Research Article

"STUDY OF ACCURACY OF iBREAST EXAM AS A SCREENING MODALITY TO DETECT BREAST LUMP- EXPERIENCE OF A TERTIARY CARE CENTRE IN CENTRAL INDIA"

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ABSTRACT

Introduction: Incidence of breast cancer is rising rapidly worldwide. Early detection improves survival rate, makes treatment less costly and lowers the overall burden of disease. Currently, there is no prescreening test that improves the accuracy, safety, and cost effectiveness of screening low-risk populations.The piezoelectric finger is a radiation-free, portable, and low-cost breast tumor detector developed as a prescreening tool to identify all breast lesions and not just cancerous lesions. Study aims to evaluate accuracy of iBreast exam in early detection and diagnosis of breast lump.

Materials and methods: This study was conducted in,"Department of General Surgery, Government Medical College, Nagpur" during 2 years from June 2016-November 2018. All females above 18 years presenting to OPD with/without symptomatic breast disease were included, evaluated and results were compared with gold standard Triple test.

Results:
• Overall females screened = 19,583
• A sample of 934 , selected by systematic random sampling
• 269 were identified with breast lumps by iBreast
• 227 were confirmed of breast lumps by clinical examination
• The sensitivity= 87.98% and specificity= 93.79%.

Conclusion: Considering sensitivity and specificity, ibreast examination was found to be highly specific to detect breast lump, specifically in younger women with dense breast.

INTRODUCTION

Breast cancer is the most common female cancer worldwide representing nearly a quarter of all cancers, with an estimated incidence of 25.9 per 100,000 women and mortality of 11.6 per 100,000 women in south Asia[1]. India is facing challenging situation due to increase in incidence and mortality. The main reasons for this observed hike in mortality is due to lack of inadequate breast cancer screening, diagnosis of disease at advanced stage and unavailability of appropriate medical facilities.

These days a combination of three tests, i.e. Clinical examination, Radiological imaging (ultrasonography / mammography) and pathological test (Fine Needle Aspiration Cytology) – 'Triple Test' is used as gold standard in diagnosing all the palpable breast lump. Mammography is the most common modality used for screening breast cancer[2], but rarely used because of its high cost. In a developing country like India, where 70% population lives in rural areas, females do not have access for screening of breast cancer. Apart from high cost[3], mammography has its hazards of radiation and does not identify the lesion correctly in young females due to dense fibrous breast tissue[3]. Whereas FNAC is a minimally invasive procedure.

Currently, there is no prescreening test that can improve the accuracy, safety and cost-effectiveness of screening low-risk population. The piezoelectric finger (PEF) – iBreastExam is a radiation-free, portable and low-cost breast tumor detector, developed to be used as a pre-screening tool to detect early breast cancer.[4]

The objective of our study was to determine the efficacy of iBreast Exam as a screening modality in terms of sensitivity, specificity, positive predictive value and negative predictive value, when compared with clinical breast examination; and to study the clinical profile of breast lump/nodule[5].

MATERIALS AND METHODS

This was a Hospital based prospective observational study conducted at Department of General Surgery, GMCH Nagpur, over a period of two years from June 2016 to November 2018. A total of 22,100 females were registered, and 19,583 were screened free of cost. The Ethical committee of the institute approved the study and an informed written consent was obtained from all the females.

Inclusion Criteria

All the females of age 18 years and above attending iBreast Clinic at our hospital for screening with or without

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symptomatic breast disease.

Exclusion Criteria

1. Ulcerated and fungating breast growth were excluded.
2. Females already diagnosed somewhere else or received neoadjuvant chemotherapy and came to surgery OPD
3. Inflammatory lesions and abscess
4. Females not giving consent or not willing for iBreastExam screening.
5. Females less than 18 years of age.

All the females attending our hospital premises including the female relatives along with them were screened foriBreast Examination in OPD routinely followed by Clinical examination. Those females who were found breast nodule on iBreast Exam, meaning a lesion was detected, were further evaluated in SOPD with Triple test (clinical examination + sonomammography + FNAC/ biopsy) and was managed accordingly as per FNAC and Tru-cut biopsy reports. Females with negative iBreast and found normal on clinical palpation were assured of and counseled regarding Breast Self Examination and follow up sos in SOPD and iBreast clinic. All the females were advised regarding iBreast screening for relatives and neighbours for social awareness to detect breast cancer at early stage.

Device

Figure 1 iBreast Device

Figure 2 parts of iBreast

The iBreastExam or iBE (Fig 1 & 2) consists of a hand- held compression probe containing a 4×4 array of piezoelectric tactile pressure sensors, a custom built electronic board and a tablet. The iBE communicates wirelessly with a mobile device to display and store the findings in real time. Compression data are recorded as a unique file at the end of every scan to the mobile device which is synced to an encrypted database via Dropbox where a copy is saved. The iBE software does not collect or store any kind of identifiable data[6].

The iBE device was built on the principle of the piezoelectric finger (PEF) detector. PEF assess and identifies tissue elasticity differences between hard and stiff breast tumors VS normal breast tissue and measures the subtle displacements electrically, all within the sensor. The iBE evaluations were performed by the staff who was trained to use the iBE[6], [7], [8], [9], [10].

The female lies comfortably in supine position on examination table in room. The iBreast device was calibrated on the breast in an uninvolved area; it can be recalibrated according to breast quadrants. The testing was done in quadrant wise fashion. The iBE records the data and collects into 4×4 array map of the breast. This map was divided into sectors demarcated by three consecutive hours of a clock in order to directly compare to the clock positioning assigned by mammography or ultrasonography. Green indicates normal breast tissue while red indicates a lesion was detected meaning these females were advised further testing to characterize the lesion[6].As iBE is designed to be a pre-screening tool to identify all lesions and not just cancerous lesions; the positive and negative classification for this study includes the presence or absence of clinically relevant detectable lesions.

After proper clinical examination and iBreast scanning, iBreast results were confirmed in SOPD itself by consultant. Physical examination of the breast was done in a standard manner.

All the benign lesions were properly investigated and treated on medical line of treatment/ surgical treatment accordingly. The malignant nodules detected in these screened females were managed as per the NCCN guidelines. Because of screening and early detection of malignancy, some of the patients were treated by breast conservation surgery and Modified Radical Mastectomy as per histopathological report.

A random sample of 934 study subjects was selected by using systematic random sampling technique from a sampling frame of 19,583 eligible women seeking care at the study setting.Data was coded and analysed with the statistical software, STATA, version 10.1, 2011.Concordance of the screening test (I-breast) with reference test was measured using an agreement statistic "kappa (k)" along with 95% CI and corresponding P-value.
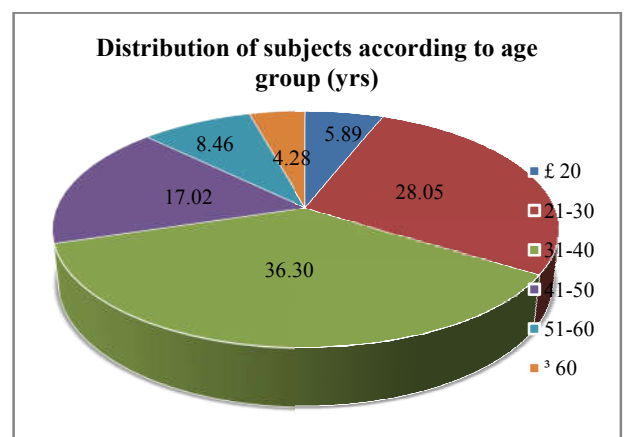
RESULTS

Figure 3 Distribution of subjects according to age group

The study consisted of 934 females who underwent screening by iBreast in department of general surgery at our college. Out of 934 females, most common age group for screening was 31-40 years (36.3%) followed by 21-30 years (28.05%) and 41-50 years (17.02%). Least common age group was more than 60 years which was 4.28%.
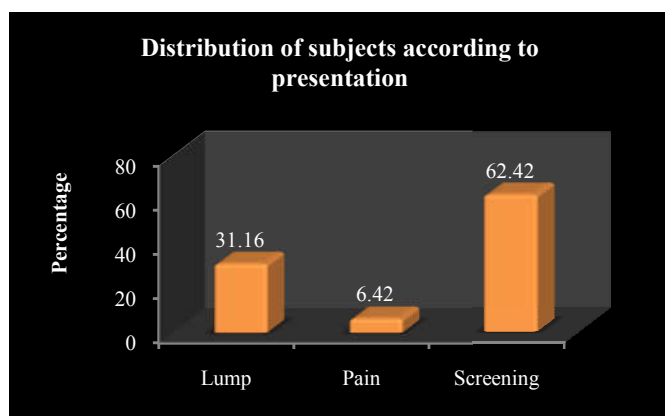
Figure 4 Distribution of subjects according to presentation

A total of 583 (62.42%) came to iBreast clinic for the sole purpose of screening without any breast complaints. 291 females (31.16%) had a feeling of lump in breast and 60 females (6.42%) came to iBreast clinic with complaints of pain in breast.

A total of 760 females (81.37%) attending iBreast clinic were premenopausal while remaining 174 females (18.63%) were postmenopausal.

Table 1 Distribution of subjects according to menstrual status

Distribution of subjects according to menstrual status		
Menstrual status	No. of subjects	Percent
Pre-menopausal	760	81.37
Post-menopausal	174	18.63
Total	934	100

Out of 934 females screened for iBreastExam, 665 females (71.2%) were found normal, meaning no lesions detected. 269 (28.8%) females were detected with some lesions on iBreastExam which were evaluated further to characterize the lesion.
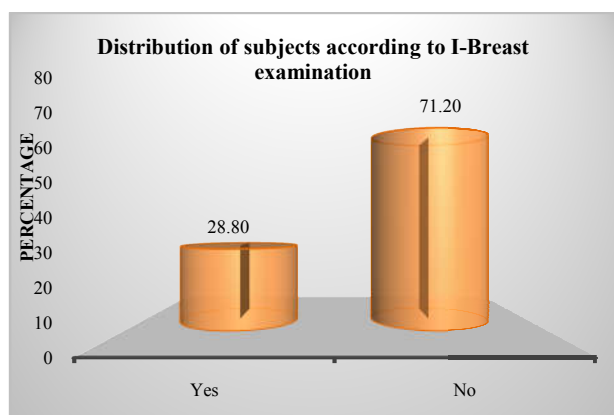

Figure 5 Distribution of subjects according to i-breast examination

Table 2 Comparison of lump detection by iBreast and clinical examination

	Clinical examination	Clinical examination	
	Lump present	Lump absent	Total
I-breast Positive	227	42	269
I-breast Negative	31	634	665
	258	676	934

The analysis of our study showed that, out of 269 females in whom the lesions were detected on iBreast, 227 females had the lump on clinical examination while in remaining 42 females, lump/nodule was not palpable.

Out of 665 females, who were normal meaning no lesion was detected over iBreast Exam, 31 females had a clinically palpable lump in their breast. And 634 females were found normal on clinical examination i.e. no lump was palpable.

Table 3 Distribution of subjects according to iBreast result

Distribution of subjects according to iBreast result		
TEST	Benign	Malignant
iBreast Positive	150	77
iBreast Negative	29	02
total	179	79

On further evaluation in the study with Triple Test, in total of 227 iBreast Exam positive females with clinically palpable lump- 150 females had benign and 77 females had malignant lesions. While out of 31 iBreast Exam negative females with clinically palpable lump, 29 females had benign lesions and 2 females had malignant lesions in their final cytology or histopathology report. In this study, the quadrant wise distribution of lumps were as follows as shown in table 5 and upper outer quadrant was seen most commonly involved in both benign and malignant lesions followed by upper inner quadrant.

Table 4: Quadrant wise distribution of breast lump

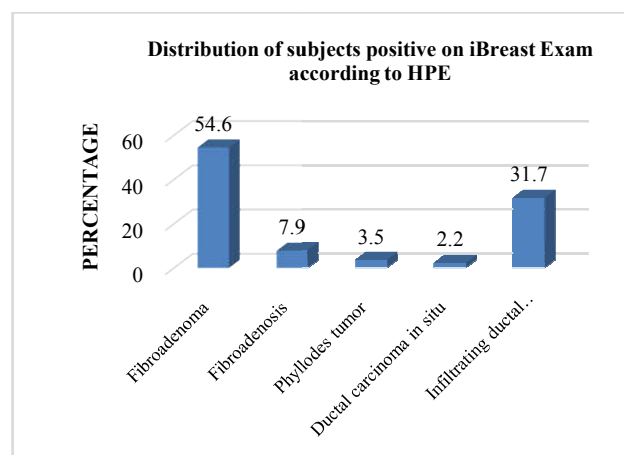| Distribution of subjects according to quadrant		
Quadrant	Benign	Malignant
Central	00	01
Lower inner	17	07
Lower outer	28	06
Upper inner	55	07
Upper outer	76	58
Whole breast	03	00
total	179	79

Figure 6 distribution of subjects according to HPE results

Present study showed that, among the lesions detected, fibroadenoma was the most common benign lesion seen followed by fibroadenosis and infiltrating ductal carcinoma was the most common malignant lesion.

Table 5: Results of iBreast screening tool

Parameter	Estimate	Lower - Upper 95% CIs	Method
Sensitivity	87.98%	(83.45, 91.4[1])	Wilson Score
Specificity	93.79%	(91.71, 95.37[1])	Wilson Score
Positive Predictive Value	84.39%	(79.57, 88.24[1])	Wilson Score
Negative Predictive Value	95.34%	(93.46, 96.7[1])	Wilson Score
Diagnostic Accuracy	92.18%	(90.28, 93.74[1])	Wilson Score

Our study the accuracy of iBreast Exam to detect breast lumps showed sensitivity of 87.98% and specificity was 93.79%. NPV was 95.34% and accuracy of the test was 92.18%.

DISCUSSION

In present study, the patients age ranged from 18 to 78 years with a mean of 36.17years. 179 females with mean age of 30.42 years had benign lesions and 79 females with mean age of 49.77 years had malignant lesions.

In study done by Broach R *et al*[6] (2016), the patients age ranged from 21 to 79 years with a mean age of 42 years. In another study by Onwuchekwa C. *et al*[11], the patients age ranged from 22 to 78 years with a mean age of 48.34 years.

Table 6 Comparison of presentation

	Onwuchekwa c *et al*[11]	present study
Lump	27.94	31.16
Pain	21.13	6.42
Screening	36.60	62.42

Onwuchekwa C. *et al*[11] studied 265 females out of which 36.6% females had come for screening and 27.94 % females came with complain of lump in breast, and 21.13% females with pain.

In our study, 62.42% females had come for screening, 31.16% females presented with lump in breast and 6.42% females with pain in breast.

Broach *et al*[6] studied 342 quadrants of the breast by iBreastExam, out of which 77.48% were negative, and 22.51% were positive, meaning the lesion is present.

In present study, 934 females were examined by iBreastExam, in which 71.19% females were negative and 28.80% were detected with positive lesions. Both study results are consistent with each other.

Singh *et al*[12] found 54.84% of the lumps in right breast and 45.16% in left breast.

Sharma R *et al*[13] also found the benign lesions more commonly involved right breast.

In present study also 50.27% of lump were present in right breast and 46.92% in left breast.

Selvakumaran et a[14]l showed that the palpable breast lump is most commonly situated in upper outer quadrant of the breast (44%), followed by lower outer, upper inner and lower inner quadrant. Sharma R *et al*[13] found that among all the quadrants involved, majority was upper outer (25%) and central quadrant/ nipple-areola complex (25%).In our study, we found 46.52% of breast lumps in upper outer quadrant.

We found that fibroadenoma was the most common lesion seen amongst benign cases in 124 cases (82.66%) and invasive ductal carcinoma was the most common malignant lesion comprising of 93.5% of all malignant lesions.

Singh *et al*[12] and Sharma R *et al*[13], both found that fibroadenoma was the most common lesion seen amongst benign cases. Ibrar Ahmed *et al* found that invasive ductal carcinoma was the most common malignant lesion (59.91%). Sharma R *et al*[13] also found that invasive ductal carcinoma to be the most malignant lesion (70%).

Table 7 Comparison of sensitivity and specificity of iBreastExam

Clinical study	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Broach RB, *et al*; Philadelphia, 2016[6]	86%	89%	70%	95%
Somashekhar SP, *et al*; Banglore,2016[15]	84%	94%	60%	98%
Geha R *et al*; Pune, 2016[16]	77%	98%	-	-
Xu X, *et al*; Philadelphia, 2013[7]	83%	88%	61%	75%
PRESENT STUDY	87.98%	93.79%	84.39%	95.34%

In present study, 227 females were correctly detected positive by iBE when compared with clinical examination (true positive); of which 150 were benign and 77 were malignant.

42 females, were diagnosed falsely positive on iBE and were negative on clinical examination, they were assured of normalcy and counseled for breast self-examination and sent home. 634 females were correctly found normal on iBE and clinical examination (true negative).31 females were found normal on iBE, which were positive on clinical examination, of which 29 had benign lesions and 2 had malignant lesions.

Out of 2, 1 was diagnosed as DCIS and Breast Conservation Surgery with Radiotherapy was given; and Another female just came for screening, further evaluated and diagnosed as proliferative epithelial hyperplasia with atypia. Wide local excision was done and HPE was s/o invasive ductal carcinoma, who further was managed by Breast Conservation Surgery and Radiotherapy.

CONCLUSION

The present study concludes that iBreastExam software shows significantly better sensitivity and higher specificity and was found to be a promising effective tool for younger women with dense breast.

In the developing county like INDIA, where 70% of the population lives in rural and underserved areas, women have no access for breast cancer screening. The iBE is a potential powerful screening tool for use in the third world countries with limited resources, where mammography and clinical breast exam by a trained physician is not readily available.

Performed by trained lay workers and with high specificity of the device, iBE is highly cost-effective in terms of maintenance of the device, transport of females to tertiary center, reducing patient load for surgeons & radiologists, and workload for machines- ultrasound and mammography.Further, more studies and clinical trial needs to be conducted in different regions to establish the iBreast Exam as a standard screening modality.

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