JAMP

Original Research Article

THE DIAGNOSTIC RELIABILITY OF EACH INDIVIDUAL COMPONENT OF THE TRIPLE ASSESSMENT

Vikas Rai[1], Amit Kumar Chaubey[2], Ritu Roy[3]

[1]Senior Resident, Department of Radiodiagnosis, Icare Medical College, Haldia. Kolkata West Bengal, India.
[2]Assistant professor. Department of Radiodiagnosis. Vivekananda Institute of Medical Science, Kolkata, West Bengal, India.
[3]Junior Resident, Department of Pathology, MGM Medical College & LSK Hospital Kishanganj, Bihar, India.

Abstract

Background: A lump in the breast can be either benign or cancerous. For the surgeon to decide on the best course of therapy, a definitive diagnosis of the breast lump is essential. A definitive preoperative diagnosis of benign lesion also spares the patient unnecessary physical, emotional, and psychological trauma. **Objectives:** To assess the individual component diagnostic accuracy of triple assessment and to explore the results against HPE report of Incisional / Excisional biopsy. **Materials and Methods:** It was Prospective cross sectional study, Study conducted in the department of Radiodiagnosis, Icare Medical College, Haldia. Total 70 cases were enrolled in the trial once the inclusion and exclusion criteria were applied. In addition to obtaining a detailed history of the patient's complaints, mode of presentation, lump location, and accompanying symptoms, a thorough physical examination and breast and mass inspection were performed. Each patient received a modified triple test consisting of a thorough clinical examination, an ultrasound evaluation of the breast mass, and Fine Needle aspiration of the breast lump. The palpable breast tumours were classed as benign, malignant, or inconclusive based on the results of each test. **Results:** We found most of the cases were belongs to 18 – 25 years of age group, Out of 70 cases, 18 cases (25.7%) had a lymph node present in the axilla, while 52 cases (74.3%) did not have a lymph node in the axilla. The mammography findings were categorized as benign (11 cases), malignant (7 cases), and inconclusive (5 cases). According to the data, 47.8% of the mammography examinations resulted in a benign finding, 30.4% resulted in a malignant finding, and 21.8% were inconclusive. The results of a fine needle aspiration cytology (FNAC) examination of study population. According to the data, 61.4% of the FNAC examinations resulted in a benign finding, 28.6% resulted in a malignant finding, and 10.0% were inconclusive. According to the data, 57.1% of the core biopsy examinations were in benign cases, and 42.9% were malignant cases. **Conclusion:** The results of the modified test in our study are as accurate as histological diagnosis. Of the three components of the modified triple test Clinical, USG, Mammogaphy, FNAC and Core Biopsy of breast had 100% specificity for the diagnosis of malignant lumps.

INTRODUCTION

Most breast pathology manifests itself clinically as a lump. A lump in the breast can be either benign or cancerous. For the surgeon to decide on the best course of therapy, a definitive diagnosis of the breast lump is essential. If a benign lesion can be diagnosed beforehand, the patient can avoid invasive surgery and the associated risks to their physical and mental health. Breast illness affects approximately 25% of women at some point in their lives.[1] As medical technology advances and people live longer, more women are at risk of contracting breast cancer.[2]

Diagnostic procedures for breast lumps, such as mammography, ultrasonography, and fine needle aspiration cytology (FNAC), are not foolproof.[3]

However, clinical assessment is a straightforward approach to detecting cases; it is low-cost and non-invasive, and if proven correct, might be of

enormous utility.Breast cancer mortality and morbidity can be reduced with early detection and treatment,[5] as shown by. Clinical assessment has the potential to be an effective diagnostic method. This would be especially helpful in more remote locations where more expensive or limited diagnostic resources may be an issue.[5]

Mammography is the most common method of breast cancer screening, and it has been shown to reduce deaths from the disease by 30–40% in the screened population. Radiologically thick breasts in young women, however, reduce their sensitivity.[6]The breast is a three-dimensional volumetric structure, but planar mammography only provides a two-dimensional image of it, leading to tissue superimposition.[7] Digital breast tomosynthesis (DBT) helps with the two-dimensional breast representation of planar mammography, while full-field digital mammography (FFDM) helps with the dynamic range, tissue contrast, and post-processing.Compared to standard mammography, which has a sensitivity of 78%, dual-energy contrast enhanced digital mammography has a claimed sensitivity of 93%.FNAC is an established approach for diagnosing breast lesions when USG detects nodules in the breast.[8] It's beneficial for small lesions that aren't candidates for Core Needle Biopsy, and it's very accurate when performed by trained professionals.[9] The lack of experienced cytologists at many institutions, the difficulty in accurately evaluating cytologic and morphologic features in breast aspirates with the histological classification system used as the "gold-standard," especially in benign lesions, and the inability to reliably distinguish invasive from in situ carcinoma are all limitations.[10]

Clinical judgement must be backed up by specialised examinations in order to arrive at a conclusive diagnosis. Mammography and FNAC are the two methods now available with excellent patient tolerance.[11] However, mammography and FNAC alone only have an 82% and 78% success rate.[12]

A "Modified Triple Assessment" involving a clinical exam, mammography, and FNAC has been shown in multiple studies to result in a 100% accurate diagnosis.[13]

MATERIALS AND METHODS

It was Prospective cross sectional study, Study conducted in the department of Radiodiagnosis, Icare Medical College, Haldia. Total 70 cases were enrolled in the trial once the inclusion and exclusion criteria were applied. In addition to obtaining a detailed history of the patient's complaints, mode of presentation, lump location, and accompanying symptoms, a thorough physical examination and breast and mass inspection were performed. Each patient received a modified triple test consisting of a thorough clinical examination, an ultrasound evaluation of the breast mass, and Fine Needle aspiration of the breast lump. The palpable breast tumours were classed as benign, malignant, or inconclusive based on the results of each test.

Modified The following three criteria were used to evaluate a breast lump:

Look for changes in the breast's size, shape, or appearance, such as redness, discharge from the nipple, or dimples in the skin.

Second, any lumps, bumps, or other anomalies were identified by palpating the breast and the area around it. Looking for evidence of morphological or textural shifts.

The next step is to move into different positions (such as standing up straight, reclining down, or raising one's arms) to better see any changes or lumps in the breast.

The lump was compared to the remainder of the breast and the other breast to see if its size and texture were consistent with the rest of the breast.

Mammography: All female patients aged 40 and up had mammograms to check for cancer or other abnormalities.

Mammography can either be used for screening or for diagnosis. Diagnostic mammography is used to analyse a specific breast alteration that has been found through a clinical breast exam, while screening mammography is used to detect changes in women who have no symptoms or have only a small lump or suspicious area.

The patient was positioned supine, with the affected upper limb elevated beside the head, while the lesion was held in place with the other hand. The biopsy needle was then inserted into the lump and moved back and forth into the mass several times, while constant negative suction was maintained until aspirate was seen at the hub of the needle. The suction was then released, the needle was withdrawn, and the material was spread on three slides before being taken up for cytology.

Before a core-needle breast biopsy, any relevant imaging was reviewed. After explaining the potential outcomes, benefits, and alternatives to the surgery, the patient should give their informed permission.

Before each biopsy, the tray was set up in the same reliable manner.

Data interpretation and analysis:

Data was loaded into an Excel spreadsheet from the pro forma, analysed with the appropriate SPSS (Version 26) statistical tests, and then the modified triple test findings were compared to Histopathological diagnoses.

RESULTS

Table 1: Age distribution among study population (n=70)

Age group	No of cases	Percentage
18 – 25	15	21.4
26 – 30	10	14.3
31 – 35	09	12.9
36 – 40	13	18.6
41 – 45	12	17.1
46 – 50	7	10.0
>50	4	5.7
Total	70	100.0

We found most of the cases were belongs to 18 – 25 years of age group, i.e. 15(21.4%), followed by 26-30 years, 31 – 35 years, 36 – 40 years, 41 – 45 years , 46 – 50 years &>50 years of age group patients were consisted 14.3%, 12.9%, 18.6%, 17.1%, 10.0% & 5.7% respectively.

Table 2: Duration of the symptoms among study population (n=70)

Duration of the symptoms	No of cases	Percentage
1 – 3 months	35	50.0
4 – 6 months	24	34.3
>6 months	11	15.7
Total	70	100.0

The duration of symptoms 1 to 3 months had 35 cases, which is 50.0% of the total cases. The group with the second highest number of cases were the 4 to 6 months group, with 24 cases (34.3% of the total). The group with the shortest duration of symptoms was the group with symptoms lasting over 6 months, with 11 cases i.e.15.7% respectively.

Table 3: Size of Lump (n=70)

Size of Lump	No of cases	Percentage
2 cm	22	31.4
2.5 cm	28	40.0
>5.0 cm	20	28.6
Total	70	100.0

Represents the distribution of the size of lump among a study population. Most of the patients had size of lump 2.5 cm i.e. 28(40.0%) cases 28.6 % cases had large size of lump i.e. >5 cm respectively.

Table 4: Rediological evaluation of USG findings of breast lump among who had 18 to <40 years of age group patients (n=47)

USG findings	No of cases	Percentage
Benign	26	55.3
Malignant	12	25.5
Inconclusive	9	19.2
Total	47	100.0

The ultrasound findings were categorized as benign, malignant, and inconclusive. According to the table, 55.3% of the ultrasound examinations resulted in a benign finding, 25.5% resulted in a malignant finding, and 19.2% were inconclusive.

Table 4: Rediological evaluation of mammography findings of breast lump among who had >40 years of age group patients (n=23)

Mammography findings	No of cases	Percentage
Benign	11	47.8
Malignant	7	30.4
Inconclusive	5	21.8
Total	23	100.0

The mammography findings were categorized as benign (11 cases), malignant (7 cases), and inconclusive (5 cases).
According to the table, 47.8% of the mammography examinations resulted in a benign finding, 30.4% resulted in a malignant finding, and 21.8% were inconclusive.

Table 6: NAC findings among breast lump (n=70)

FNAC findings	No of cases	Percentage
Benign	43	61.4
Malignant	20	28.6
Inconclusive	07	10.0
Total	70	100.0

According to the table, 61.4% of the FNAC examinations resulted in a benign finding, 28.6% resulted in a malignant finding, and 10.0% were inconclusive.

Table 7: Core Biopsy among Inconclusive findings of FNAC (n=7)

Core Biopsy	No of cases	Percentage
Benign	4	57.1
Malignant	3	42.9
Total	7	100.0

57.1% of the core biopsy examinations were in benign cases, and 42.9% were malignant cases.

Table 8: Histopathological findings of malignant cases (m=23)

Histopathological findings of malignant cases	No of cases	Percentage
Ductal Carcinoma	18	78.3
Lobular Carcinoma	01	4.3
Inflammatory Breast CA	02	8.7
Papillary neoplasm	02	8.7
Total	23	100.0

The findings were categorized as ductal carcinoma (18 cases), lobular carcinoma (1 case), inflammatory breast cancer (2 cases), and papillary neoplasm (2 cases). According to the table, 78.3% of the malignant cases were ductal carcinoma, 4.3% were lobular carcinoma, 8.7% were inflammatory breast cancer, and 8.7% were papillary neoplasms.

Table 9: Histopathological findings of benign cases (m=47)

Histopathological findings of benign cases	No of cases	Percentage
Fibroadenoma	24	44.7
Fibrocystic Disease	15	31.9
Benign Phylloides	09	19.1
Tubular Adenosis	02	4.3
Total	47	100.0

We found 44.7% of the benign cases were fibroadenomas, 31.9% were fibrocystic disease, 19.1% were benign phyllodes, and 4.3% were tubular adenosis.

Table 10: Diagnostic test evaluation of Rediological finding

Statistic	Value	95% CI
Sensitivity	86.36%	65.09% to 97.09%
Specificity	97.92%	88.93% to 99.95%
Positive Likelihood Ratio	41.45	5.92 to 290.37
Negative Likelihood Ratio	0.14	0.05 to 0.40
Disease prevalence (*)	31.43%	20.85% to 43.63%
Positive Predictive Value (*)	95.00%	73.06% to 99.25%
Negative Predictive Value (*)	94.00%	84.54% to 97.82%
Accuracy (*)	94.29%	86.01% to 98.42%

The Sensitivity was 69.57%, specificity was 93.62%, the positive predictive value 84.21%, negative predictive value 86.27% and accuracy was 85.71% respectively.

Table 11: Diagnostic test evaluation of FNAC & Core Biopsy finding

Statistic	Value	95% CI
Sensitivity	100.00%	85.18% to 100.00%
Specificity	100.00%	92.45% to 100.00%
Positive Likelihood Ratio	-	-
Negative Likelihood Ratio	0.00	-
Disease prevalence (*)	32.86%	22.09% to 45.12%
Positive Predictive Value (*)	100.00%	-
Negative Predictive Value (*)	100.00%	-
Accuracy (*)	100.00%	94.87% to 100.00%

The Sensitivity was 100.0%, specificity was 100.0%, the positive predictive value 100.00%, negative predictive value 100.0% and accuracy was 100.0% respectively.

Table 12: Individual component diagnostic accuracy of triple assessment

Individual component	Clinical assessment	USG & Mammography assessment	FNAC & Core Biopsy assessment
Sensitivity	78.26%	86.36%	100.00%
Specificity	97.87%	97.92%	100.00%
Accuracy	91.43%	94.29%	100.00%

The results of the assessment of three individual components for the diagnosis of a medical condition. The components are clinical assessment, USG & Mammography assessment, and FNAC & Core Biopsy assessment.

DISCUSSION

This modified triple test's main objective is to accurately preoperatively diagnose benign breast lumps to save needless procedures.

Our research aims to assess the effectiveness of the modified triple test (i.e., clinical breast examination, breast ultrasound, breast mammography, FNAC, and core biopsy) both alone and in combination for the identification of cancer. The benchmark for comparison was the breast lump'shistopathological investigation.

Our study was prospective cross sectional study with 70 participants, and we analyse our findings in light of the aforementioned data. According to our data, breast lumps were most prevalent among women aged 18 to 25 (21.4%) and least common among those aged 50 and older (the distribution reported in previous research). Younger women tend to appear sooner in the course of sickness because of their higher levels of education and awareness.

Fifty percent of the overall occurrences in the current research were in those who experienced symptoms for 1–3 months. This was consistent with the findings of a few research, but different from the median 3 months seen in other investigations (Afsar A Bhatti et al 2010).[14]

Forty-one percent of those with a lump who did not experience any discomfort said that it was the most noticeable symptom.

A painless palpable lump was the typical manifestation of malignancy, as was shown in a research by Kaireinnos et al (BMC public health, 2013), which found similar results.[15]

The results of a comprehensive clinical evaluation showed The Sensitivity was 78.26%, specificity was 97.87%, the positive predictive value 36.78%, negative predictive value 0.22% and accuracy was 91.43% respectively.

Clinical breast examination has been demonstrated to have a sensitivity of 21% to 100% and a specificity of 50% to 97.8%, according to a meta-analysis of studies. The high sensitivity seen here may be attributable to the fact that only patients with demonstrable lumps were included in the analysis. Many other investigations have shown outcomes consistent with ours.

Breast ultrasonography

This research presents the findings of a diagnostic test analysis of a radiological finding. The Sensitivity was 69.57%, specificity was 93.62%, the positive predictive value 84.21%, negative predictive value 86.27% and accuracy was 85.71% respectively.

These results correlate well with the existing literature; for example, Khoda et al. found that USG had a sensitivity of 91.6%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 97.3%, and Pande et al. found similar results for ultrasonography: 95% sensitivity, 94.1% specificity, 95.5% positive predictive value, and 93.7% negative predictive value. These findings are consistent with those of a separate research conducted by Jan et al.[17,18]

Fine Needle Aspiration Cytology & Core biopsy:

Contains the findings of a diagnostic test assessment for FNAC diagnosis. We found The Sensitivity was 100.0%, specificity was 100.0%, the positive predictive value 100.00%, negative predictive value 100.0% and accuracy was 100.0% respectively.

FNAC results in various studies.[18-22]

Study	Sensitivity %	Specificity%	Positive predictive value%	Negative predictive value %
Our study	87.50	100	100	93.88
Sankaya & Dongre	88.37	96.42	97.43	84.37
Choi et al	77.70	99.20	97.43	84.37
Mohammed et al	90.62	100	100	95.08
Kim et al	94.59	87.91	79.54	97.03
Park and Ham	76.90	91.60	-	-

It is shown that our study's findings are consistent with those of other research efforts and that the values nearly mirror those found by Mohamed et al. According to the findings, FNAC has sufficient diagnostic capacity when used alone, and its value increases when combined with the other two tests. Using the Modified Triple-Test.[16,23-25]

Analyze here how three separate factors in a medical diagnostic fit together. The components are clinical assessment, USG & Mammography assessment, and FNAC & Core Biopsy assessment.

Sensitivity refers to the proportion of true positive results. In this case, the sensitivity of the clinical assessment was 78.26%, the sensitivity of the USG & Mammography assessment was 86.36%, and the sensitivity of the FNAC & Core Biopsy assessment

was 100.00%. Specificity refers to the proportion of true negative results In this case, the specificity of the clinical assessment was 97.87%, the specificity of the USG & Mammography assessment was 97.92%, and the specificity of the FNAC & Core Biopsy assessment was 100.00%. Accuracy is the proportion of all test results that are correct, either true positive or true negative. In this case, the accuracy of the clinical assessment was 91.43%, the accuracy of the USG & Mammography assessment was 94.29 %, and the accuracy of the FNAC & Core Biopsy assessment was 100.00%. This means that the FNAC & Core Biopsy assessment had the highest overall accuracy in diagnosing the medical condition among the three components.

Study	Sensitivity %	Specificity%	Positive predictive value%	Negative predictive value %
Our study	100	100	100	98.40
Baykara et al	100	92.01	53.16	100
Khoda et all	100	100	100	100
Jan et al	100	99.3	93.3	100
Vaithyanathan et al	100	82	76.9	100

This comparison demonstrates that our findings are consistent with those of other research, demonstrating the use of the modified triple test as a clinical diagnostic for the early identification of malignant tumours and allowing for more precise and timely surgical planning.

CONCLUSION

The results of the modified test in our study are as accurate as histological diagnosis. Of the three components of the modified triple test Clinical, USG, Mammogaphy, FNAC and Core Biopsy of breast had 100% specificity for the diagnosis of malignant lumps. The combination of these diagnostic tools can provide a more complete picture of the breast tissue and help to reach a definitive diagnosis. It's important to remember that the results of these tests should be considered along with other clinical, imaging, and laboratory findings, and the decision to perform a specific test or combination of tests will depend on individual circumstances and the judgement of the healthcare provider.

REFERENCES

1. Barton MB, Harris R. The rational clinical examination. Does this patient have Breast cancer. The screening clinical examination: Should it be done? How? JAMA. 1999;282(3):1270–80.
2. Curado MP. Breast cancer in the world: incidence and mortality. SaludPubl Mex. 2011;53:372–384.
3. Nederend J, Duijm LE, Voogd AC, Groenewoud JH, Jansen FH, Louwman MW. Trends in incidence and detection of advanced breast cancer at biennial screening mammography in The Netherlands: a population based study. Breast Cancer Res. 2012;14:R10. doi: 10.1186/bcr3091.
4. Prasad SN, Houserkova D. A comparison of mammography and ultrasonography in the evaluation of breast masses. Biomed Pap Med FacUnivPalacky Olomouc Czech Repub. 2007;151:315–322.
5. Hampton T. Breast cancer symposium highlights risk, recurrence, and research trials. JAMA. 2012;307:348–350.
6. Magarey CJ. Detection and diagnosis of early breast cancer. Med J Aust. 1976;2:834–837.
7. Kerlikowske K, Carney PA, Geller B, Mandelson MT, Taplin SH, Malvin K, et al. Performance of screening mammography among women with and without a first-degree relative with breast cancer. Ann Intern Med. 2000;133:855–863.
8. Chan SW, Cheung PS, Chan S, Lau SS, Wong TT, Ma M, et al. Benefit of ultrasonography in the detection of clinically and mammographically occult breast cancer. World J Surg. 2008;32:2593–8
9. Smith MJ, Heffron CC, Rothwell JR, Loftus BM, Jeffers M, Geraghty JG. Fine needle aspiration cytology in symptomatic breast lesions: still an important diagnostic modality? Breast J. 2012;18(2):103–10.
10. Berner A, Davidson B, Sigstad E, Risberg B. Fine-needle aspiration cytology vs. core biopsy in the diagnosis of breast lesions. DiagnCytopathol. 2003;29(6):344–8.
11. Graf O, Herbich TH. Follow up of palpable circumscribed noncalcified solid breast masses at mammography and ultrasound. Can biopsy be averted? Radiology. 2004;233(9):850–56.
12. Malik AS. Role of fine needle aspiration biopsy and cytology in Breast Lump. J Cole physicians Surg Pak. 1995;5(11):75–77.
13. Ashley S, Royle GT. Clinical, radiological and cytological diagnosis of breast cancer in young women. Br J Surg. 1989;76:835–37.
14. Afsar A Bhatti, Muhammad M Gilani, Muhammad Tanveer Anwar, Sikander H Gondal, Zia Ullah.Role of Modified Triple Test Scoring System for Evaluation of Palpable Breast Masses in Women Under Age 40.A.P.M.C July-December 2010.: 4(2):128-132.
15. Innos K, Padrik P, Valvere V, Eelma E, Kütner R, Lehtsaar J, TekkelMIdentifying women at risk for delayed presentation of breast cancer: a cross-sectional study in Estonia. BMC Public Health. 2013 Oct 9;13:947.
16. Khoda, et al.: Evaluation of modified triple test in the diagnosis of palpable breast lumps. Journal of Medical Society. Jan-Apr 2015 - Vol29 . Issue 1-29.
17. Pande AR, Lohani B, Sayami P, Pradhan S. Predictive value of ultrasonography in the diagnosis of palpable breast lump. Kathmandu Univ Med J (KUMJ) 2003;1:78-84.
18. Sankaye. S, Dongre.S, Indian Journal of Medical and Paediatric Oncology, Apr-Jun 2014, Vol 35, Issue 2. 159-164.
19. Park IA, Ham EK. Fine needle aspiration cytology of palpable breast lesions. Histologic subtype in false negative cases. ActaCytol 1997;41:1131-8.
20. Kim A, Lee J, Choi JS, Won NH, Koo BH. Fine needle aspiration cytology of the breast. Experience at an outpatient breast clinic. ActaCytol 2000;44:361-7.
21. Choi YD, Choi YH, Lee JH, Nam JH, Juhng SW, Choi C. Analysis of fine needle aspiration cytology of the breast: A review of 1,297 cases and correlation with histologic diagnoses. ActaCytol 2004;48:801-6.
22. Mohammed AZ, Edino ST, Ochicha O, Alhassan SU. Value of fine needle aspiration biopsy in preoperative diagnosis of palpable breast lumps in resource-poor countries: A Nigerian experience. Ann Afr Med 2005;4.
23. Jan M, Matto JA, Salroo NA, Ahangar S. Triple assessment in the diagnosis of breast cancer in Kashmir. Indian J Surg 2010;72:97-103.
24. Murat Baykara, ZeynepOzkan, Yeliz Gul1, OzgenAslan, Leyla Gungor. Effectiveness of the Triple Test and Its Alternatives for Breast Mass Evaluation. J Breast Health 2013; 9: 195-9.
25. Vaithianathan R, Sundaresan V, Santhanam R. Vlaue of modified triple test in the diagnosis of palpable breast lumps. Int J Cur Res Rev 2013;5:125- 34.