RESEARCH ARTICLE ISSN: 2349-2678

Contents lists available at www.ijpba.in
International Journal of Pharmaceutical and Biological Science Archive
NLM (National Library of Medicine ID: 101732687)
Index Copernicus Value 2019: 71.05
Volume 8 Issue 3; May-June; 2020; Page No. 20-25

PREVALENCE & DIAGNOSIS OF BREAST LUMPS BY TRIPLE ASSESSMENT COMBINED WITH CLINICAL EXAMINATION, ULTRASONOGRAPHY AND FINE-NEEDLE ASPIRATION CYTOLOGY

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Conflicts of Interest: Nil
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ABSTRACT

Background: The most frequent symptom of breast cancer is a lump in the breast. The triple breast assessment, which includes clinical breast examination, radiographic breast examination, and fine needle aspiration cytology (FNAC), is relatively straightforward, reliable, reproducible, and cost-effective.

Aim: The purpose of this study was to determine the sensitivity, specificity, positive and negative predictive values of a triple test (TT) consisting of a physical examination (PE), sonomammography, and fine needle aspiration cytology (FNAC) in the evaluation and characterization of a palpable breast lump.

Material and Methods: A total of 100 participants were enrolled in the study, all of whom had a breast lump. All of the patients were assessed using the three components of the triple evaluation, and the excised mass was histopathologically examined.

Results: Malignant lesions were discovered more frequently (62.0%) than benign tumours. With a p-value of 0.001, the accuracy, sensitivity, specificity, PPV, and NPV of triple breast assessment were 94.0 %, 100 %, 84.2 %, 91.2 %, and 100 %, respectively.

Conclusion: The breast triple evaluation is a very valuable technique for evaluating breast disorders. Clinical examination (by competent hands) combined with cytologic and radiologic assistance is sufficient to rule out cancer in patients with distinct lumps.

Keyword: Breast lump, Clinical examination, sonomammography, fine needle aspiration cytology, triple assessment

Introduction

Breast cancer is the most frequent cancer in women, and it is the leading cause of cancer death in women aged 20 to 59 years around the world. Breast cancer is the most common cancer among women in India, with an age-adjusted incidence of 25.8 per 100,000 women and a death rate of 12.7 per 100,000 women[1]. Such information emphasises the importance of comprehending the symptoms of breast cancer and the importance of appropriately detecting it. The most frequent symptom of breast cancer is a lump in the breast. With increased understanding and awareness of breast cancer, lumps in the breast have become a common complaint among patients, with 40-70 % of patients seeking assistance, and the number of such complaints is projected to climb[2]. The patient and family members suffer physical, emotional, and psychological trauma when a lump is discovered, whether by themselves or by a professional. Fortunately, the majority of breast lumps are benign. This does not negate the importance of evaluating a breast lump, as failing to do so can result in the patient's morbidity and mortality, as well as a malpractice lawsuit against the practitioner[3]. As a result, both the patient and the clinician must be able to distinguish between benign and malignant lesions. A definite diagnosis of benign lesion not only spares the patient from unnecessary physical, emotional, and psychological suffering, but it also relieves the health-care system of undue strain[4]. A definitive pre-operative identification of a malignant lesion, on the other hand, opens up numerous chances for patient counselling and planning of

prospective one-stage surgical treatment or neoadjuvant chemotherapy. TAB, which consists of a clinical examination of the breast, a radiological examination of the breast, and fine needle aspiration cytology (FNAC), is a relatively simple, reliable, reproducible, cost-effective, less invasive, less traumatic, and less upsetting procedure that can be performed on an outpatient basis[5]. In this study, the results of TAB were compared to those of an open biopsy. Ultrasonography (USG) is employed instead of mammography (traditional TAB) for the radiological evaluation due to the absence of mammography in our institute and the recognised higher yield of USG.

AIM: The purpose of this study was to determine the sensitivity, specificity, positive and negative predictive values of a triple test (TT) consisting of a physical examination (PE), sonomammography, and fine needle aspiration cytology (FNAC) in the evaluation and characterization of a palpable breast lump.

Material and Methods

An observational research was conducted on 100 individuals who presented to the emergency room with a breast lump and/or were admitted to the ward. All of the patients were assessed using the three components of the triple evaluation, and the excised mass was histopathologically examined.

Criteria for inclusion: A 30-year-old woman presents with a lump in her breast.

Criteria for exclusion: Patients were 30 years old and had acute inflammation. Patients with a fungus-infested mass, pregnant woman

Prior to enrolling patients, the study's conduct was approved by the Institutional Ethical Committee. All eligible patients were assessed using clinical, ultrasonographic, and cytological methods at the time of presentation and on the ward, and the results were documented in a structured questionnaire that had been pre-tested. The history, principal complaint, prior history, family history, personal history, obstetric and menstrual history, physical examination, local examination, ultrasonographic impression, FNAC impression, and histological impression were all recorded on the proforma. Following the completion of the Proforma, a thorough analysis was conducted, and numerous observations were drawn, discussed, and concluded. All of the patients who took part in the trial gave their written and informed consent.

Clinical Assessment: Clinical evaluations were conducted in daylight, with the patient in a sitting position, in both the OPD and the ward. The clinical evaluation began with a history of the lump in the breast (mode of onset, duration, rate of growth), the presence of any pain, its duration and periodicity if present, the presence and type of discharge from the nipple, and any co-morbid illnesses (e.g. diabetes mellitus, hypertension, tuberculosis, etc.). Any previous history of comparable complaints, a history of breast biopsy, a history of breast cancer, and a history of hospitalisation were all investigated. Personal, menstrual, and obstetric history were all taken into account. A family history of breast cancer or cancer of other organs, particularly in the mother or grandmother, or in the sister, was investigated. Any weight loss, fever, cough, hemoptysis, back discomfort, abdominal pain, or swelling anywhere else in the body are all investigated. After obtaining proper consent, the patient was examined in daylight while ensuring proper privacy in the presence of a female nursing assistant. Both the sitting and supine positions were used to examine the patient.

Ultrasonographic Assessment: Using a 5-10 MHz hand-held linear probe and ultrasound transmission gel, an ultrasonographic assessment was performed in the USG room in the Radiology Department with the patient in a sitting and supine posture. The BIRADS system was used to classify the lesions. BI-RADS 1-3 were classified as benign (B) lesions, while BI-RADS 4-6 were classified as malignant (M) lesions.

Cytological Assessment: After USG, FNAC was completed. After proper labelling, the smear was fixed with alcohol (90 % ethanol) and stained with Papanicolaou or Hematoxylin and Eosin. Benign (B), Suspicious for malignancy (S), or Positive for malignancy (P)

was the classifications provided to the reports (M).

Statistical analysis: The Chi-Square test or Fisher's exact probability test were used to determine the statistical significance of the intergroup difference in categorical variable distribution. For lump detection by clinical examination, USG, and FNAC against HPE as a gold standard, diagnostic effectiveness measures such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were established. The Cohen Kappa Statistic was used to assess the statistical agreement between clinical examination, USG, FNAC, and HPE methods. Before statistical analysis, all of the data was entered into MS Excel. Statistical significance was defined as a p-value of less than 0.05. Against each null hypothesis, all hypotheses were formed using two-tailed alternatives (hypothesis of no difference). Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation, USA) for MS Windows was used to analyse all of the data.

Results

32 cases (32%) had a lump that lasted less than 6 months, 8 of which were malignant (8%) and 24 of which were benign (24%); 50 cases (50%) had a lump that lasted between 6 and 12 months, 38 of which were malignant (38%) and 12 of which were benign (12%); 16 cases (16%) had a lump that lasted between 12 and 24 months, 14 of which were benign (12%).

Table 1: Distribution of cases according to clinical diagnosis, USG, FNAC and Histopathology findings

Diagnosis		No. of cases	% of cases
Clinical Findings	Benign	52	52%
	Malignant	48	48%
USG Findings	Benign	36	36%
	Malignant	64	64%
FNAC Findings	Benign	36	36%
	Malignant	56	56%
	Suspected	8	8%
HPE Findings	Benign	38	38%
	Malignant	62	62%

On clinical evaluation, 52 cases (52.0 %) were benign and 48 cases (48.0 %) were malignant out of 100 cases investigated. 36 instances (36.0 %) were benign on USG examination, while 64 cases (64.0 %) were malignant. On FNAC evaluation, 36 (36.0 %) cases were benign, 56 (56.0 %) cases were malignant, and 8 (8.0 %) cases were suspicious (non-confirmed). On the basis of HP examination, 38 cases (38.0%) were benign and 62 cases (62.0%) were malignant.

Table 2: Diagnostic efficacy of Clinical, USG, FNAC according to Histopathology examination (Gold Standard)

	Diagnostic Modality	Sensitivity	Specificity	PPV	NPV
Concordant Group	Clinical	100	100	100	100
	USG	100	100	100	100
	FNAC	100	100	100	100
Discordant Group	Clinical	12.5	100	100	30
	USG	87.5	33.3	77.8	50
	FNAC	100	66.7	88.9	100

Clinical examination: On the basis of clinical impression, 52 cases (52.0%) were classified as benign and 48 cases (48.0%) as malignant. CBE assessed malignancy in four of the 24 discordant cases, with all four cases being identified as malignant on HPE. Only six of the remaining 20 instances that CBE deemed benign were classified as benign on HPE, with the remainder being confirmed as malignant. With a p-value of 0.001, the clinical diagnostic and histopathological agreement %age was 86.0 %, and the sensitivity, specificity, and positive predictive value were 77.4 %, 100.0 %, and 100.0 %, respectively (statistically highly significant).

USG examination: On USG, 36 instances (36.0%) of the 100 cases were found to be benign, whereas the remaining 64 cases (64.0%) were found to be malignant. USG indicated benign nature in four of the 24 discordant instances, two of which were identified as benign on HPE and the other as malignant. USG classified the remaining 20 discordant instances as malignant; 20 of these were diagnosed as malignant on HPE, while the remaining four were classified as benign. With a p-value of 0.001, the agreement %age between ultrasonography and histology was 94.0 %, and the sensitivity, specificity, and positive predictive value were 96.8%, 89.5 %, and 93.7 %, respectively (statistically highly significant).

Fine Needle Aspiration Cytology (FNAC): On cytology, 36 cases (36.0 %) of breast lumps were found to be benign, while 56 cases (56.0 %) were found to be malignant. There were eight cases (8.0%) that were suspected of malignancy, six of which were proven to be malignant on HPE and one benign. When a report is benign or malignant, FNAC has a 100% accuracy rate, and when a report is questionable, it has a 75% accuracy rate. FNAC classified four of the 24 discordant instances as benign and twelve as malignant, with all 12 cases agreeing with the HPE diagnosis. On HPE, six of the eight FNAC-identified suspicious lesions were found to be malignant and two to be benign.

With a p-value of 0.001, the proportion of agreement between fine needle aspiration cytology and histopathology was 98.0 %, and the sensitivity, specificity, and positive predictive value were 100.0 %, 94.7 %, and 96.9 %, respectively (statistically highly significant). This examination has the highest %ages of accuracy (98.0%) and sensitivity (100.0%), as well as a very high specificity (94.7%) and positive predictive value (94.7%) among all comparisons in this study (96.9 %). As a result, FNAC is the most dependable component of TAB.

Triple Breast Assessment: Of the 100 cases examined, 32 (32.0 %) were benign on TAB (i.e., all components were benign), while 68 (68.0 %) were malignant (i.e., any of the components showing malignant). With a p-value of 0.001, the agreement %age of triple breast and histopathological assessment was 94.0 %, and the sensitivity, specificity, and positive predictive value were 100.0 %, 84.2 %, and 91.2 %, respectively (statistically highly significant). There were 76 concordant instances out of the 100 investigated, 44 of which were identified as malignant and 32 as benign by triple test, and all of them were appropriately diagnosed, as found on HPE.

With a p-value of 0.001, the agreement %age of concordant TAB and histology was 100.0 %, and the sensitivity, specificity, and positive predictive value were all 100.0 % (statistically highly significant). Twenty-four of the hundred instances analysed were discordant, with 18 of them being identified as malignant on histology. 75.0 % of discordant TAB and histology were in agreement. FNAC has the best accuracy (90.9%), sensitivity (100%), and NPV (100%) among the discordant cases, while CBE has the highest specificity (100%) and PPV (100%). (100 %). Only FNAC shows a statistically significant p-value of 0.011 among the discordant group. TAB was malignant (i.e., any or all of the components of TAB suggesting malignancy or suspected of malignancy) in 68 of the 100 cases analysed, with 62 of them being malignant and 6 being benign on histology. On histology, all of the remaining 32 instances that were benign on TAB (i.e., all of

the components suggesting benign) were found to be benign.

Discussion

On TAB, 32 instances (32.0 %) were benign (all components indicating benign) and 68 cases (68.0 %) were malignant (all components showing malignant) (i.e., any of the components showing malignant). With a p-value of 0.001, the agreement %age of triple breast and histopathological assessment was 94.0 %, and the sensitivity, specificity, and positive predictive value were 100.0 %, 84.2 %, and 91.2 %, respectively (statistically highly significant). There were 76 concordant instances out of the 100 investigated, 44 of which were identified as malignant and 32 as benign by triple test, and all of them were appropriately diagnosed, as found on HPE. Jan M et colleagues discovered that when all of the modalities utilised in triple assessment were integrated, the sensitivity and specificity were 100 % and 99.3 %, respectively. The triple assessment had a concordance of 99.3%, a positive predictive value of 93.3 %, a negative predictive value of 100 %, a sensitivity of 100 %, and a specificity of 99.3%. The significance of the p value (0.000). The sensitivity of clinical, mammographic, and cytologic exams was 82 %, 73 %, and 68 %, respectively, in a study by Martelli G et al. When they were linked, the %age jumped to 95%. 63 %, 80 %, and 97 % specificity, respectively[5]. The triple test has a 100 % predictive value for positive results. The sensitivity and specificity of the individual tests were found to be 89 % and 73 % for mammographic examination, 93 % and 97 % for FNA cytologic examination, and 89 % and 60 % for physical examination in a study by Kaufman Z et al. The sensitivity of the combined triad of tests was 100%, and the specificity was 57%. All patients with breast cancer obtained positive results for malignancy in one or more diagnostic tests, indicating that the tests were 100 % sensitive[6]. All patients with benign lesions exhibited negative findings for malignancy in all three diagnostic tests, indicating a 100% negative predictive value. The triple test has a concordance of 98.8%, a specificity of 100%, and a sensitivity of 95.5 %, according to Steinberg et al. Nodal status, tumour size, and outcome were similar whether the triple test was positive or not, but oestrogen (p 0.05) and progesterone (p 0.03) receptor levels were more likely to be negative when the triple test was positive. According to Ahmad et al, 19 instances were benign (54.28 %) and 16 cases were malignant (45.71 %) [7]. All of the benign cases found by the triple test turned out to be benign on final biopsy (100 % specificity and NPV), while all of the malignant lesions detected by the triple test turned out to be malignant on final biopsy (54.28 %) (100 % sensitivity and PPV). In 16 cases, the triple test was inconclusive (45.71 %). The combined results of two factors among three components were used to determine whether the Triple Test was benign or malignant[8]. Eleven of the instances were cancerous, while the other five were benign. The components of the triple test, BIRAD IV on mammography and minor abnormal cells without frank malignancy on FNAC, were worrisome in four patients. TAB's diagnostic efficacy in our investigation was comparable to that of other studies. Because of two cases of benign lesion that was evaluated as indicative of malignancy on FNAC, our study's specificity was reduced.

Conclusion

TAB (triple assessment of breast) is an effective method for assessing breast illnesses. Clinical examination (by competent hands) combined with cytologic and radiologic assistance is sufficient to rule out cancer in patients with distinct lumps. Without any difficulties, a triple assessment can be performed as an outpatient procedure. The triple assessment did not require hospitalisation and was completed without difficulties in the outpatient setting. Non-invasive or minimally invasive methods are employed. Breast cancer diagnosis has become easier and more accurate because to recent improvements in imaging and cytopathology.

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