesion on ultrasonography was seen in females of age range less than 20 years as depicted in Table 2.

Table 2: Correlation of the age range with ultrasonographic diagnosis in the study subjects

S. No	Age range	Diagnosis		Total	Malignant lesion percentage
		Benign	Malignant		
1.	<20	15	0	15	0
2.	21-30	33	1	34	2.94
3.	31-40	34	9	43	20.93
4.	41-50	28	34	62	54.83
5.	51-60	13	16	29	55.17
6.	>60	7	10	17	58.82
7.	Total	130	70	200	35

For the overall assessment results of the modified triple assessment in study subjects, false positive results were seen in 4, 4, and 1 subjects on clinical assessment, ultrasonographic examination, and FNAC assessment respectively. Malignant lesions were seen in 75, 47, and 72 subjects on clinical, radiographic, and FNAC assessment respectively. False-negative results were obtained in 6, 4, and 2 subjects respectively on clinical, radiographic, and FNAC findings. Benign lesions were seen in 125, 130, and 125 subjects on clinical, radiographic, and FNAC findings respectively. On histopathological assessment, malignant and benign lesions were seen in 76 and 124 study subjects respectively as summarized in Table 3.

Table 3: Overall study results from the individual component of modified triple assessment

S. No	Lesion type	Diagnosis			
		Clinical	Ultrasonographic	FNAC	Histopathology
1.	False positive	4	4	1	
2.	Malignant	75	47	72	76
3.	False-negative	6	4	2	
4.	Benign	125	130	125	124

Considering the percentage of benign lesions on ultrasonography in study subjects, it was seen that there were 6.15% (n=8) benign lesions that were cystic and there were 4% (n=8) benign cystic lesions among all 200 breast lesions assessed in the present study. There were 11.53% (n=15) cystic lesions among 130 benign lesions and 7.5% (n=15) inflammatory lesions among all 200 lesions assessed. For fibrocystic lesions, there were 28.46% (n=37) fibrocystic lesions among all 130 benign lesions and 7.5% among all 200 lesions assessed. There were 53.84% (n=70) fibroadenoma in a total of 130 benign lesions and 35% in all 200 assessed breast lesions (Table 4).

Table 4: Percentage of benign lesions seen on ultrasonography

S. No	Ultrasonography diagnosis	Benign lesions diagnosed (n=130)	Percentage in total benign lesions (n=130)	Percentage in total breast lesions (n=200)
1.	Cystic lesion	8	6.15	4
2.	Inflammatory	15	11.53	7.5
3.	Fibrocystic	37	28.46	18.5
4.	Fibroadenoma	70	53.84	35

The study results showed that for FNAC and histopathological confirmation of different breast lesions in study subjects, there were 11 cystic lesions seen on FNAC whereas 8 were confirmed on histopathology. On FNAC, 14 inflammatory lesions were seen whereas histopathology showed 16 inflammatory lesions. On FNAC, 41 fibrocystic lesions were seen, whereas, 35 lesions were confirmed on histopathology. There were 63 fibroadenomas diagnosed on FNAC, whereas, histopathology confirmed 65 fibroadenomas among 200 breast lesions assessed. There were 71 carcinomas diagnosed on FNAC assessment, whereas, histopathology reports confirmed 76 carcinoma lesions among 200 assessed breast lesions as seen in Table 5.

Table 5: FNAC and histopathological confirmation of different breast lesions in study subjects

S. No	Lesion	FNAC	Histopathology confirmed
1.	Cystic lesion	11	8
2.	Inflammatory	14	16
3.	Fibrocystic	41	35
4.	Fibroadenoma	63	65
5.	Carcinoma	71	76

For the sensitivity and specificity of different assessment components of modified triple assessment in study subjects, FNAC showed the specificity, sensitivity, negative predictive value, and positive predictive values of 99.14%, 95.77%, 94.24%, and 99.38% respectively. Ultrasonographic assessment showed specificity, sensitivity, negative predictive value, and positive predictive values of 97.87%, 89.68%, 95.87%, and 95.68% respectively. Clinical examination showed specificity, sensitivity, negative predictive value, and positive predictive values of 95.31%, 90.86%, 94.85%, and 94.14% respectively (Table 6).

Table 6: Sensitivity and specificity of different assessment components of modified triple assessment in study subjects

S. No	Method	Specificity	Sensitivity	Negative predictive value	Positive predictive value
1.	FNAC	99.14	95.77	94.24	99.38
2.	Ultrasonography	97.87	89.68	95.87	95.68
3.	Clinical	95.31	90.86	94.85	94.14

DISCUSSION

The present clinical study assessed 200 female subjects with a mean age of 38.68±12.28 years and an age range of 10-65 years that presented with the breast lump to the institute. The highest number of malignant lesions were seen in the females of age range 41-50 years with 56.9% (n=37) females, whereas, the majority of the benign breast lesions were seen in 32 females of 21-30 years of age. The second majority of malignant lesions were seen in the>60 years age group with 58.82% (n=10) females followed by 56.66% (n=17) in 51-60 years, 25R (n=10) in 31-40 years, and at least 3.03% (n=1) in 21-30 years age range. These data correlated with Ahmad I et al[6] in 2007 and Vetto JT et al[7] in 2002 where the highest prevalence of breast lesions was seen in subjects aged >60 years and in the age range of 51-80 years.

Concerning the correlation of age range with ultrasonographic diagnosis in the study subjects, it was seen that the majority of malignant breast lesions were seen in >60 years of age range with 58.82% (n=10) females followed by 55.17% (n=16) in 51-60 years, 54.83% (n=34) lesions in 41-50 years age range, 20.93% (n=9) in 31-40 years, 2.94% (n=1) lesion in 21-30 years age range, and no malignant lesion on ultrasonography was seen in females of age range less than 20 years. These results were consistent with the studies of Mohammad AZ et al[8] in 2005 and Pandey AR et al[9] in 2003 where authors reported a comparable correlation of age range with ultrasonographic diagnosis in their study subjects.

For assessment of the overall assessment results of the modified triple assessment in study subjects, false positive results were seen in 4, 4, and 1 subjects on clinical assessment, ultrasonographic examination, and FNAC assessment respectively. Malignant lesions were seen in 75, 47, and 72 subjects on clinical, radiographic, and FNAC assessment respectively.

False-negative results were obtained in 6, 4, and 2 subjects respectively on clinical, radiographic, and FNAC findings. Benign lesions were seen in 125, 130, and 125 subjects on clinical, radiographic, and FNAC findings respectively. On histopathological assessment, malignant and benign lesions were seen in 76 and 124 study subjects respectively. These results were in agreement with the findings of Yang WT et al[10] in 1996 and Gokhle S[11] in 2009 where authors reported comparable benign, malignant, false positive, and false negative results.

On assessing the percentage of benign lesions on ultrasonography in study subjects, it was seen that there were 6.15% (n=8) benign lesions that were cystic and there were 4% (n=8) benign cystic lesions among all 200 breast lesions assessed in the present study. There were 11.53% (n=15) cystic lesions among 130 benign lesions and 7.5% (n=15) inflammatory lesions among all 200 lesions assessed. For fibrocystic lesions, there were 28.46% (n=37) fibrocystic lesions among all 130 benign lesions and 7.5% among all 200 lesions assessed. There were 53.84% (n=70) fibroadenoma in a total of 130 benign lesions and 35% in all 200 assessed breast lesions. These results correlated with Lingaraju N[12] in 2016 and Chaudhari R et al[13] in 2017 where authors reported similar incidences of cystic, inflammatory, fibrocystic lesions, and fibroadenoma in their study population.

It was also seen that for FNAC and histopathological confirmation of different breast lesions in study subjects, there were 11 cystic lesions seen on FNAC whereas 8 were confirmed on histopathology. On FNAC, 14 inflammatory lesions were seen whereas histopathology showed 16 inflammatory lesions. On FNAC, 41 fibrocystic lesions were seen, whereas, 35 lesions were confirmed on histopathology. There were 63 fibroadenomas diagnosed on FNAC, whereas,

histopathology confirmed 65 fibroadenomas among 200 breast lesions assessed. There were 71 carcinomas diagnosed on FNAC assessment, whereas, histopathology reports confirmed 76 carcinoma lesions among 200 assessed breast lesions. These results were similar to the studies of Shetty MK et al[14] in 2003 and Bhavinder A[15] in 2015 where authors reported a comparable correlation between FNAC and histopathologic assessment in their study subjects.

The study results showed that the sensitivity and specificity of different assessment components of modified triple assessment in study subjects, FNAC showed the specificity, sensitivity, negative predictive value, and positive predictive values of 99.14%, 95.77%, 94.24%, and 99.38% respectively. Ultrasonographic assessment showed specificity, sensitivity, negative predictive value, and positive predictive values of 97.87%, 89.68%, 95.87%, and 95.68% respectively. Clinical examination showed the specificity, sensitivity, negative predictive value, and positive predictive values of 95.31%, 90.86%, 94.85%, and 94.14% respectively. These results were in line with Khoda L[16] in 2015 and Chandak NS[17] in 2017 where clinical, radiographic, FNAC, and histopathology showed similar sensitivity and specificity as in the present study.

CONCLUSIONS

Considering its limitations, the present study concludes that the assessment of breast lesions using the clinical, radiographical, and FNAC assessment forms a reliable criterion for the assessment, diagnosis, and management of breast lesions. Also, modified triple assessment is a patient-compliant, rapid, least invasive, cost-effective, and easily available tool for the assessment of breast lesions. The few limitations of the study being study including both radiologists and pathologists, advanced breast lesion assessment, difficult assessment of subjects with breast implants, and pregnant females.

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