Validation of Different Techniques in Physical Examination of Breast

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Abstract The majority of patients attending breast clinics are found to be suffering from benign conditions. The detailed investigations of every patient would add to the cost of care and burden the laboratories. A detailed clinical evaluation might limit the use of thorough investigations for suspicious lesions only. This cross sectional study involved the patients with various benign and malignant conditions of breast, who attended outpatient clinic and surgical ward at All India Institute of Medical Sciences, New Delhi from June 2009 to May 2011. The study started with a training of the resident (observer 2) in various breast examination techniques by a professor of surgery (observer 1), who was well trained in the discipline of breast surgery by internationally renowned breast experts. The different techniques of breast examination were validated after calculation of intra and inter-observer variation. Excellent agreement was observed between both the observers. The diagnostic accuracy ratio for most variables ranges from 0.9 to 1. The dimpling of skin on inspection had a low kappa (coefficient of agreement=0.48) and consistency of lymph node on palpation had a kappa 0.38. All other variables showed high agreement. The present study was successful in training the resident and validating the different techniques in physical examination of breast.

Keywords Breast · Validation · Clinical breast examination · Diagnostic indices · Resident training

Introduction

The population burden of diseases of the breast is on the rise. The increase in prevalence involves both benign and malignant afflictions of the breast. The objective of detailed clinical evaluation is to separate benign conditions, which necessitate only reassurance from suspected malignancy, which requires thorough investigation to rule out malignancy. Since ratio of benign to malignant is about 9:1 in most breast clinics, detailed investigations of all women presenting to physicians would not only be unnecessary but would also add to the cost of care and burden the laboratories. Since breast cancer is rapidly increasing in our community, our doctors and other health professionals have to be trained in the technique of physical examination of breast.

The technique of training on breast examination should incorporate only those methods which have been validated and which have high diagnostic accuracy, high sensitivity, and high positive predictive value. The primary objective of this study was to evaluate the sensitivity, specificity, positive and negative predictive value, positive and negative likelihood ratio, overall diagnostic accuracy, and diagnostic odds ratio for the various components employed in physical evaluation of breast diseases.

Patients and Methods

The study was carried out at outpatient clinic and surgical ward of Department of Surgery, All India Institute of Medical Sciences, New Delhi, from June 2009 to May 2011.

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Patients visiting outpatient's clinic with various benign and malignant conditions were included in the study after an informed written consent. It was a cross sectional study with sample size of 100 patients. The study was approved by Institute ethics committee.

Inspection was carried out in sitting positions with arms at side, arms raised over the head, pressing on the hips and leaning forward. Breast was inspected for any change in size, shape, and symmetry. Nipple was inspected for inversion, discharge, ulcer or erosion, and retraction. Skin was inspected for dilated subcutaneous veins, redness, edema and ulcer, and scar marks (Fig. 1a, b).

Palpation was carried out in the supine position with “Dial of clock” method. In dial of clock method, palpation was performed in segmental manner until entire breast was examined with “pads of middle three fingers” (index, middle, and ring) with hand held in slightly bowed position (Fig. 1c, d). In this method, the whole breast was palpated as if it was “dial of a clock”, 12 o'clock being the highest point at upper edge of breast just below the mid-clavicular point and 6 o'clock being at the infra-mammary crease. The palpation was begun at 12 o'clock from periphery to the nipple by describing small circles of about 3 cm in diameter. The breast was palpated by making circular movements of the “pad of fingers”, three

times with increasing pressure and without lifting the fingers. The next circle was palpated towards the nipple, overlapping with the previous circle to about half in diameter (Fig. 1d). Once the areola and nipple area was reached, the next segment/sector was palpated at 1 o'clock. The inner half of mammary gland was palpated in supine position. The lady was requested to roll over the opposite side for palpation of outer half of mammary gland. This rolling over, allows the mammary tissue to fall towards the midline by gravity resulting in flattening of lateral half of mammary gland. This in turn makes a lump in lateral half more discernible.

The lump size was measured using Vernier calipers (Fig. 1g). The palpation of mammary ducts was carried out by gently rolling the ducts between the index finger and the thumb (Fig. 1e). Any thickening, tenderness, or discharge was noted while palpating the mammary ducts. In case of retraction of the nipple, an attempt was made to pull the nipple forward to see if the nipple could be brought forward or not. Presence of any lump underneath the areola and its adherence to nipple/ areola, was noted. The skin overlying the lump was gently pinched and moved with the fingers to assess its fixity to the lump. If the skin was free from the lump but the movement of lump away from skin caused dimpling of skin, the skin was considered “tethered” (Fig. 1j, k). If no movement of

Fig. 1 **a** Inspection—raising arms over the head. **b** Inspection—visible bulge and dilated subcutaneous vein. **c** Palpation—pads of middle three fingers while keeping the hand in slightly bowed position for palpation of lump. **d** Palpation of breast lump following “dial of clock” method. **e** Method for palpation of mammary ducts. **f** Maneuver to check fixity of lump to underlying pectoralis major muscle. **g** Measurement of breast lump with vernier caliper. **h** Palpation of axillary lymph nodes. **i** The “mirror image method” of axillary palpation showing use of left hand for left axilla and right hand for right axilla. **j** Mobility of breast lump without moving the overlying skin when movement of lump is within the arc. **k** Indentation of overlying skin on pulling the lump outside the arc suggests tethering due to shortened Cooper's ligament. **l** No movement of lump without moving the overlying skin suggests fixity to skin

skin was possible, it was considered “fixed” (Fig. 11). The fixity of lump to underlying pectoralis major muscle was ascertained by requesting the lady to push against the hip to contract the muscle and then moving the lump at right angles to long axis of pectoralis muscle fibers (Fig. 1f).

For axillary nodes palpation, pectoralis muscle was relaxed by supporting patient’s forearm with examiner’s own forearm, while facing the patient (Fig. 1h). The medial, central, pectoral, and lateral axillary nodes were palpated from in front while supra-clavicular, infra-clavicular, and posterior axillary nodes were palpated in sitting position with examiner standing behind the patient. The “mirror image method” of palpation was utilized while examiner standing behind the patient and using left hand for palpating left axilla and right hand for right axilla as described by Prof LE Hughes of Cardiff U.K. (Fig. 1i) [1]. The techniques used for performing breast and axilla examination in the present study may be visualized in a video (aiimsbreastcourse.in/video-gallery).

Training Phase and Validation Phase Study started with training of the resident henceforth called observer 2 by a professor of surgery (Anurag Srivastava), observer 1, who was well trained in the discipline of breast surgery by internationally renowned breast experts (at Cardiff Breast unit, University Hospital of Wales, UK with Prof LE Hughes, Prof RE Mansel, and DJT Webster). Both observer 1 and observer 2 examined the patients independently. The intra-observer variation for observer 2 and inter-observer variation between observer 1 and observer 2 were calculated.

After training of observer 2, the validation phase was started. The details of the patient were recorded on structured Proforma by both the observers separately. In patients being managed conservatively for benign conditions, and those receiving neoadjuvant chemotherapy, the findings of clinical examination were compared with ultrasonographic and mammographic findings. In patients undergoing operation without neoadjuvant chemotherapy, findings of clinical examination were compared with intra-operative findings. For the size of lump assessment, intra-operative findings were taken as gold standard for those being operated soon after clinical examination. For those patients being treated by neoadjuvant chemotherapy or conservative treatment of benign conditions, ultrasound-measured size was considered gold standard.

Results

A total of 100 women presenting with various benign and malignant conditions of breast were studied. Their mean age was 40.5 years with a standard deviation of 14.6 years. Sixty percent patients complained of pain. Eighty one percent of patients presented with complaint of lump in breast. The most common site of lump was left upper outer quadrant (26.88 %),

followed by right upper outer quadrant (21.51 %), and least common site was left lower inner quadrant (2.15 %). The prevalence of nipple abnormalities was as follows: nipple retraction in 3 %, nipple discharge in 6 %, and nipple erosion/ulcer in 2 %.

Inspection On inspection, there was perfect agreement between both observers for nipple retraction, nipple erosion, and asymmetry of nipple areola complex (NAC) whereas agreement was almost perfect for asymmetry of breast, any visible lump, skin discoloration, and skin edema (Table 1). When observer 1 was considered as gold standard and various diagnostic tests were applied, the value of sensitivity, specificity, positive predictive value and negative predictive value for nipple erosion, retraction, and asymmetry of NAC were 100 % (Table 2).

Palpation

Well-Defined Lump The lump was defined as well defined by both observers in 62 patients (62 %). The percent agreement was 100 % and kappa = 1; i.e., perfect agreement (Table 1). On considering observer 1 as gold standard the value for sensitivity, specificity, positive predictive value, and negative predictive values were 100 % (Table 3).

Size of Lump The Bland–Altman plot was constructed to assess the relative agreement between the two observers. In most cases, there was high agreement between observer 1 and observer 2 as most values were near the mean. There were only a few outliers (Fig. 2). Outliers were defined as those having values greater than 2 standard deviation from the mean.

Consistency of Lump The lumps were described as mostly firm (observer 1—85.71 % and observer 2—87.3 %), soft (observer 1 and 2 both—3.17 %), hard (observer 1—11.11 % and observer 2—9.52 %). The inter-observer percentage of agreement was 95.24 % and kappa 0.80, i.e., substantial agreement (Table 1).

Fixity of Lump The fixity of lump to skin, chest wall, and pectoralis major muscle and serratus anterior muscle (for lumps located in lower outer quadrant) was assessed in both sitting and supine positions. On comparing fixity of lump to skin, pectoralis major, and chest wall in sitting and supine position (in 63 patients) in a single observer (intra-observer variation), no difference was seen. So percentage agreement was 100 % and kappa = 1, i.e., perfect agreement, between findings of both supine and sitting positions. On comparing fixity of lump in sitting and supine position (in 63 patients) between observer 1 and 2 (inter-observer variation), there was 100 % agreement for fixity of lump to pectoralis major and

Table 1 Inter-observer variation between observer 1 and observer 2

	Percentage agreement	kappa	Comment on kappa
Inspection:			
Asymmetry in size	99	0.96	Almost perfect agreement
Asymmetry in shape	98	0.93	Almost perfect agreement
Any visible bulge	97	0.91	Almost perfect agreement
Skin discoloration	98	0.90	Almost perfect agreement
Dilated blood vessels	91	0.79	Substantial agreement
Skin edema	99	0.93	Almost perfect agreement
Nipple retraction	100	1	Perfect agreement
Nipple erosion	100	1	Perfect agreement
Asymmetry of nipple areola complex	100	1	Perfect agreement
Dimpling of skin	98	0.48	Moderate agreement
Satellite nodules	100	1	Perfect agreement
Breast palpation:			
Well defined lump	100	1	Perfect agreement
Consistency of lump	95.24	0.80	Substantial agreement
Fixity of lump			
Sitting position—skin	98.41	0.93	Almost perfect
Sitting position—pec major	100	1	Perfect
Sitting position—chest wall	100	1	Perfect
Supine position—skin	98.41	0.93	Almost perfect
Supine position—pec major	100	1	Perfect
Supine position—chest wall	100	1	Perfect
Axilla palpation:			
Number	99.00	0.96	Almost perfect
Consistency	77.78	0.38	Fair
Matted	100.00	1	Perfect

chest wall whereas agreement was 98.41 % for fixity of lump to skin both in sitting and supine position (Table 1).

Lymph Nodes in Axilla Observer 1 found lymph nodes in axilla on palpation in 19 patients while observer 2 found axillary

nodes in 18 patients. Among 19 patients with enlarged nodes—12 patients (63.15 %) had metastasis to lymph node and rest 7 (36.85 %) had no evidence of malignancy on histopathology. Thus, positive predictive value for malignancy for a palpable node was 63 % while false positive value was 36.85 %.

Table 2 Inspection—on considering observer 1 as gold standard

	SEN	SPE	PPV	NPV	LR+	LR–	DA	DOR
Asymmetry in size	94.44	100.00	100.00	98.80	∞	0.05	0.99	∞
Asymmetry in shape	100.00	97.59	89.47	100.00	41.49	0	0.98	∞
Any visible bulge	95.45	97.44	91.30	98.70	37.28	0.04	0.97	798
Skin discoloration	84.62	100.00	100.00	97.75	∞	0.15	0.99	∞
Dilated blood vessels	90.32	91.30	82.35	95.45	10.38	0.10	0.91	98
Skin edema	88.89	100.00	100.00	98.91	∞	0.11	0.98	∞
Nipple retraction	100.00	100.00	100.00	100.00	∞	0	1	∞
Nipple erosion	100.00	100.00	100.00	100.00	∞	0	1	∞
Asymmetry of NAC	100.00	100.00	100.00	100.00	∞	0	1	∞
Retraction of nipple	100.00	100.00	100.00	100.00	∞	0	1	∞
Dimpling of skin	50.00	98.98	50.00	98.98	49.01	0.50	0.98	97

SEN sensitivity, SPE specificity, PPV positive predictive value, NPV negative predictive value, LR + positive likelihood ratio, LR – negative likelihood ratio, DA diagnostic accuracy, DOR diagnostic odds ratio, NAC nipple areola complex, I indeterminate, ∞ infinity

Table 3 Palpation—on considering observer 1 as gold standard

	SEN	SPE	PPV	NPV	LR+	LR-	DA	DOR
Well defined lump	100.00	100.00	100.00	100.00	∞	0	1	∞
Palpation of mammary ducts (ducts thickened)	25.00	100.00	100.00	96.77	∞	0.75	0.96	∞
Palpation of mammary ducts (ducts retracted)	50.00	100.00	100.00	98.92	∞	0.50	0.98	∞
Discharge on palpation (mammary ducts)	50.00	100.00	100.00	97.83	∞	0.50	0.97	∞
Discharge on palpation (rest of breast)	I	100.00	I	100.00	I	I	1.00	I

I indeterminate, ∞ infinity

Time Taken for Clinical Breast Examination On comparison of observer 1 and observer 2 for mean time taken for inspection (24.01 and 23.6 s), bilateral breast palpation (92.77 and 97.95 s), and lymph node palpation (33.31 and 33.87 s), it was found that observer 2 took more time as compared to observer 1. It is worthy of note that this is only a mean time taken to examine the whole group of patients where some patients were suffering from mastalgia or benign nodularity without a discrete lump. In women with a lump or palpable node, we spent more time for its detailed evaluation. The mean total duration of time taken for women with lump for observer 1 was 161.77 s and for observer 2 was 165.24 s.

Diagnosis On clinical breast examination 53 patients were considered to have benign disease—all these patients had benign disease on histopathology—i.e., 100 % agreement between clinically diagnosed benign disease and investigations. On clinical breast examination, 47 patients were considered to have malignant disease—among them—11 patients had benign disease and the rest 36 patients had malignant disease. Thus, for clinical diagnosis of malignancy, there was 76.5 % agreement with histopathology.

Fig. 2 Bland–Altman plot for comparison between observer 1 and observer 2 for size of lump during palpation

Discussion

The clinical breast examination (CBE) can be used either for screening (to detect breast cancer in asymptomatic women) or diagnosis (to evaluate breast complaints, primarily to rule out cancer). It seeks to detect breast abnormalities or evaluate patient's symptoms to find palpable breast cancer at an earlier stage, when treatment is more effective and treatment options are greater than for later stage of disease. The examination techniques for clinical breast examination have been described in diagnostic textbooks [1], as well as several reviews [2–4]. Although these descriptions vary in some details of how to perform a CBE and few address how to report CBE results, all include visual inspection and palpation of breasts and lymph nodes as central components of examination. Literature is bereft of good studies on detailed evaluation of clinical breast examination. Scientific validation of individual steps of inspection and palpation of clinical breast examination has not been reported in detail.

Inspection

Very few studies [5, 6] have evaluated the independent contributions of visual inspection to the early detection of breast cancers. Some older studies indicate that visual inspection alone identifies only a small percentage of breast cancers, even in symptomatic women. In a Canadian case series published in 1982, only 4 % (11 of 286) of breast cancers were identified by visual inspection alone, i.e., 1 % by retraction (skin or nipple) and 3 % by nipple abnormality [7]. In an Australian study in 1990, 13 % (22 of 169) of breast cancers (with no palpable lump) were identified through observable symptoms that included inverted nipple, swollen arm, alteration in breast shape, ulcer, breast swelling, skin retraction, Paget's disease, and nipple discharge [8]. These are both small studies and do not describe the detailed diagnostic indices of individual physical signs.

In the present study, detailed diagnostic indices of following physical signs were evaluated by two independent observers in different positions: asymmetry in size, asymmetry in shape, any visible bulge, skin discoloration, dilated blood vessels, skin edema, skin ulcer, nipple retraction, nipple

erosion, asymmetry of nipple areola complex, retraction of nipple on arm elevation, dimpling of skin on arm elevation, and satellite nodules on visual inspection and palpation.

Statistical Assessment of Inter-observer and Intra-observer Agreement Landis and Koch [9] in 1977 characterized values of kappa <0 as indicating no agreement and 0–0.20 as slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1 as almost perfect agreement between two independent observers. In the present study, percentage of agreement between both observers for inspection was in the range of 91 to 100 %, and kappa for most components of inspection was more than 0.9, i.e., almost perfect agreement. The sensitivity, specificity, positive predictive value, and negative predictive value was 95–100 %, likelihood ratio for positive test result (LR+) for most variables >10, and likelihood ratio for negative test result (LR–) <0.1. Diagnostic accuracy ratio for most components was from 0.9 to 1 with a high diagnostic odds ratio. No other study has assessed the influence of position on clinical breast examination accuracy, as measured by sensitivity and specificity, nor any studies has evaluated the relative contributions of different arm positions to the identification of breast cancers during visual inspection, described variously as arms relaxed at sides, arms raised over head, and hands pressed at hips.

The predictive values (PPV and NPV) and to some extent the sensitivity of a test are dependent on prevalence of a disease in a study population [10]. Hence, likelihood ratio has been developed as a “prevalence independent characteristic” of a diagnostic test. A likelihood ratio for a positive test result (L.R. +) of 10 or more is considered almost diagnostic or pathognomonic for a disease. Similarly likelihood ratio for a negative test (L.R. –) of less than 0.1 is considered very strong evidence for excluding a disease if the test is negative [11].

Palpation

The most widely published and studied technique for breast palpation is the MamaCare method, developed by Pennypacker and colleagues [4, 12]. Several other studies [2, 3, 13] have also described various methods of breast palpation with flat of fingers but no study has indicated which part of fingers should be used except in MammaCare method. There is a need of standardization of various components of breast palpation, i.e., position of breast tissue, extent of area examined, type of finger motion, number of fingers, part of finger, pressure, search pattern, and duration of search. At present, no standardized system exists for performing, interpreting, and reporting the results of CBE.

In the present study, an effort has been made to validate individual steps and different techniques in palpation of breast and axillary lymph nodes by assessing the degree of agreement between both observers and also comparing the findings of both

observers with the gold standard. The percentage of agreement between both observers was in the range of 91 to 100 %, and kappa for most of the observations more than 0.9—almost perfect agreement. The sensitivity, specificity, positive predictive value, and negative predictive value were 95–100 % for most variables. The likelihood ratio L.R. + for most variables was >10 and L.R. – was <0.1. Diagnostic accuracy ratio for most components ranged from 0.9 to 1 with a high diagnostic odds ratio.

Bland–Altman’s analysis has been used to assess the relative agreement and to identify possible outliers for the measurement of lump size between both observers and also between observer and gold standard. Most data in the plot were between ± 1.96 standard deviation and very few outliers were present. Hence, there was good agreement between the size of lump measured by both observers and gold standard. No study has examined the relationship between lymph node palpation characteristics and sensitivity or specificity in finding lumps in breast [3, 13].

Time Duration

In the present study, the mean total duration of time taken for examination was 149.03 s by observer 1 and 153.96 s by observer 2. Goodson et al. [2] states that CBE is a rapid procedure that can be carried out in 2 or 3 min. In a study by Fletcher et al. [14], duration was the component most consistently shown to have a positive relationship for detection of lump. Yet, no study has provided evidence supporting an optimal palpation time frame. In our study, the mean time was 149 s, which is less than the recommended time for examining a lump. This is because in our study some patients presented with only mastalgia without a lump and in these patients less time was required to complete the palpation.

Conclusion

Excellent agreement was observed between both the observers. Diagnostic accuracy ratio for most variables varied from 0.9 to 1. The dimpling of skin on inspection had a low kappa (coefficient of agreement=0.48) and consistency of lymph node on palpation had a kappa 0.38. All other variables showed high agreement. The present study was successful in training the resident and validating the different techniques used in physical examination of breast.

Future Direction

Additional information is needed about the relationship between specific CBE components and CBE accuracy. Model systems need to be developed and validated for comparing information across different hospitals and studies. The specific components of training programs need to be standardized to increase proficiency of doctors and breast care nurses.

Limitations

Fixity of lump to skin, pectoralis muscle, and chest wall could not be assessed intraoperatively because most of these patients received neoadjuvant chemotherapy and were operated, 3 to 4 months after initial palpation.

Compliance with Ethical Standards Patients visiting outpatient's clinic with various benign and malignant conditions were included in the study after an informed written consent. The study was approved by Institute ethics committee.

Conflict of Interest The authors declare that they have no conflict of interest.

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