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Original Research Article

Experience and yield of mass breast screening among working women in major cities of India: a mixed-method study

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ABSTRACT

Background: iBreast™ tool is simple, safe, a handy device which is designed for mass breast cancer screening tool in a community or hospital setting. This study determined the yield and basic characteristics of women attending the breast cancer screening programme. The study also determined the overall experience of women who underwent breast cancer screening using iBreast™ tool.

Methods: This study was a multicentric, retrospective observational study conducted in Mumbai, Bangalore, Chennai and Hyderabad as a part of routine work-place breast cancer screening programme supported by Mfine. Screening was done by iBreast™, which is a hand-held compression device. After proper clinical examination and iBreast™ scanning, results were confirmed by a consultant trained in interpretation of findings. The overall experience of the women who underwent screening was also determined using a questionnaire. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. The qualitative assessment and thematic analysis of the qualitative data was done.

Results: A total of 1080 eligible female employees were present in the approached IT companies and out of that 451 women (41.75%) had consented and participated in the screening program. The acceptance rate was highest in Bengaluru city (65%) followed by Mumbai (53%), Chennai (33%) and least in Hyderabad (18%). 31 participants documented positive findings had in the scan and were referred for further evaluation. The quantitative and qualitative data determined that iBreast™ scan was highly accepted by all participants. Customer service, screening location and overall experience was deemed good by the participants with an average score of 4.8.

Conclusions: The iBreast™ has the potential to be a promising tool in providing effective diagnosis after breast examinations.

Keywords: Breast cancer, iBreast™ exam, Mammography

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide, representing nearly a quarter of all cancers and in India, it accounts for 14% of all cancers in women.^{1,2}

In a span of 4 years from 2008-2012, India faced a challenging rise of 11.54% occurrence and 13.28% rise in

mortality of breast cancer cases.³ It can occur at any age, but the incidence begins to rise in the early thirties and peak at ages 50-64 years (WHO, 2019).²

In the majority of resource-poor settings, a high proportion of breast cancer cases are diagnosed at an advanced stage. This contributes to higher morbidity, mortality, health care costs, and poor quality of life among affected women.^{4,5} Poor access and

underutilization of screening services is the primary reason for the delay in diagnosis.¹ Measures aimed at early breast cancer detection are reported to have a significant positive impact on cure rates, morbidity and mortality. Accessibility to early screening services coupled with efforts to increase the awareness levels of women have been regarded as the two key strategies in this regard.^{4,6}

Mammography is the most widely used screening modality for breast cancer in many settings. But the availability of Mammography is still limited to urban environments in resource-poor developing nations. Also, the cost and complexity make it not amenable for adaptation as a screening tool. Breast cancer screening relies on breast self-examination and clinical breast examination, which are quite subjective and can't detect subclinical lesions.^{7,8} These concerns prompt us to look for cheaper, easy and accessible means of screening to make an impact at the national level.

iBreast™ is a simple, non-invasive, handheld device amenable for use as a mass screening tool in non-hospital settings. The device is radiation-free, which can also be operated by grass-root health workers with minimal training.⁹ It contains lead zirconate titanate piezoelectric cantilever sensor which precisely detects atypical, abnormal parts of the breast by comparison of the degree of deflection.¹⁰ This could be a potential powerful screening tool in resource-poor and highly populated nations like India.⁹ Studies documenting the acceptance of a device-based mass screening for breast cancer in a non-hospital setting are scarce. Also, the diagnostic yield and women's experience with iBreast™ device is not yet well studied. This study aimed to analyze the age distribution, history of any breast-related symptoms and family history of breast cancer in routine breast cancer screening programme held for female attendees working in the IT sector in selected metropolitan cities in India. To determine the yield (proportion of women with positive findings out of total women screened) of the breast cancer screening programme among the study population and explore the overall experience of women who underwent breast cancer screening using iBreast™ tool.

METHODS

The study was a multicentric, retrospective observational study. The breast cancer screening programme was conducted in Mumbai, Bangalore, Chennai and Hyderabad as a part of routine workplace health check-up supported by Mfine.

The convenience sampling technique was used to collect the sample in the study. The data collection for the study was done between January 2018 to December 2019.

Women 18 years of age or older who underwent breast cancer screening as part of a workplace comprehensive

health check. Women with history of breast cancer, inflamed or ulcerated lesions, abscesses or fungating growths were excluded.

All the women at the workplace setting were educated on the need for breast cancer screening, the complete details of the procedure and further steps to be followed depending on the screening test result. A complete printed copy of the participant information sheet was provided to each woman in the English language. Any concerns regarding the procedure or results were addressed by a team led by a qualified gynaecologist. All the participants provided informed digital/written consent to undergo screening.

Waiver of participant consent for utilizing the data for the study was obtained from the ethical committee, and the study was approved by the Digital Health Research Independent Ethics Committee (approval number: DHRIEC/SAL03/21052020, dated: 21.5.2020).

Screening tool

Screening was done by iBreast™, which is a hand compression probe containing a four × four array of piezoelectric tactile pressure sensors, a custom-built electronic board and a tablet. It determines tissue elasticity difference between hard and stiff breast tumours in comparison to healthy breast tissue and measures the subtle displacements electrically. It communicates wirelessly with a mobile device to display and store the findings in real-time. The iBreast™ records the data and collects into four × four array map of the breast. This map is usually divided into sectors demarcated by three consecutive hours of a clock to directly compare to the positioning clock assigned by Mammography or ultrasonography. Green indicates healthy breast tissue while red indicates a lesion. All the iBreast™ evaluations were performed by qualified and trained staff.

Screening procedure

The screening procedure was performed in a supine position on the examination table in a secluded room. After initial calibration of the device in an uninvolved breast area for each breast quadrants, the testing was done in quadrant wise fashion. It was detected meaning these females were advised further testing to characterize the lesion. As designed to be a pre-screening tool to identify all lesions and not 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 by a consultant trained in the interpretation of findings. Physical examination of the breast was also done conventionally by a qualified female gynaecologist.¹¹ Women found with positive lesions were provided with appropriate post-test counselling and were referred for further screening. Participants who were found negative

were educated about breast cancer and were counselled about the need to perform regular breast self-examination and undergo regular screening.

We also determined the overall experience of the women who underwent screening. All the participants were asked to rate their experience on a scale of 0 to 5 (0 being poor and 5 being great) using a questionnaire. The rating was done on four domains including overall experience, room ambience/ cleanliness, customer service and Scan. Average rating of all the four domain-specific responses was also calculated.

Operational definitions

The acceptance rate of the screening procedure was defined as the percentage of women who provided informed written consent and underwent the procedure out of total women provided pre-screening counselling and sought consent. The yield was defined as the percentage of women found with positive lesions out of total women who underwent screening.

Statistical methods

The yield was considered as primary outcome variables. Age, family history and symptoms will be considered as primary explanatory variables. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. IBM SPSS version 22 was used for statistical analysis.¹² At the end of the programme, the qualitative assessment of the participants was done to determine their experience with the screening programme. Thematic analysis of the qualitative data was done to analyze the data.

RESULTS

A total of 1080 eligible female employees were educated on the protocol out of which, 41.75% consented for the iBreast examination. The approached IT companies and out of that 451 women (41.75%) had consented and participated in the screening program. The acceptance rate was highest Bengaluru city (65%) followed by Mumbai (53%), Chennai (33%) and least in Hyderabad (18%) (Table 1).

Table 1: Overall city wise summary of the overall screening activity.

City	Total number of female employees	Total number screened	%
Bengaluru	300	194	65
Chennai	700	232	33
Mumbai	30	16	53
Hyderabad	50	9	18
Total	1080	451	41.75

Majority of the participants 42.57% were aged 25 to 29 years, followed by 19.95% participants between 30 to 34 years, 19.51% participants were <24 years and 12.41% participants were between 40 to 44 years age group (Table 2).

Table 2: Age profile of the women screened and women with positive symptoms.

Age distribution in years	Number	%
<24	88	19.51
25 to 29	192	42.57
30 to 34	90	19.95
35 to 39	56	12.41
40 to 44	19	4.21
45 to 49	4	0.88
More than 50	0	0
Total	451	100

Table 3: Family and personal history.

City	Family history N (%)	Personal history N (%)
Bengaluru (n=194)	39 (20.10)	50 (25.77)
Chennai (n=232)	34(14.65)	32 (13.79)
Mumbai (n=16)	2 (12.5)	1 (6.25)
Hyderabad (n=9)	0 (0)	0 (0)
Total	75 (16.63)	83 (18.40)

Table 4: City wise yield of screening by I breast scan.

Parameter	Total number screened	Total number with lesions	Percentage of positive lesions out of screened
City			
Bengaluru	194	16	8.24
Chennai	232	10	4.31
Mumbai	16	5	31.25
Hyderabad	9	0	0
Total	451	31	6.87
Age group in years			
<24	88	5	5.68
25 to 29	192	10	5.21
30 to 34	90	10	11.11
35 to 39	56	5	8.92
40 to 44	19	1	5.26
45 to 49	4	0	0
More than 50	0	0	0
Total	451	31	6.87

In Bengaluru city, 20.10% of participants had a family history, and 25.77% had a personal history of breast cancer. In Chennai city, 14.65% had family history and

13.79% a had personal history of breast cancer. In Mumbai, city 12.5% a had family history and 6.25% had a personal history of breast cancer. In Hyderabad city, no one had a family history and personal history of breast cancer (Table 3).

Out of the 451 women screened, 31 (6.87%) had positive findings in the Scan and were referred for further evaluation (Table 4). The feedback was collected from

Table 5: Customer satisfaction rate of different aspects of the screening process on a Likert scale of 0 to 5 (0 being poor and 5 being great).

City	Bengaluru	Chennai	Mumbai	Hyderabad	Average
My clinicare scan (iBreast™ Scan)	4.8	4.8	4.7	4.9	4.8
Customer service	4.9	4.9	4.9	4.9	4.9
Room, ambience, cleanliness	4.8	4.8	4.8	4.7	4.77
Overall experience	4.8	4.8	4.8	4.9	4.82
Average	4.8	4.8	4.8	4.8	4.8

DISCUSSION

In spite of effective, low-cost techniques of early detection for breast cancer, the majority are detected in advanced stages.¹³ Poor awareness regarding disease, signs/symptoms, the social stigma of cancer coupled with limited access to screening, early diagnosis and health services.¹⁴ As a result, fewer than 30% of patients in India survive more than five years after diagnosis.^{14,15.}

In the present study, a total of 1080 female employees were present in the approached IT companies. Family history of breast cancer ranged from 0-20% in various study centres. All females included were educated and employed. Despite inviting 1080 participants, only 41.75% turned up for the screening program. The acceptance rate of screening varied from as low as 18% to 65% in different cities. Studies conducted in western settings have reported considerably higher acceptance rates ¹⁶ In a study by Khandelwal.¹⁷ about 1420 Indian women were requested to participate in a breast cancer screening study, but only 1300(91.5%) population agreed to participate. The study setting of this study was not explicitly specified but was likely to be in health care institutional setting led by trained community health workers well acquainted with the community. Many reasons have been proposed for low acceptance of breast cancer screening. The reason stated by Vidyarthi, A. et al.¹⁶ were that even well-educated, affluent, younger Indian women face embarrassment and anxiety due to lack of awareness. These women mainly had emotional rather than a logistic barrier to seeking treatment for breast cancer.¹⁶ This emphasizes the need for a culturally appropriate, targeted health education programmes to increase the acceptance of cancer screening in general and more so of breast cancer.

the participants, and the average score of all participants was computed. It was seen that iBreast™ Scan was highly accepted by all participants. Customer service, screening location and overall experience were deemed good by the participants with an average score of 4.8 (Table 5).

In the present study, out of the 451 women screened, the overall yield was 31 (6.87%) and was referred for further evaluation. Khandelwal had 146 (11.2%) yield when iBE or Clinical Breast Examination (CBE) was done.¹⁷ Kerlikowske et al found that the with screening mammography in their study was 7%.⁸ Kumar et al found the yield to be 5.1% on mammography.⁵ The studies on iBreast™ examination tool are limited. One of the studies determined the sensitivity and specificity of iBreast™ device. Kr, A., in their triple-blinded prospective study, examined women by either iBreast™, CBE or Breast Imaging (Mammography or breast ultrasound) in a third world country setting. About women of 916 enrolled participants. iBE gave significantly better sensitivity, by 19 %, compared to CBE in detecting lesions in the breast. Also, it had a high specificity of 94 %. Even in younger subjects with high breast density, usually below 40 years of age, iBE demonstrated good results.¹⁰ Broach et al reported a sensitivity of 86 % and specificity of 89% with iBE.⁹

So far, the most widely used tools globally for breast cancer examination are Mammography, clinical breast examination (CBE), and breast self-examination (BSE).²⁰ Mammography and regular CBE are known to reduce fatality through early detection of breast cancer even in asymptomatic subjects.²¹

However, its discomfort, high cost and cumbersome nature dismiss its use in developing countries like India.²⁰ Even BSE even though very effective, may not be the best tool in breast cancer detection due to several limitations associated with it; Lack of education about the procedure and poor access to the healthcare facilities to name a few.²¹

Khandelwal mentioned in their study that women were taking iBE test were comfortable, and the procedure was socio-culturally acceptable, even in the rural environment. The reason being its radiation-free and painless nature. Breast examination by a radiation-free and painless electro-mechanical handheld breast palpation device (iBreast™).¹⁷

It is important to catch breast cancer at its earlier stage as it leads to better survival rate, reduces the cost of treatment and the overall burden of breast cancer, which is especially needed in developing countries like ours.¹⁹ The iBreast™ has a potential to be a promising tool in providing effective diagnosis after breast examinations even in young women with dense breasts. It can prove to be a boon in low-resource settings in catching breast cancer at its early stages.¹⁰ Moreover, it has the advantage of requiring less screening infrastructure.¹⁹ However, this requires further research and investigation.

The qualitative exploration of the data showed that women's experiences of iBE in the breast screening setting were pleasant. Additionally, the experienced staff and well-organized screening programme, the entire process was successful. However, we did not conduct an in-depth qualitative study on patient experience with iBreast™ Scan with face to face interview or focus group discussions. In future, it's recommended to conduct a phenomenological qualitative study with a semi-structured interview in order to get new insights into an area which has received little or no prior qualitative research attention.

The limitation of our study was that the low overall response rate in the community. Secondly, only women from the IT sector were invited to take part in the study. They were well educated and belonged to the urban area, as compared to most Indian women. Another limitation was the retrospective nature of the study. Additionally, the qualitative data that was collected was also limited and did not capture the emotions and in-depth experience of the women who underwent screening. Due to these limitations, the study could only be generalized with caution. The future investigation must focus on the acceptance rate of iBreast™ screening in different settings, factors determining the acceptance and interventions effective in increasing the acceptance rates. Also, prospective studies with well-established referral mechanisms are needed to document the diagnostic accuracy of iBreast™ as compared to existing screening method.

CONCLUSION

iBreast is a safe, convenient and handy device to screen for breast cancer in educated/motivated women. The experience was pleasant and deemed safe by majority. iBreast should be considered for screening for rural population based on the present experience.

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