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Effectiveness of iBreast examination for screening breast lesions among women in India

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ABSTRACT

The breast has long been a representation of women's identity and an essential component of fertility. The breast lesions refer to an area of abnormal breast tissue. One frequent medical ailment that might worry women is breast lesions. It is estimated that at least 20% of females may develop breast lesions. It may vary in size, shape, and texture can be either benign or malignant. Mammography, clinical breast examination (CBE), and self-breast inspection are the accepted early breast cancer detection techniques. Mammography application in low and middle-income countries is limited because most of the women in these countries cannot afford it. Hence, iBreastExam was identified and validated as an alternative source for screening at the village level to identify breast lesions at an early stage. For the study, a cross-sectional research design using a quantitative research methodology was used. Adopted areas of the selected colleges were the setting for the study: MA Chidambaram College of Nursing, Adyar, Chennai; Sri Balaji College of Nursing, Chrompet, Chennai; Madha College of Nursing, Kundrathur, Chennai; Omayal Achi College of Nursing, Puzhal, Chennai. The sample size consisted of 14,000 women across all the 4 settings. A convenient sampling technique was used to select the samples for the study. A total of 13,988 women were screened, 55 women had positive breast lesions, and out of this 5 were confirmed to have breast cancer through mammogram diagnosis.

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1. INTRODUCTION

Women's breast has always been a vital part of fertility and also a symbol of womanhood. It is a modified sweat organ with considerable significance for its lactating capacity and for cosmetic reasons. This dynamic organ, under the influence of various hormones, is subjected to constant physiological variations throughout the reproductive life and beyond, giving rise to various types of breast abnormalities or lesions [1]. The breast lesion refers to an area of abnormal breast tissue. One frequent medical ailment that might worry women is breast lesions. It is estimated that at least 20% of females may develop breast lesions [2]. It may vary in size, shape, and texture can be either benign or malignant. Cysts, fibroadenomas, papillomas, ductal carcinoma in situ, and invasive ductal carcinoma are among the several forms of breast

lesions [3]. Benign lesions are not life-threatening and are often treated by excision or observation. In contrast, malignant lesions involve early identification and prompt treatment such as chemotherapy, radiation, or hormone therapy. The optimal course of therapy will depend on the lesion's nature and stage, as well as the woman's general health [4]. Although non-cancerous (benign) breast lesions may sometimes progress to cancer, they do not have the capacity to spread to other areas of the body and result in mortality. Even though this metamorphosis is uncommon, it is crucial to have a medical team examine any breast lesion in order to keep an eye out for any growth or changes. Untreated benign breast lesions might potentially raise the chance of getting breast cancer later on [5].

Benign lesions are often treatable with inspection and do not pose a danger to life. On the contrary, malignant lesions necessitate timely classification and rapid treatment [6]. The nature and stage of the lesion and the woman's overall health will establish the appropriate course of therapy. Normal (non-cancerous) breast lesions may sometimes develop into cancer, but they cannot spread to other areas of the body and result in death [7]. Even if this metamorphosis is uncommon, it is nevertheless crucial to have a medical team assess any breast lesions in order to monitor for any changes [8]. Untreated benign breast lesions may potentially increase the chance of developing into breast cancer in the future [9]. Breast cancer is the most common cancer among women in India and accounts for 14% of all cancers in women. India is faced with a sizable cancer incidence burden, which continues to grow exponentially [10]. The 2020 World Health Organization (WHO) ranking on cancer burden in terms of new yearly reported cases had ranked India at the third position after China and the U.S., respectively [11]. A GLOBOCAN 2020 research found that a woman in India receives a breast cancer diagnosis every four minutes. Every year, around 1,78, 000 new cases are diagnosed [12].

Breast cancer is now the most frequent cancer among Indian women, surpassing cervical cancer in frequency. The fact that it is increasingly being identified in India ten years sooner than in the West is even more concerning [13]. Tragically, a woman in the nation dies from breast cancer every eight minutes, accounting for 90,000 fatalities annually [14]. One woman dies from breast cancer for every two who get a diagnosis. Delays in early detection and a lack of preventative breast health exams are the two main causes of the startlingly high death rate. Therefore, it is essential to create a screening method that is both economical and efficient in order to aid in the early identification and timely treatment of breast diseases [15].

According to a recent systematic review and meta-analysis of breast cancer risk factors, women between the ages of 40 and 49 who have very thick breasts and first-degree relatives with breast cancer are at least twice as likely to get breast cancer [16]. Personalized mammography screening may benefit from an awareness of these risk variables [17]. In India, breast cancer occurrence peaks before the age of 50 years, and a current evaluation of the evidence established on eight trials conducted between 2001 and 2008 proposed that mammographic screening is also helpful in this younger age group [18]. Therefore, screening women between the ages of 40 and 49 is necessary to determine the effectiveness of breast cancer screening in this demographic [6].

Breast cancer may be identified and treated early since it develops in a visible organ 4. If identified early, the 5-year survival rate is 85%; if detected late, it is 56% [19]. Common breast cancer screening methods that have been proposed to reduce morbidity and mortality include breast self-exams (BSE), clinical-breast examinations (CBE), and mammograms [20]. For the majority of people, breast cancer does not exist till their safe ones are manufactured. After that, it goes without saying that most individuals only give when the illness starts to show symptoms, and most "symptomatic" malignancies are often stage 2b and above [21]. Patients with breast cancer are not inclined to live longer if the disease is discovered later, since, even with successful therapy, the size of the tumor at diagnosis significantly affects survival. One major strategy in reducing breast cancer humanity is the habit of screening methods, for instance [22]. BSE is a promising clinical result among breast cancer patients. Early discovery assists in the treatment before metastasis and is connected with an outstanding forecast. Breast cancer screening is established to minimize the risk of humanity by 20%. Despite the existence of several screening methods, common of breast cancer cases are identified by women themselves, stressing the significance of BSE [23]. Figure 1 explains the Weibull distribution of all filler concentrations. Number of new cases in females in 2020. In addition, Figure 2 explains the iBreastExam.

Significance and need for study: the most common disease and the primary cause of cancer-related mortality for women globally is breast cancer [23]. The majority of breast cancer cases are discovered early in high-income nations with strong healthcare systems and population screening initiatives, and treatment results are excellent. Low-income and middle-income countries (LMICs) often have advanced presentations, and treatment results are subpar because of delayed discovery, a lack of diagnostic tools, and limited access to healthcare. As a result, initiatives to enhance early diagnosis will be beneficial [24]. Mammography, clinical breast examination, and self-breast inspection are the acknowledged early breast cancer detection techniques [25]. Mammograms are the gold standard for screening for breast cancer in high-income nations. Mammography application in low- and middle-income countries is limited because most women in the

communities cannot afford a mammogram [26]. Hence, iBreastExam was identified and validated as an alternate source for screening at the village level to identify breast lesions at an early stage [27].

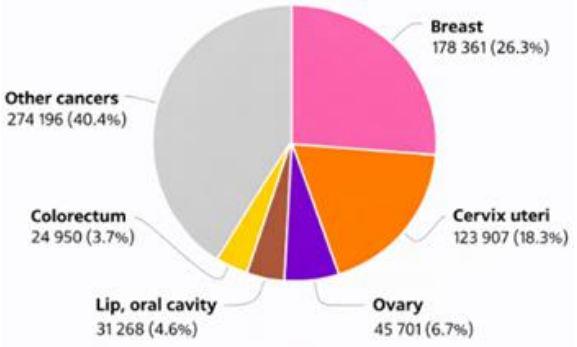

Figure 1. Weibull distribution of all filler concentration numbers of new cases in females, 2020 [12]

Figure 2. 2iBreastExam

The iBreastExam is a noninvasive, handheld, quick, and easy solution for breast lesion detection. It is a completely safe, pain and radiation-free technique with low cost at the village level, and its dealings tissue elasticity and identifies abnormal (stiffer and harder) breast tissue as small as 3 mm within 5 minutes. By contacting the skin's surface from the top down, this inexpensive elastic modulus sensor can determine the stiffness and compression of tissue. The gadget is connected to a smartphone app that alerts the user in the event that aberrant tissue is found. CBE should be used in conjunction with the iBreastExam once it is completely accessible, prioritizing the women for further testing. Therefore, the iBreastExam may be a useful tool for early pre-screening of clinically important breast abnormalities.

The manufacturer and one of the study's lead investigators (OO) provide iBreastExam training. Each nurse completed 30 iBreastExam exams prior to enrolling, which were reviewed by the primary agent to initiate technique ability (i.e., proper device performance and presence of entire breast tissue). The iBreastExam was analytically motivated over the breasts while the patients were in the prostrate position. On the colour chart, green indicates negativity and red indicates positivity. Surveys on the event were completed by women. It is confirmed how long it takes to complete the iBreastExam and the CBE. The Rotary Club of ChennaPatna through its global grant project under the chairmanship of Dr. Ani Grace Kalaimathi, had chosen to screen 14,000 women for breast lesions using the iBreastExam. The iBreastExam Scan Kit consisted of an iBreast scanner, one Android mobile phone with charger, and seven sensor cartridges. Each sensor cartridge has 500 licenses from UE LifeSciences.

In women, breast cancer is a prevalent malignancy. In both established and emerging locations, it is a recurring cancer. Breast cancer is becoming more common in India, the most populous developing nation. In India, breast cancer has surpassed cervical cancer as the most prevalent malignancy among women in a number of regions. Breast cancer mortality rates are unnecessarily high in India, where the age-standardized incidence rate is 22.9/100,000, one-third that of Western nations. The data from atlas project recommend that breast cancer in city regions of India is three times superior to in rural regions of the country. There is no planned, systematic, administration-funded screening program for breast cancer in India. The screening in formulating countries can be regarded as "opportunistic screening". The WHO suggests mammography every 1-2 years for women aged 50-69. In India, breast cancer occurrence peaks before the age of 50 years, and a recent evaluation of the proof in younger women based on eight trials guided among 2001 and 2008 intimates that mammographic screening is also valuable in this younger age group. In order to determine the effectiveness of breast cancer screening, women between the ages of 40 and 49 must be screened.

For countries with limited resources, where treatment and diagnostic capabilities are lacking, and where the cost of appropriate breast cancer care often exceeds monthly revenues, there is a great deal of disagreement. According to several studies conducted in settings with limited resources, the majority of breast cancer patients get their diagnosis at a late stage, making treatment more difficult and less successful. Both systemic (poor quality and accessibility of health care services, deficiency of specific public services and essential drugs, elevated diagnosis and action costs, and smallest breast cancer responsiveness) and individual (low breast cancer responsiveness and knowledge, myths and ideas, mistrust of the health care system, and economic and access barriers) factors have been identified as contributing to late appearance to health care providers. Breast cancer screening programs are widely available in high-income countries,

but few or no screening programs exist in LMICs, where treatment options are limited locally, and the population is young. They are likely to be exclusive as well as unsuccessful. Measuring the prevalence of breast symptoms that need diagnostic services, probable follow-up, and treatment is essential for the improvement, extension, and amplification of health care plans and breast cancer screening programs. Nonetheless, the discovery of breast screening is covered in a relatively little amount of literature. Therefore, there is room to assess the clinical profile and prevalence of breast illnesses in Nepalese women as well as their relationship to socioeconomic factors.

In the United Kingdom (UK), screening mammograms for breast cancer are presently offered to women between the ages of 50 and 70 every three years. Life expectancy is increased with breast screening. According to the panel's analysis of the benefit evidence, which includes both contemporary observational studies and older randomized controlled trials (RCTs), women who are invited for screening had a 20% lower death rate. Although there is a lot of uncertainty in this estimate, it is the panel's summary of the data. This translates to one death prevented from breast cancer for every 180 women who attend screening and one death prevented for every 235 women asked to do so during a 20-year period. According to the panel's best estimate, the UK's breast screening program, which invites people between the ages of 50 and 70 every three years, avoids around 1,300 deaths from breast cancer annually, which is a really positive thing for both public health and women.

Since 2004, a countrywide study known as the Korean National Cancer Screening Survey (KNCSS) has been carried out every year. The purpose of this research was to examine the trends in Korea's cancer screening rates for the five main cancers: stomach, liver, colorectal, breast, and cervix uteri. This research made use of KNCSS data gathered from 2004 to 2011. Since 2004, there has been a rise in lifetime screening rates as well as screening rates with recommendations. On average, screening rates with recommendations have increased by 0.2% (95% CI, -0.9%-1.3%) for cervical cancer and 4.0% (95% CI, 3.0%-4.9%) for breast cancer annually. Screening rates for stomach and breast cancer, in particular, showed a considerable rise. Despite having a formalized screening program, Sri Lankan female healthcare professionals' knowledge and behaviors about breast and cervical cancer screening are widespread. Convenient sample techniques were used to pick 219 female health care professionals from six districts in Sri Lanka, including public health midwives (68.9%), for a cross-sectional study. The data came from a capacity-building training program using a self-administered questionnaire as a pretest. More than 98% were aware of the self-breast exam. Only 47.9% practiced it on a monthly basis, despite the fact that 84.1% did. 64.3% and 94.1% of people were aware of mammography and CBE, respectively. Just 3.6% had ever had a mammogram, and 19.2% had had a CBE during the previous 12 months.

The controversy around mammography screening for women under 50 has been rekindled by recent recommendations from the United States preventive task force (USPTF). For women between the ages of 40 and 49, the USPSTF advises avoiding regular screening mammograms. Individual factors, such as the patient's views about certain advantages and hazards, should be taken into account when deciding whether to begin routine, biannual screening mammography before the age of 50. For women aged 50 to 74, the USPSTF advises screening mammograms every two years. Annual mammograms are advised by the American Cancer Society beginning at age 40 and continuing for as long as a woman is healthy. Women 40 years of age and older should get a CBE annually. For women 40 years of age and older, screening mammograms are advised by all major US medical organizations. At 14 years of follow-up, screening mammography lowers breast cancer mortality by around 20% to 35% in women aged 50-69 and somewhat less in women aged 40-49.

The iBreastExam is a noninvasive, handheld, quick, and easy solution for breast lesion detection. It is a completely safe, pain and radiation-free technique with low cost at the village level, and it measures tissue elasticity and detects abnormal (stiffer and harder) breast tissue as small as 3 mm within 5 minutes. It is a low-cost elastic modulus sensor that can measure tissue compression and stiffness by top-down touching of the skin surface. When the iBreastExam is totally accessible, CBE must complement the iBreastExam, triaging the women for further investigations. So, the iBreastExam can be a promising tool for pre-screening of clinically relevant breast lesions at an early stage.

2. METHOD

2.1. Statement of the problem

In India, breast cancer has become one of the main causes of cancer-related morbidity and death for women. Because of low knowledge, poor screening facilities, and socioeconomic hurdles, a large percentage of cases are discovered at an advanced stage. Even though mammography is an excellent screening method, it is often unavailable in rural and semi-urban areas because to high prices, a shortage of qualified radiologists, radiation exposure concerns, and low female compliance. Therefore, in India, early diagnosis of breast lesions continues to be a significant public health concern.

2.2. Research objectives

A cross-sectional study to screen for breast lesions among women using breast exams in selected settings. This study aimed to detect the breast cancer rate. To screen for breast lesions using iBreastExam among women aged 30 years and above residing in the selected settings.

2.3. Operational definitions

Breast lesions refer to women with abnormalities in the breast tissue, such as lumps, pain, and nipple discharge, as assessed by iBreast scan equipment. iBreastExam is a noninvasive, handheld/ easily portable, pain—and radiation-free device to detect non-palpable breast lesions at an early stage. Women represents who are in the age group of 30 years and above residing in the selected settings.

2.4. Research approach and design

A quantitative research approach using a cross-sectional research design was adopted for the research work:

- Population: all women who were aged 30 years and above were the target population and women residing in the adopted areas of the selected colleges were the accessible population.
- Sample: women aged 30 years or above who fulfilled the inclusion criteria were selected as samples.
- Sample size: the sample consisted of 14,000 women in all 4 settings.
- Sampling technique: a convenient sampling technique was used to select the samples for the study.

2.5. Research setting

Adopted areas of the selected colleges were the setting for the study:

- M.A. Chidambaram College of Nursing, Adyar, Chennai.
- Sri Balaji College of Nursing, Chrompet, Chennai.
- Madha College of Nursing, Kundrathur, Chennai.
- Omayal Achi College of Nursing, Puzhal, Chennai.

2.6. Criteria for selection of samples

Inclusion criteria: women who are:

- residing in the adopted areas of the community health center of selected colleges.
- aged 30 years and above.

Exclusion criteria: women who are:

- Pregnant and lactating.
- Diagnosed with breast cancer.
- Underwent breast screening in the last 6 months.
- Underwent any kind of breast surgery in the last 6 months.

2.7. Procedure for data collection

The breast exam project was undertaken as a part of the global grant funding by the Rotary Club of Madras Chennapatna for the early detection of breast lesions among women aged 30 years and above under the Chairmanship of Rtn. Dr. S. Ani Grace Kalaimathi. The inauguration was held at VHS-M.A. Chidambaram College of Nursing on 01.02.2022 with the presence of rotarians from Rotary Club of Madras Chennapatna, trainers from UE LifeSciences, principals and faculty trainees (2 faculty from each college) from four Nursing Institutions (VHS-M.A. Chidambaram College of Nursing, Sree Balaji College of Nursing, Matha College of Nursing and Omayal Achi College of Nursing). The iBreastExam Scan Kit was handed over to the four nursing institutions, and a brief introduction to the device was given. The training program was conducted at four nursing colleges by the trainers from UE LifeSciences on the 1st week of February 2022. The iBreastExam Scan Kit consisted of an iBreast scanner, one Android mobile phone with charger, and seven sensor cartridges (each sensor cartridge can do 500 scans) from UE LifeSciences. A total of 3,500 scans were done by each institution, totaling 14,000 scans overall. The refresher training was conducted at Sri Balaji College of Nursing on 25.03.2022, followed by the third training at M.A. Chidambaram College of Nursing on 17.06.2022 on using a newer version of the application. After due training and permission from the village leaders/councilors, the researchers undertook the project with informed consent from the women.

The investigator briefly introduced themselves and the screening's objectives. In order to get their cooperation during data collection, they were forced to sleep comfortably on the bed in a room with good ventilation, and secrecy about the data was guaranteed. The participants provided written and verbal informed permission about their desire to participate in the screening. After obtaining the consent, the investigator first collected demographic variables, followed by breast screening for lesions using a breast exam. A total of 13,988 women were screened; however, within one year of time (each nursing college 3,500 scans).

3. RESULT AND DISCUSSION

The goals of the research guided the organization, tabulation, and analysis of the data that was gathered. The following are the conclusions drawn from the descriptive statistical analysis. The main focus of this study was to screen breast lesions using iBreastExam among women at selected areas, the results of the screening revealed that out of the 13,988 women who were screened, 6,525 (46.66%) were in the age group of 30-40 years, 4,436 (31.71%) were between 41-50 years and 3,027 (21.63%) were above 50 years. Of the total women screened, 13,933 had no lesions, and 55 women were identified to have positive breast lesions; of these, 5 were confirmed to have breast cancer through Mammogram diagnosis. The women were referred to Kilpauk Medical College Hospital, Rajiv Gandhi Medical College Hospital, and Pennalam for further management for confirmatory diagnosis.

The iBreastExam gadget, which auto-calibrates and may improve recovery specificity, was made accessible. The assessment of false positives brought on by the iBreastExam's usage must be outweighed by the increased accessibility to breast examination. For breast finding, the iBreastExam demonstrates a superior sensitivity to CBE. In a community context, the iBreastExam might be used in conjunction with clinical history and breast examination to triage patients to determine who needs further diagnostic evaluation. We discovered that if the iBreastExam and clinical breast examination were applied equally, sensitivity for questionable masses would advance, but specificity would drop. Figure 3 explains distribution of samples according to age. Figure 4 describes number of breast lesion identified according to age, and Figure 5 indicates the number of confirmed positives according to age of samples. The gathered information was arranged, tallied, and examined in accordance with the study's goals. Table 1 displays the results of the descriptive statistical analysis.

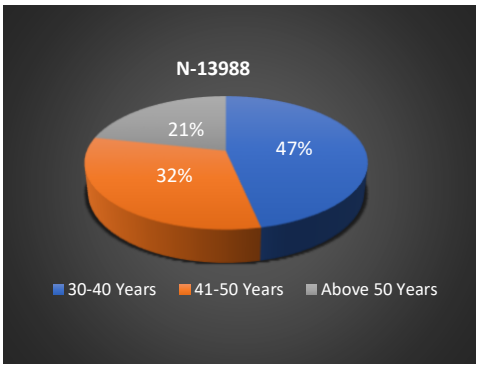

Figure 3. Distribution of samples according to age

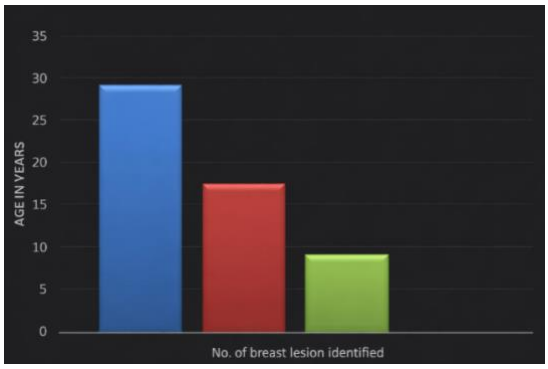

Figure 4. Number of breast lesion identified according to age

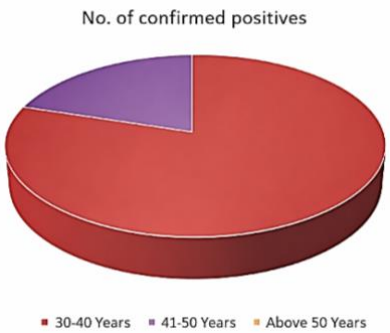

Figure 5. Number of confirmed positives according to age of the samples

Table 1. Frequency and percentage distribution of age of women who underwent iBreast screening-N =13,988

Age in years	N	%	No. of breast lesions identified	No. of confirmed positives
30-40 years	6,525	46.66	29	4
41-50 years	4,436	31.71	17	1
Above 50 years	3,027	21.63	9	0
Total	13,988	100	55	5

4. CONCLUSION

The main focus of this study was to screen breast lesions using iBreastExam among women at selected areas; the results of the screening revealed that out of the 13,988 women who were screened, 6,525 (46.66%) were in the age group of 30-40 years, 4,436 (31.71%) were between 41-50 years and 3,027 (21.63%) were above 50 years. The study concluded that of the 13,988 women, 13,933 had no lesions, and 55 women were identified to have positive breast lesions. Out of 55 women who had breast lesions, 5 were confirmed to have breast cancer through Mammogram diagnosis; other women had fibroadenomas and were treated at the referral areas. iBreastExam was easy, hand-held equipment that was portable and used by nurse researchers, even for household screenings where women could not reach health centers. Also, the utilization and maintenance of the equipment were simple. This breast exam can be used as a pre-screening device by nurses and other healthcare professionals in marginalized areas for early detection of breast lesions/cancers.

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AUTHOR CONTRIBUTIONS STATEMENT

This journal uses the Contributor Roles Taxonomy (CRediT) to recognize individual author contributions, reduce authorship disputes, and facilitate collaboration.

Name of Author	C	M	So	Va	Fo	I	R	D	O	E	Vi	Su	P	Fu
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Sambavadas Kanchana	✓	✓		✓	✓	✓		✓		✓			✓	
Radhakrishnan Sudha	✓		✓				✓	✓		✓		✓	✓	
Peruma Tamilarasi		✓		✓		✓				✓	✓	✓		

C : **C**onceptualization
M : **M**ethodology
So : **So**ftware
Va : **Va**lidation
Fo : **Fo**rmal analysis
I : **I**nvestigation
R : **R**esources
D : **D**ata Curation
O : Writing - **O**riginal Draft
E : Writing - Review & **E**diting
Vi : **Vi**sualization
Su : **Su**pervision
P : **P**roject administration
Fu : **Fu**nding acquisition

CONFLICT OF INTEREST STATEMENT

Authors state no conflict of interest.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author, [SAGK], upon reasonable request.

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