

# Accuracy of Clinical Examination of Breast Lumps in Detecting Malignancy: A Retrospective Study

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**Abstract** Clinical examination is a simple method to detect breast lumps and their nature as it is inexpensive and non-invasive and if found to be accurate, might be of great value as a diagnostic tool. The aim of this study was to evaluate the accuracy of clinical examination and its contribution towards the diagnosis of a palpable breast lump. The study was record based and conducted at a University Medical College Hospital and a tertiary referral centre of South India. Patient files of those women who presented with a breast lump between January to December 2011 were studied. A total of 120 patients were obtained following necessary exclusions. The accuracy of clinical assessment at an outpatient facility was determined by comparing the physician's diagnosis with the final histopathological diagnosis. The inter-observer agreement (kappa) for diagnosing a breast lump was 81 % (95 % Confidence Interval=71 % to 92 %) indicating a good agreement between clinical and pathological diagnoses. McNemar test also indicated a high degree of concordance between the two diagnoses (4.17 % discordance). Sensitivity, specificity, positive and negative predictive values of clinical breast examination in comparison to histopathology were 95, 88, 87, and 95 % respectively, with an overall accuracy of 90.8 %. 11 lumps were wrongly diagnosed at the time of clinical examination. Clinical examination of breast lumps was found to have a high sensitivity (94.5 %) and specificity (87.7 %) and can be used as the diagnostic tool to identify the nature of the lump, however, its value in diagnosing breast malignancy remains contributory due to the possibility that malignant lumps

could be overlooked and present as advanced cancer at a later stage. Histopathology is recommended in all cases unless clinical examination is supported with strong evidence of benignity based on repeated breast imaging via ultrasound or mammogram (>35 yrs).

**Keywords** Breast cancer · Clinical examination · Biopsy · Surgery

## Introduction

Breast cancer is the second most common cancer (10.4 % of all cancer incidence, both sexes counted) and the fifth most common cause of cancer death in the world [1]. In 2005, breast cancer caused 502,000 deaths worldwide (7 % of cancer deaths; almost 1 % of all deaths) [2]. One-fourth of women suffer from breast disease in their life time [1, 2]. With the improvement in health care and increasing life expectancy, more and more women are being exposed to the risk of developing breast cancer. Majority of women who come to the surgical OPD complain of either pain or lump in the breast or discharge from the nipple [3].

There are various modalities for the diagnosis of a breast lump such as mammography, ultrasonography, fine needle aspiration cytology (FNAC) but none of them are without impunity [4]. Clinical evaluation, however, is a simple method to detect cases as it is inexpensive and non-invasive and if found to be accurate, might be of great value [5]. Timely and accurate diagnosis of a breast lump with early intervention can bring down morbidity and mortality of malignant disease. Clinical evaluation could function as a valuable diagnostic tool. This would prove to be highly useful particularly in rural areas where funds and/or facilities may not be available for more sophisticated diagnostic

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methods [6]. The systematic use of the clinical examination criteria and the organizational platform would allow the clinicians to select malignant cases and plan inpatient/outpatient surgical treatment so as to avoid unnecessary admissions which will reduce hospital bed occupancy and expenditures incurred on the part of the patient.

Breast lump is a very sensitive issue for the patient so a reliable, non-invasive and prompt diagnosis helps to lessen the associated anxiety and leads to early definitive treatment.

## Review of Literature

Early work by Magarey CJ et al. [7] was concerned with the development of a management plan for the outpatient diagnosis of breast symptoms and they concluded that in the majority of patients the presence or absence of malignancy can be established with a high degree of certainty before biopsy. Several groups of researchers have evaluated the diagnostic efficacy of what is known as the triple test score, or the clinical-radiologic-cytological triad [8–12]. Majority of them advocate this system of diagnosis and suggest that it should be followed by definitive treatment, based on the high accuracy values obtained by the studies. However, Crone P et al. [9] found that while the diagnostic sensitivity of clinical examination was high, around 98 %, the specificity was rather low, averaging 48 %. In addition, the study disclosed a statistical possibility of overlooking a few malignant tumors when using these three procedures and they recommended excision of all palpable breast lumps.

Reeves MJ et al. [13] developed a clinical decision rule for triage of women with palpable breast masses into open biopsy or follow-up and concluded that it reduced the number of open biopsies performed. There is an overall consensus that clinical breast examination (CBE) is useful in screening as well as in evaluation of a lump. About 3 % to 45 % of cancer diagnoses missed by mammography were reported as having been detected by CBE. Although the sensitivity of mammography is greater than that of CBE, there is a residual diagnostic value of CBE that favors its continued use in screening [14].

## Patients and Methods

The study design was record based. The records of women who presented with a breast lump or referred for breast examination to this University Medical College Hospital and a tertiary referral centre of South India, during the time period January to December 2011 were studied. Structured performas were filled based on the information obtained from the individual patient files. Out of a total of 207

women who presented to our outpatient department with a breast lump, 87 exclusions were made when the diagnosis was known prior to examination (For example, if they were diagnosed elsewhere and had come for a second opinion), when patients who were admitted for treatment or follow-up and if the clinical impression following examination was not documented, or where pathological confirmation of the diagnosis was absent. Information was obtained regarding the clinical impression and differential diagnosis as recorded by the physician at the time of examination, following which histopathology lab reports of those were patients were accessed to obtain the final/confirmatory diagnosis.

Collected data were analyzed using SPSS 16.0. The sensitivity, specificity, positive predictive value, negative predictive values were calculated. An inter-observer reliability analysis using the Kappa statistic was performed to determine consistency between clinical and pathological findings. McNemar test was performed to test the degree of discordance between the findings. Sensitivity, specificity, predictive values and accuracy were calculated by using standard formulae on the 2×2 table.

## Results

A total of 120 patients fulfilled the inclusion criteria of whom clinically, 60 (50 %) were benign and 60 (50 %) were suspicious for malignancy. Of the 23 patients that underwent mammography, 9 (39 %) were benign and 14 (61 %) were suspicious for malignancy. Histopathology revealed 65 (54.2 %) to be benign and 55 (45.8 %) to be malignant. Clinical examination was found to have a sensitivity of 94.5 %, i.e., 52 out of 55 malignant lumps were detected clinically, and a specificity of 87.7 %, i.e., 57 out of 65 benign lumps were clinically diagnosed to be benign. The predictive value of a positive was 86.7 %, the predictive value of a negative test was 95 % (Table 1). 109 out of 120 lumps were diagnosed correctly (overall accuracy of 90.8 %). The inter-observer agreement (Kappa) was 0.817

**Table 1** Accuracy of clinical diagnosis (when compared to histopathological diagnosis)

Histopathology → Clinical impression	Malignant	Benign	Total
Malignant	52	8	60
Benign	3	57	60
Total	55	65	120

a) Sensitivity= $52/55 \times 100 = 94.5\%$  b) Specificity= $57/65 \times 100 = 87.7\%$   
c) Positive predictive value= $52/60 \times 100 = 86.7\%$  d) Negative predictive value= $57/60 \times 100 = 95\%$

e) Accuracy= $52 + 57/120 = 90.8\%$

(81 %) with  $p < 0.001$ , 95 % confidence interval (71 %, 92 %) indicating a strong agreement existed between the clinical examination and histopathological impressions. McNemar test: The difference between clinical diagnosis and histopathological diagnosis was 4.17 % with 95 % confidence interval from -2.01 % to 8.06 %, ( $P = 0.226$ , not statistically significant).

## Discussion

In our study, retrospective analysis of clinical examination of 120 patients and confirmation of the results with the histopathological findings showed CBE to have a high sensitivity and specificity. However, despite an overall accuracy of 90.8 %, in 11 patients, the nature of the breast lump was not detected clinically. 3 patients with malignant breast lumps were clinically diagnosed to be benign and 8 women with benign lumps were diagnosed clinically to have breast cancer.

Peak incidence of malignancy was seen in the 41–50 age group. The mean age of diagnosis of a benign lump was 34.8 years and of a malignant lump was 47.7 years. 14 of the malignant lumps were in women under 40, and 18 of the benign lumps were in women over 40, therefore age cannot be used as a reliable indicator of the nature of the lump (Table 2).

The most common location of any breast lump was the upper outer quadrant (29.2 %). 11 % of malignant lumps were soft in consistency while 8 % of benign lumps were hard in consistency. Majority of the lumps examined were mobile (82.5 %). Of the malignant lumps, 65.5 % were mobile and 34.5 % were fixed to the chest wall. 27.5 % of the lumps had an ill-defined margin, out of which 84.8 % were found to be malignant (Table 3). Thus, while these factors are contributory to the clinical diagnosis, they are imprecise and cannot alone decide the nature of the breast lump.

The sensitivity, specificity, positive predictive value and negative predictive values obtained on comparison of clinical examination with mammogram were 100 %, 77.8 %, 87.5 % and 100 % respectively. Out of 15 malignant patients

**Table 3** Chart indicating the characteristics of the breast lumps examined

Examination finding	Benign (65)	Malignant (55)	Total (120)
<b>Location</b>			
-Upper Outer Quadrant	19	16	35 (29.2 %)
-Upper Inner Quadrant	13	11	24 (20.0 %)
-Lower Outer Quadrant	14	8	22 (18.3 %)
-Lower Inner Quadrant	7	13	20 (16.7 %)
-Central	12	7	19 (15.8 %)
<b>Consistency</b>			
-Soft	40	6	46 (38.3 %)
-Firm	20	16	36 (30.0 %)
-Hard	5	33	38 (31.7 %)
<b>Mobility</b>			
-Mobile	63	36	99 (82.5 %)
-Fixed	2	19	21 (17.5 %)
<b>Margins</b>			
-Regular	60	27	87 (72.5 %)
-Irregular	5	28	33 (27.5 %)

that had undergone both mammogram and confirmatory histopathology, clinical examination detected a case of malignancy that was missed by mammogram. Clinical examination, used in conjunction with mammogram may be used for early screening since they would have an additive value. The quality of clinical breast examination needs to be increased by standardizing examination procedures. Careful, systematic palpation has been shown to increase detection of breast lumps. Patient position, palpation of breast boundaries, and examination pattern and technique are important variables in CBE [14].

9 % of lumps were misdiagnosed clinically. Considering the prevalence of breast cancer, in a large population that would amount to too many missed cases that could have been avoided by use of improved diagnostic techniques that are available, such as mammogram, ultrasound, FNAC and biopsy.

## Conclusion

While we found the sensitivity and specificity of clinical examination to be high, with an overall accuracy of 90.8 %, it cannot be used as a stand-alone diagnostic tool when tools with higher diagnostic value are at our disposal. It is, however, a reasonable assessment tool to determine how to proceed from the point of presentation. If the clinical examination of the breast lump points towards malignancy, a biopsy must be arranged. In case of a clinically benign lump, an ultrasound and a mammogram (in women above 35 years) must be arranged. If the breast

**Table 2** Chart indicating the characteristics of the study population

Age	Number of lumps	Benign	Malignant
<20	10	9	1
21–30	23	22	1
31–40	28	16	12
41–50	40	15	25
51–60	11	3	8
61–70	4	0	4
71–80	4	0	4

imaging suggests benign nature - cyst or clear cut fibroadenoma with BIRADS 2 lesion, a biopsy may be avoided and patient called for six monthly follow up by repeat breast imaging. In case of BIRADS 3, 4 or 5 lesions a biopsy is mandatory.

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