The Professional Medical Journal
www.theprofesional.com

ORIGINAL PROF-2577

CLINICAL BREAST EXAMINATION;
THE DIAGNOSTIC ACCURACY IN PALPABLE BREAST LUMPS

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Article received on:
05/07/2014
Accepted for publication:
30/08/2014
Received after proof reading:
15/12/2014

ABSTRACT… Objective: To determine sensitivity and specificity of standardized clinical breast examination (CBE) for benign and malignant breast lumps. **Design:** A prospective validation study. **Place & duration of study:** The study was conducted at Railway hospital, Rawalpindi from September 2008 to February 2010. **Patients & Methods:** A total of 110 female patients presenting with breast lumps were recruited in the study. All of them underwent a standardized clinical breast examination along with complete triple assessment. The sensitivity and specificity of CBE was calculated and compared with that of triple assessment in the same patient. Likelihood ratios for individual characteristics of breast lumps were also calculated. **Results:** Sensitivity of a structured CBE to pick up carcinoma breast in a patient with lump breast was 100% (95% CI, 0.8-1) while specificity was 94.6% (95% CI, 0.86-0.97). The likelihood ratio for carcinoma breast was 17.8 (95% CI, 7.6 - 41.7). **Conclusions:** The standardized CBE can differentiate between palpable benign and malignant lumps reliably. This is especially important in benign lumps where a policy of follow up clinical examination can be utilized, particularly when the investigative facilities may not be readily available.

Key words: Clinical breast examination, breast lump, benign breast lumps, carcinoma breast screening.

Article Citation: Zafar A. Clinical breast examination; the diagnostic accuracy in palpable breast lumps. Professional Med J 2014; 21(6):1147-1152.

INTRODUCTION

Clinical breast examination (CBE) is one of the components of the triple assessment performed on the patient's first encounter with a health professional for evaluation of breast lumps[1,2]. The utility of CBE has been questioned in literature recently because of the better diagnostic yield of the other investigative tools available especially in context of breast cancer screening. This has led to a decrease in utilization of the CBE[3,4]. CBE has been termed inaccurate, and has been shown to have low sensitivity and specificity to detect breast cancer in many studies[5,6]. US Preventive Task Force recommendations went as far as to recommend against the clinical breast examination in women 40 years and older and in teaching patients self-breast examination[7]. Other objections on CBE are inadequate data to assign any significant benefit, lack of standardization, lack of physicians' confidence in their CBE skills and its lower specificity than that of mammography[8,9].

There are other facts however which emphasize the importance of performing a CBE in all patients both for screening purpose and making a diagnosis. CBE alone can detect 3% to 45% of breast cancer missed by screening mammography[1,6,10,11]. As many as 22% of women eventually diagnosed with a palpable breast cancer can have a normal (false negative) mammogram[12]. Moreover having a normal mammogram can impact on the time of having a biopsy of a palpable lesion causing delays in diagnosis by the false sense of security that it confers both on the patient and the physician[4,13]. A significant number of women present with palpable breast cancer within 1 year of a normal mammogram out of which many have an aggressive cancer[14,15]. In a study most women survivors of carcinoma breast (57%) reported a detection method other than mammographic examination.[16] A large percentage of breast cancers was detected by the patients themselves either by self-examination (25%) or by accident (18%)[16].

In poor countries like Pakistan where access to investigations like mammogram and even a breast ultrasound and fine needle aspiration

cytology (FNAC) are out of reach of a large number of patients, clinical breast examination is the only tool that is readily available to a primary care physician or surgeon to determine whether the lump needs further evaluation or not[8,9,17,18]. Therefore its importance in our setup cannot be ignored. It has also been contemplated that in countries where breast cancer is diagnosed at an advanced stage (like Pakistan), screening by CBE with the teaching of breast self examination as an integral component will probably be effective in reducing breast cancer mortality[18,19].

In clinical practice breast lumps are very common, most of them being benign[1,20,21,22]. It is therefore, important to see CBE in this context also so that further investigations should be directed for those patients only who really need further evaluation rather than submitting every patient to scan and biopsy[18].

The above facts mandate that clinical breast examination should be evaluated formally for its capability to detect and diagnose a breast lump. Unfortunately there are no studies available which directly assess the accuracy of the diagnostic capability of CBE for breast lumps prospectively[18,23].

This study was therefore conducted to see the sensitivity and specificity of a standardized and structured clinical breast examination to diagnose palpable breast lumps and that whether specificity of triple assessment combined in the same patient was any superior to the structured clinical examination done alone.

MATERIAL AND METHODS

The study was conducted at Railway hospital, Rawalpindi, Pakistan from September 2008 to February 2010. A total of 110 female patients of all age groups presenting in the surgical OPD with the complaint of a breast lump were included in the study.

The sample size was calculated to achieve a precision of 0.1 with 95% confidence level with the expected sensitivity 0.55 and specificity of 0.99. The expected prevalence was calculated as 0.88 from a previous study[20].

We defined a lump as "a cystic or solid lesion reported by a patient which was discernible on clinical examination alone or which correlated with a lesion on imaging (ultrasound or mammogram)."

A standard structured format of clinical breast examination was adopted with a single examiner performed all the examinations according to the ACS/CDC consensus report as follows[8].

The examination included inspection and palpation both in sitting and lying position. Inspection was done with patient sitting and hands both by the side of the patient and raised above head. The nipple was considered normal only if there was no retraction in both positions. Palpation covered the area between clavicle superiorly and inframammary fold inferiorly and midsternum to midaxillary line. Both axillae and supraclavicular nodes were also examined.

The sinister signs (table-I) were especially looked for in each lump. If any one of these features was present the lump was labeled as suspicious for malignancy. Rest of the lumps was categorized as benign.

All of the lumps underwent a triple assessment that included along with the CBE an ultrasound or a mammogram and a FNAC for confirmation of the clinical diagnosis made. The triple test score (TTS) of 4 or less was taken as benign and 6 or more as malignant[2]. In the suspicious range an excision/tru-cut biopsy was performed to confirm the diagnosis.

Sensitivity and specificity rates for the CBE were determined from the standard formulae, as follows: sensitivity= TP/ (TP+FN), and specificity=TN/(TN+FP), where TP indicates true positive; TN, true negative; FP, false positive; and FN, false negative[24]. The criterion standard was the pathologic result of the lumps on FNAC or biopsy.

The sensitivity and specificity of triple test assessment (TTA) was also calculated.

Likelihood ratios (LR +ve) were calculated for individual characteristics of the lumps on clinical examination.

RESULTS

The ages of the patients ranged from 13 to 70 years with a mean of 30.55. Out of 110, 21 patients (19.1%) had lumps diagnosed as carcinoma breast while rest of them (80.9%) was benign. In the benign category the most frequent diagnosis was fibroadenoma (45.5%) followed by prominent nodularity of breast (12.7%), fibrocystic disease (10.9%) and acute/chronic mastitis (6.4%).

The age range for malignancy was from 30 – 70 years with a mean of 50 years (SD ± 11.09). The age range for benign lumps was 13 - 60 years with a mean of 25.97 (SD ± 10.5).

The sizes of malignant breast lumps ranged from 1.2 cm to 11 cm with a mean size of 6.5 cm (SD ± 2.5) and those of benign breast lumps ranged from 1-10 cm with a mean of 3 cm (SD ± 1.9).

Sensitivity of CBE to pick up carcinoma breast in these patients was 100% (95% CI, 0.8-1) while specificitywas 94.6% (95% CI, 0.86-0.97). The likelihood ratio for carcinoma breast was 17.8 (95% CI, 7.6 - 41.7).

Sensitivity of TTA to pick up carcinoma breast was 95% (95% CI, 0.74-0.99) while specificity was 100% (95% CI, 0.9-1).

The likelihood ratios for individual characteristics of a malignant breast lump are shown in table II.

SINISTER SIGNS
Firm to hard or hard consistency
Irregularity
Skin dimple overlying lump or any other evidence of skin tethering or fixation on skin pinching
Nipple defacement/ retraction
Peau'd orange
Chest wall fixation
Axillary lymph node enlargement
Size ≥ 2 cm

Table-I. Sinister Signs

FINDING	Sensitivity, %	Specificity, %	PPV*	NPV†	LR‡ +ve	LR -ve
Irregularity	81	72	0.404	0.941	2.88	0.26
Hard consistency	61	100	1	0.91	Infinity	0.38
Firm to hard consistency(rubbery)	28	95	0.6	0.85	6.36	0.74
Size ≥ 2 cm	95	21	0.22	0.95	1.2	0.22
Skin tethering	66	93	0.7	0.92	9.88	0.35
Peu'd orange	42	100	1	0.88	Infinity	0.57
Nipple defacement/ retraction	38	97	0.8	0.87	16.95	0.63
Chest wall fixation	57	100	1	0.91	Infinity	0.42

Table-II. Likelihood ratios of individual characteristics of lumps in carcinoma breast

**PPV= positive predictive value †NPV= negative predictive value*
‡LR= likelihood ratio: LR is the probability that persons with a disease have a particular finding divided by the probability that persons without the disease have it. LR +ve indicates likelihood ratio of a positive finding while LR –ve indicates likelihood ratio of a negative finding.

DISCUSSION

The sensitivity and specificity of structured CBE for lump breasts shown in our results was much higher than that calculated for CBE in breast cancer screening[25]. Sensitivity of CBE for carcinoma breast is estimated to be 54% (95% CI, 48%-60%) and specificity ranged from 86-99% in different studies done in population being screened for carcinoma breast[6]. Reason for the low sensitivity of CBE in those studies is the high case picking capacity of mammography in a stage when lumps are still not palpable[26]. The high sensitivity of CBE in our study conveys the ability of structured CBE to diagnose a lump even when it is small. In other words if physical examination does not reveal any sinister sign of malignancy in a lump there is nearly 100 percent chance that it is benign. This is in contrast to the study by Barton and colleagues[6] that indicated that a positive finding on examination conveys more information about an increased chance of cancer than does the finding of benign examination offer certainty about the absence of breast cancer.

Another reason for high sensitivity in our study is probably using a checklist of sinister signs that a malignant lump may show and giving importance to even a single positive finding thereby reducing the threshold for further investigations.

As a matter of fact, the sensitivity and specificity of clinical breast examination has mostly been defined in context of screening for breast cancer[25]. Conclusions drawn from performance of CBE in breast screening on normal population cannot be compared with its performance in patients with palpable lumps. Both situations are two distinct entities with different implications of results and must be treated separately.

Studies assessing CBE as part of triple assessment have shown variable sensitivity and specificity. Two studies showed a lower sensitivity and specificity (the sensitivity 87% and specificity 80%) than our study[2,23] while another study showed a concordance of 97.3%, PPV of 80%, NPV 99.3%, sensitivity of 92.3% and specificity of 97.8%[27]. None of these studies provide any information on how the CBE was performed and what made the basis of diagnosis of lump as benign or malignant on clinical examination.

Many textbooks on physical examination leading to clinical diagnosis give directions for carrying out a breast examination. They all involve inspection and palpation, but research has stressed on palpation only declaring importance of inspection as unproved[6]. However we found that certain indicators of malignancy can only be picked on inspection like slight nipple defacement and subtle skin dimpling. Therefore we stress that inspection is a definite part of CBE and without it the CBE should be considered incomplete.

In our study even lumps less than 2 cm had other features of malignancy like hard and irregular (See table II). This is in contrast to other studies where likelihood ratios for the presence of signs of malignancy (mass, fixed, hard, irregular, >2 cm lump) have been shown to be unimpressive except for fixed lesions and lumps greater than 2 cms[6].

Another significant finding in our patients was a firm to hard consistency of malignant lumps (LR: 6.36 (95% CI: 1.96 – 20.53). Generally only “hard in consistency” is considered a sign of malignancy (LR +ve: infinity).While we found that a lump that had a consistency of even firm to hard is worth investigating since not all carcinomas are hard.

One of the objections on CBE is lack of its objectivity[6,28]. However this objection can be rectified by making CBE structured and standardized. Our results, as in other studies, stress on standardization of the CBE and training of healthcare professionals on standardized material so as to yield maximum information from CBE[6,8,9,29].

Although there are reports published of breast cancer mimicking fibroadenomas[30] but this case series of 5 patients includes image detected breast lesions and it is not mentioned whether clinical breast examination of these patients was normal or not. We did not encounter any patient whose

lump was clinically benign and triple assessment showed it to be otherwise.

Triple test score (TTS) has been proven as the most accurate in evaluation of breast lumps[2,31]. Our study had a comparable result of TTS with CBE with a bit lower sensitivity for carcinoma breast.

The negative predictive value (NPV) of CBE in our study is also 100% therefore it seems reasonable to follow up benign lumps on clinical examination. Other studies also suggest follow-up ultrasound to be an acceptable alternative to biopsy for solid masses with benign morphologic features due to extremely high negative predictive value (99.8%)[24,32,33,34]. Theses lesions are estimated to have a very low probability (<2%) of being malignant, so short-term follow-up is proposed as management strategy[32].

The main problem in CBE's utility as a diagnostic tool is its lack of standardization because there is variation in its performance and reporting by different examiners[8]. Recommendations that have been made regarding standardization of CBE to enhance its sensitivity include following a particular sequence of examination and spending at least 5 minutes on examination emphasizing that a structured evaluation can maximize cancer detection and minimize unnecessary investigations and procedures[1,10,16,22,33]. However, we in our study concentrated on certain clinical findings (sinister signs) as basis of standardization (structured CBE). Our data suggests that no matter what sequence of examination is chosen if certain features are focused and found to be absent, the diagnosis of clinically benign swellings can be made quite confidently. This has also been termed as "focusing attention" during CBE in literature and has been stressed to be more important than any special CBE choreography[35].

CONCLUSIONS

The standardized CBE can differentiate between palpable benign and malignant lumps reliably. This is especially important in benign lumps where a policy of follow up clinical examination can be utilized, particularly when the investigative facilities may not be readily available.

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