

Original Research Article

Role of triple assessment modalities in diagnosis of palpable breast lump

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ABSTRACT

Background: One fourth of women suffer from breast disease in their lifetime. Carcinoma of breast is the second most common cancer in the world. Timely and accurate diagnosis of breast lump with early intervention can be life saving. There are various modalities for the diagnosis of breast lump such as USG, FNAC and Mammography, MRI etc. but none of them is perfect. There are numerous reports suggesting that if the results of clinical assessment, mammography and FNAC are all combined, the diagnostic accuracy is nearly 100%. Furthermore, these techniques also provide information about tumor size, number, extent and grade preoperatively.

Methods: Study was randomized, prospective, observational and longitudinal including 100 patients, selected according to inclusion criteria.

Results: The sensitivity, specificity and accuracy of triple test in present study were 98.68%, 87.5%, and 96% respectively. Out of 100, 76 patients were confirmed as having benign lesion and 24 patients having malignant lesion by histopathology examination.

Conclusions: Results of triple assessment are same as the results by histopathology examination in majority of cases. It is highly accurate, can be used as a confirmatory diagnostic tool for breast lump, thus there is no need to perform diagnostic open biopsy for breast lump.

Keywords: Breast lump, Carcinoma breast, Clinical examination, Fine-needle aspiration cytology, Mammography, Triple assessment modalities, Ultrasonography

INTRODUCTION

One fourth of women suffer from breast disease in their lifetime.¹ Carcinoma of breast is the second most common cancer in the world.² with improvement in health care and increasing longevity, more and more females are being exposed to risk of developing breast carcinoma. In developing countries, incidence of breast cancer ranges from 18-19/million leading to 5-10 deaths/million.¹ In India, an average of 80,000 women are diagnosed with breast cancer and 40,000 die of the disease every year.² Lump in breast has been viewed with skepticism resulting in delay in seeking treatment. Timely and accurate diagnosis of breast lump with early

intervention can be life saving. There are various modalities for the diagnosis of breast lump such as USG, FNAC and Mammography, MRI etc. but none of them is perfect. Delay can lead to deprivation of curative treatment whereas aggressive management can expose the patient to unwarranted surgeries and hence cause psychological and social trauma to the patient. Distinction of benign from malignant is of paramount importance for patient care and proper management.

A definitive preoperative diagnosis of malignant lesion provides an ample opportunity for patient counseling and for planning of possible surgical treatment.

The first step in the evaluation of breast lump is the clinical examination. Although many-a-times, clinician can confidently make diagnosis of benign or malignant lesions, possibility of mistakes is always there even in experienced hands. Imaging evaluation of the breast is established as an essential part of modern multidisciplinary approach for effective investigation and management of breast lump i.e. USG, conventional and digital mammography. Then another way of diagnosis is tissue diagnosis either in the form of FNAC, Trucut biopsy or open biopsy. Open biopsy is considered as a gold standard for confirming the diagnosis, but it has significant morbidity, is costly and time consuming.³

The two techniques currently available which are having excellent patient tolerability are Mammography and FNAC. But if employed alone, the reliability of mammography and FNAC is only 82% and 78% respectively.⁴ There are numerous reports suggesting that if the results of clinical assessment, mammography and FNAC are all combined, the diagnostic accuracy is nearly 100%.^{5,6} Furthermore, these techniques also provide information about tumor size, number, extent and grade preoperatively. This triple assessment is quick, least invasive and cost effective in terms of time and money.

This study is done to evaluate this triple assessment technique in our clinical setup.

METHODS

In the present study which was randomized, prospective, observational and longitudinal. Protocol of trial procedure was formed along with proforma, patient information sheet and informed consent. The study was carried out from January 2015 to October 2016, consisting 100 patients. Patients’ selection was done according to following criteria.

Inclusion criteria

Patient presented to surgical outpatient department with different complaints related to breast lump was examined and admitted in department of surgery.

Exclusion criteria

- Patients previously operated for breast surgery
- Recurrent cases
- Pregnancy and Lactating mothers
- Patients with skin disorders
- Patients not giving consent for examination and surgery.

Patient’s detailed history was taken in general and in view of breast lump and was examined thoroughly by standard technique as mentioned preciously. Examination of abdomen and other parts of the body was also done and noted on examination sheet. Examination was done by the same technique in all the patients.

After that patients were sent to radiology department for mammography. Mammography was done by standard technique. It was done by standard medio-lateral and craniocaudal views and then mammography plates were examined and reported by radiologist. After that FNAC of all patients were taken by standard technique as mentioned below. Slides were prepared and stained and then sent to pathology department for reporting.

Then the patients underwent surgical intervention either in form of excisional biopsy or modified radical mastectomy depending on the condition diagnosed.

Histopathology reports of all the patients were studied and after that all the results of clinical examination, mammography and FNAC were combined and then compared with histopathology examination. All these findings were noted as per the proforma for study.

RESULTS

A study of 100 cases of breast lump was carried out by triple test along with its correlation with histology findings. During this period, all 100 cases underwent each component of triple test followed by surgical intervention and then histopathology reports were studied.

Procedure of data analysis

The triple test (TT) 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
- FN, false negative
- Sensitivity = TP / (TP+FN)
- Specificity = TN / (TN+FP)
- Accuracy = TP+TN / (TP+FP+TN+FN)

Table 1: Age incidence in present study.

Age in years	No. of cases (out of 100)	Percentage (%)
≥20	18	18
21 to 40	52	52
41 to 60	27	27
More than 60	03	03

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. All the patients under study were grouped on the basis of age of 20 years duration.

The incidence of the breast lump was more in patients above 20 years of age. It also shows that maximum patients were in the age groups of 21-40 years. 79% patients were in the age group of 21 to 60 years. None of the patients included were more than 75 years of age. Mean age of patients in our study group is 35.32.

Table 2: Findings by histopathology examination.

Finding	No. of cases (out of 100)	Percentage
Benign	76	76%
Malignant	24	24%

Table 2 shows that out of 100, 76 patients (76%) were diagnosed as a benign lesion and 24 patients (24%) were diagnosed as a malignancy by histopathology.

Table 3: Results of clinical diagnosis.

Findings	Clinical diagnosis	Histology	
		B	M
Benign	77	69	08
Malignancy	23	07	16

B - Benign lesion; M - Malignant lesion

Table 3 shows that out 100, 77 patients were diagnosed as a benign lesion out of which 63 were confirmed on histology as benign and 8 patients were diagnosed as a malignant on histology. While 23 patients diagnosed as malignant by clinical diagnoses, 16 were confirmed malignant on histopathology and 7 patients were diagnosed as benign on histopathology. This suggests that clinical diagnosis has sensitivity of 89.6%, specificity of 66.6% and accuracy of 85%.

Table 4: Result of FNAC.

Findings	FNAC	Histology	
		B	M
Benign	78	76	02
Malignancy	22	00	22

B - Benign lesion; M - Malignant lesion

Table 4 shows that out 100, 78 patients were diagnosed as a benign lesions, out of which 76 were confirmed on histology as benign and 2 patients were diagnosed as a malignant on histology. While 22 patients diagnosed as malignant by FNAC, all patients were confirmed malignant on histopathology. This suggests that FNAC has sensitivity of 100% specificity of 91.66% and accuracy of 98%.

Table 5 shows that out 100, 77 patients were diagnosed as a benign lesions, out of which 73 were confirmed on

histology as benign and 4 patients were diagnosed as a malignant on histology. While 23 patients diagnosed as malignant on mammography, 20 were confirmed malignant on histology and 3 patients were diagnosed benign on histopathology. This suggests that mammography has sensitivity of 96% specificity of 83.33% and accuracy of 93%.

Table 5: Result of mammography.

Findings	Mammography	Histology	
		B	M
Benign	77	73	04
Malignancy	23	03	20

B - Benign lesion; M - Malignant lesion

Table 6: Result of triple test.

Findings	Triple test	Histology	
		B	M
Benign	78	75	03
Malignancy	22	01	21

B - Benign lesion; M - Malignant lesion

Table 6 shows 78 patients diagnosed as benign by triple test, 75 were benign on final histopathology report while 3 patients were diagnosed malignant lesion. And 22 patients diagnosed as malignant by triple test 21 were malignant on final histopathology report while only one patient was diagnosed benign lesion.

Table 7: Findings of different modalities of triple test.

Clinical	Mammography	FNAC	Triple test benign or malignant	Histology	
				B	M
B	B	B	67 -B	67	00
B	B	M	02 -B	00	02
B	M	B	03 -B	02	01
B	M	M	05 -M	00	05
M	B	B	06 -B	06	00
M	B	M	02 -M	00	02
M	M	B	02 -M	00	02
M	M	M	13 -M	00	13

B - Benign lesion; M - Malignant lesion

Table 7 shows that triple test was concordant in 80 cases out of 100 cases. No discrepancy was noted in final histopathology report. Total 67 benign cases were detected by triple test with all three components suggesting benign lump. Total 13 malignant cases were detected by triple test with all three components suggesting malignant lesion. Out 100 cases, 20 cases had non-concordant triple test in which either one or two components of all three components were not same. Out of 20 non-concordant cases, 9 patients were diagnosed malignant. Out of 9, in 5 results clinical assessment was non-concordant. And Mammography and FNAC were non-concordant in 2 results each. Eleven non-concordant

results were benign in which 6 results of clinical assessment were non-concordant. Out of 11, in 3 results Mammography was non-concordant and in 2 results FNAC was non-concordant. Above test also shows that, FNAC had 2 false negative results and mammography had 4 false negative results. Whereas clinical examination had 08 false negative result.

FNAC had no false positive results. Whereas mammography had 3 false positive results and clinical assessment had 7 false positive results.

Table 8: Age related incidence of benign or malignant lump.

Age (years)	No. of cases (out of 100)	Benign or malignant		% of malignancy in different age groups
		B	M	
≥ 20	18	17	1	5.5
21 to 40	52	46	6	11.5
41 to 60	27	13	14	51.8
More than 60	03	00	03	100

B - Benign lesion; M - Malignant lesion

Table 8 shows that as age increases incidence of malignancy in different age groups increases. In age groups of more than 60 years of age, percentage of malignancy in different groups is 100%. No patient is of more than 75 years

DISCUSSION

Triple test is a simple, safe, cost effective and rapid method depending upon which definitive treatment can be started.

After getting the results of each component and triple test we compared it with other studies and according the sensitivity and specificity of the same has been compared as shown in the Table 9, 10 and 11.

Table 9: Correlation of clinical examination with other studies is as follows.

Author	Sensitivity	Specificity
Kaufman Z et al ⁷	89%	60%
Morris KT et al ⁸	87%	80%
Al-Mulhim et al ⁹	82%	97%
Ahmad I et al ¹⁰	83%	76%
Mande et al ¹¹	99%	68%
Ghimire et al ¹²	94%	64%
Mokri et al ¹³	87%	86%
Present study	89%	66%

According to study of Kaufman Z et al, on 234 patients sensitivity and specificity for clinical examination was 89% and 60% respectively.⁷ While the same for mammography examination was 89% and 73%

respectively. While FNAC was 93% sensitive and 97% specific.⁷

According to study of Morris KT et al, on 984 patients sensitivity and specificity for clinical examination was 87% and 80% respectively. While the same for mammography examination was 91% and 78% respectively. While FNAC was 92% sensitive and 96% specific.⁸

According to study of Al-Mulhim et at, on 140 patients sensitivity and specificity for clinical examination was 82% and 97% respectively. While the same for mammography examination was 87% and 97% respectively. While FNAC was 91% sensitive and 100% specific.⁹

According to study of Ahmad I et al, on 35 patients sensitivity and specificity for clinical examination was 83% and 76% respectively. While the same for mammography examination was 88% and 81% respectively. While FNAC was 88% sensitive and 100% specific.¹⁰

According to study of Mande et al, on 200 patients sensitivity and specificity for clinical examination was 99% and 68% respectively. While the same for Mammography examination was 93% and 98% respectively. While FNAC was 93% sensitive and 98% specific.¹¹

According to study of Ghimire et al, on 50 patients sensitivity and specificity for clinical examination was 94% and 64% respectively. While the same for Mammography examination was 95% and 93% respectively. While FNAC was 97% sensitive and 99% specific.¹²

According to study of Mokri et al, on 100 patients sensitivity and specificity for clinical examination was 87% and 86% respectively. While the same for Mammography examination was 93% and 79% respectively. While FNAC was 89% sensitive and 90% specific.¹³ According to study of Hermansen et al, on 650 patients sensitivity and specificity of only FNAC was 96% and 95% respectively.¹⁴

Table 10: Correlation of mammography results of this study with other studies is as follows.

Author	Sensitivity	Specificity
Kaufman Z et al ⁷	89%	73%
Morris KT et al ⁸	91%	78%
Al-Mulhim et at ⁹	87.5%	97%
Ahmad I et al ¹⁰	88%	81%
Mande et al ¹¹	93%	98%
Ghimire et al ¹²	95%	93%
Mokri et al ¹³	93%	79%
Present study	96%	83%

Table 11: Correlation of FNAC with other studies is as follows.

Author	Sensitivity	Specificity
Kaufman Z et al ⁷	93%	73%
Morris KT et al ⁸	92%	96%
Al-Mulhim et al ⁹	91%	100%
Ahmad I et al ¹⁰	88%	100%
Mande et al ¹¹	93%	98%
Ghimire et al ¹²	97%	99%
Mokri et al ¹³	89%	90%
Present study	96%	95%

Thus, getting results of all the components of triple test, findings of triple test were studied. Triple assessment of all 100 patients shows that out of 100 patients, 78 patients were diagnosed as having benign lesion whereas 22 patients were diagnosed as having malignant lesion. Out

of 78 patients diagnosed as having benign lesion, 75 were confirmed as having benign lesion, while 3 patients turned out to be malignant on histopathology examination. Out of 22 patients diagnosed as having malignant lesion by triple assessment, all the patients except one (benign) were found to be malignant on histopathology examination.

Thus, by comparing the results of triple assessment with histopathology examination, sensitivity of triple assessment in present study is 100% while specificity is 87.5%. Thus, triple assessment is a reliable tool for the diagnosis of the breast lump and definitive treatment can be started based upon its results. Thus, definitive decision about management of breast lump can be started without need for open biopsy and within short time. The results of the above study are comparable to other studies as shown in Table 12.

Table 12: Comparison of triple assessment of present with other studies is as follow.

Author	Patients examined	Sensitivity	Specificity
Morris A et al ⁴	261	100%	100%
Kaufman Z et al ⁷	234	100%	97%
Morris KT et al ⁸	984	100%	100%
Ahmad I et al ¹⁰	35	100%	96%
Mande et al ¹¹	200	100%	100%
Ghimire et al ¹²	50	100%	95%
Mokri et al ¹³	100	98%	100%
John V et al ¹⁵	46	100%	100%
Jin S et al ¹⁶	278	99%	97%
Present study	100	98%	87.5%

CONCLUSION

Sensitivity, Specificity and accuracy of triple assessment in diagnosis of breast lump is 98%, 88%, 96% respectively in the diagnosis of the breast lump. Results of triple assessment are same as the results by histopathology examination in majority of cases. As triple assessment is highly accurate, we can use it as a confirmatory diagnostic tool for breast lump.

Thus, there is no need to perform diagnostic open biopsy for breast lump reducing unwarranted surgeries, it's cheaper and it reduces the morbidity to the patient. Thus, 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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Ethical approval: The study was approved by the Institutional Ethics Committee

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