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Breast-I AS A screening tool in detecting early breast lesions in women-An experimental study in tertiary care centre Chennai

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Abstract--Background: India is facing challenging situation because the incidence of breast cancer has increased by 14% and the mortality rate has increased by 11.1%. Breast- i is a new tool for effective breast cancer screening, especially for detecting both non-palpable and very small lesions often missed by Clinical Breast Examination (CBE). This device is expected to help in detecting tiny breast lesions in the outpatient clinic itself, helping in reducing morbidity and mortality associated with late diagnosis of carcinoma breast. **Objectives:** To analyze diagnostic accuracy of Breast-i and to study the prevalence of Breast Cancer in the study population. **Materials and Methods:** The experimental study was conducted at Sree Balaji Medical College and Hospital, Chennai over eighteen months with sixty female patients using Breast-i for early diagnosis of Breast lesions. Detailed history was taken and CBE was done. Later, patients were screened with Breast-i and further evaluation was done if abnormalities were detected with Breast-i. The findings obtained from Breast-i were compared with FNAC and Trucut Biopsy finding. The obtained data were processed with MedCalc Software Version 19.0. **Results:** The mean age of the study participants was 34.75±13.99 years. Breast-i results were compared with the FNAC/Trucut biopsy report showed 100 % sensitivity and 71.43 % specificity. Breast-i screening had revealed 71.42% (10 out of 14 patients) of malignancy in age of 41-60

and 28.57% (4 out of 14 patients) in more than 60 years, which correlated with the similar findings on FNAC and Trucut biopsy. The prevalence of malignancy of breast was 23.33% (14 out of 60 patients) in our study. *Conclusion:* The BREAST-i LED machine is a highly sensitive tool for screening of breast cancer and it can be recommended as auxiliary screening device.

Keywords---Breast-i, Breast cancer, Clinical Breast Examination, Screening, Biopsy.

Introduction

Breast cancer is the most common cancer among women worldwide accounting for 11.7% of all cancer cases [1]. In India, breast cancer accounted for 13.5% of all malignancy cases and mortality rate of 10.6% as per Globocan's Women 2020 report [2]. India is facing a challenging situation because the incidence of breast cancer has increased by 14% and the mortality rate has increased by 11.1% [3]. The prime reasons for the remarkable increase in death rate are lack of screening, detection of advanced cancer, and paucity of appropriate medical facilities. Screening is the most efficient way of detecting early breast malignancy [4]. The size of breast cancer lesion is one of the principal prognostic indicators and a decisive factor in determining the surgical treatment plan. The ability to precisely measure the size is crucial before any surgical treatment or major medical treatment. With the advent of minimally invasive breast surgery techniques and popularity of neoadjuvant therapies, the ability to meticulously and non-invasively determine the largest tumour size has become increasingly important. The decision to provide patients with the main drug treatment for operable breast cancer is mainly determined by the size of the tumour presented and tumors larger than 30 mm are usually used as the cut-off value for recommending the main drug treatment. Various studies have been conducted on the combination of mammography and other methods to enhance the sensitivity of screening of breast malignancy. In addition to mammography, clinical breast examination (CBE) by palpation can increase sensitivity by 4%. The sensitivity and specificity of CBE ranged from 28% to 36% [5].

Breast cancer screening can be recommended in women of age between 30 to 35 years. In general, breast clinical examination for screening is a time consuming procedure lasting up to 20 minutes, hence there is a necessity to quick and handy tool to detect breast masses in community. Breast-i-LED machine, which uses trans-illumination, resolves this issue by aiding in the diagnosis. Cutler in 1929 first used this followed by various other people. This device utilizes the tumour associated angiogenesis when the oxyhaemoglobin in the RBC absorb the light at 615nm. Various studies done in sub Saharan countries and other reported this tool being effective, sensitivity of 66.66%, specificity of 51.06%, positive predictive value of 8% and negative predictive value of 96% [6,7]

Mammogram is the main imaging-based test used in clinical practice and is regarded as the "gold standard" screening test for detecting breast abnormalities, including breast cancer-related worrisome lesions. Mammograms focus on the

fact that health must be affordable and available to the general public. Although mammography seems convenient as a technique for detecting breast abnormalities, this non-invasive examination necessitates exposure to X-rays, regulated settings, and requires handling by qualified staff. The discomfort and suffering experienced during the test are well-known factors that deter women from getting their annual mammograms. More crucially, mammography may not be the ideal screening method for women with dense or highly dense breast tissue, which the cancer assessment models deem to be a risk factor for breast cancer. Since thick breast tissue is thought to be a risk factor for breast cancer, the former raises concerns in the clinical and public health communities if incidences of breast cancer are underreported or incorrectly diagnosed (increasing false negative results) among women between the ages of 40 and 74. New technologies that can overcome costs, cultural and religious beliefs, complaints about discomfort, and the possibility of falsely negative results on thick breast tissue are greatly desired because they have similar or higher sensitivity and specificity.

So, an Experimental study was done to identify breast cancer using Breast-i-LED machine. The study aimed to investigate the diagnostic accuracy of Breast-i. The diagnostic characteristics of Breast-i as a first line screening tool was assessed.

Materials and Methods:

An Experimental study was conducted in Sree Balaji Medical College and Hospital, Chennai, from February 2019 to August 2020. The approval from Institutional Ethics Committee was obtained (Ref no.002/SBMC/IHEC/2018/1138). The sample size was estimated to be 60 considering 95% CI and 80% power. After obtaining informed written consent from the participants, sixty patients were enrolled.

Inclusion criteria: Patients of age above 12 years and below 80 years of age, those who were willing to participate in the study, asymptomatic patients registered for screening purpose. Exclusion criteria: Women with palpable breast lesions, metastatic disease, prior radiotherapy to the breast. Sixty patients were included in the study and twenty six patients were excluded (16 had clinical breast mass, 10 not willing for FNAC/Biopsy).

The study was done in two sections. Part I consisted of recording the demographic details, menstrual history and Part II consisted of clinical breast examination (CBE) and Breast-i LED machine finding of visible mass recorded (dark spot). Breast-i-LED machine is hand-held probe which works by the principle of transillumination and provides optical image of the breast when the red blood cells absorb the light emitted at 615 nanometer (Table/Fig-1). The red light transillumination of the breast tissue represents the vascularity of the breast tissue. Generally there is a red transillumination in normal breast, whereas a dark spot indicating high vascularity represents a suspicious breast lesion (benign or malignant) (Table/Fig-2, Table/Fig-3). The privacy of the participant was maintained adequately. At the end, results of examination were categorised as lump present or absent and if lump was detected they were subjected to biopsy after revealing to the participants for pathological examination (i.e.,

benign or malignant). The Breast-i findings was compared with the FNAC/Trucut biopsy findings.



Fig. 1:Breast-i device



Fig. 2: Normal appearing breast by using Breast-i device



Fig. 3: Suspicion of malignancy appearing as dark spot by using Breast-i device

Statistical Analysis

The obtained data were entered in excel sheet. Subsequently data processing was done with Medcal software version 19.0. Percentage were used to represent categorical variables. The continuous variables were expressed as mean $\pm$ standard deviation. The statistical significance of mean differences was compared using unpaired t-test. The diagnostic accuracy was calculated using ROC analysis. All values were considered significant if the P value was < 0.05 (Fig. 4). The present study was conducted diligently by adhering to ethical guidelines as mentioned in the Helsinki declaration.

Results

Among the 60 female patients studied, the study participants belonged to 14-70 years of age and mean age was 34.75 ± 13.99 years. None of the patients observed breast lumps or were they clinically palpable. Four patients (6.66%) had nipple discharge and the remaining patients had no such complaints. Among the study participants, 50 % had normal menstrual cycles, 28.33 % had irregular cycles and 21.66 % were postmenopausal women. 16.66 % of the study participants underwent hormonal therapy previously. 51.66 % of the study patients had given childbirth and breastfed. The previous breast surgeries were done in 6.66 % of the study population. The family history of breast cancer was observed at 13.33 % in the study participants (Table 1)

Table 1: Baseline characteristics of the study participants

Variables	Mean $\pm$ SD	
Age	34.75 ± 13.99	

Status of symptoms and the previous history	Yes N (%)	No N (%)
Lump in the breast	0	60 (100)
Any Nipple Discharge	4 (6.66)	56 (93.33)
Regular cycles	30 (50)	17 (28.33); Post-menopausal-13 (21.66)
Hormonal therapy	10 (16.66)	50 (83.33)
Given birth	31 (51.66)	29 (48.33)
Breastfed	31 (51.66)	29 (48.33)
Any previous breast surgery?	4 (6.66)	56 (93.33)
Family history of breast Cancer	8 (13.33)	52 (86.66)
Is the lump clinically palpable?	0	60 (100)

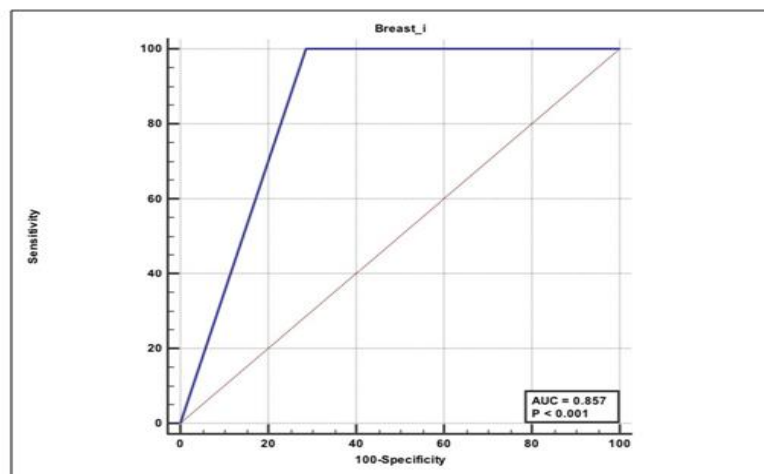


Figure 4: ROC of Breast-i

Breast-i detected lesions were subjected to FNAC/ Trucut biopsy to categorise them into benign or malignant lesions. The Breast-i was compared with the FNAC/Trucut biopsy findings which was statistically significant ($P < 0.0001$). It showed that 100 % sensitivity and 71.43 % specificity. The area under the curve was 0.857. The positive predictive value was 43.75 % and negative predictive value was 100 %. The accuracy of Breast-i was 76.92 %. The total prevalence of breast carcinoma was 23.33 % (14 out of 60 patients) in the present study.

The study population were categorised based on age and compared with each other (Table 2). The significant difference was observed among the age groups that group I (age <40) vs Group II (age belonging to 40-60) ($P < 0.0001$); group II vs group III (age, >60) ($P = 0.0032$) and group I vs group III ($P < 0.0001$). The FNAC/Trucut biopsy has shown higher prevalence of malignancy in age groups 41-60 and > 60 years. Similarly, the Breast-i has also shown higher percentage of malignancy in age groups of 41-60 and > 60 years. Hence, the 41-60 years and >60 years were vulnerable age groups susceptible for breast cancer development in the study. The prevalence of breast cancer in the present study was 0 % at the age group <40 years; 77 % in the age group of 41-60 and 100 % was observed in the age group > 60 years.

Diagnostic accuracy	Age <40 years	41-60 years	Age > 60 years
Sensitivity %	-	100	100
Specificity %	67.42	50	-
PPV %	-	76.92	100
NPV %	100	100	-
Accuracy %	-	81.25	-

PPV- Positive Predictive Value, NPV- Negative Predictive Value

Table 2: Diagnostic accuracy of Breast-i in various age group

The Breast-i was compared with the FNAC/Trucut biopsy based on the age groups. In the present study, Breast-i was able to screen the abnormalities in the breast and they were compared with FNAC/Trucut biopsy results which showed that it was 100 % sensitive and 50 % specific in the 41-60 years age group, where 77 % of the breast cancer in this study was observed. Similarly, in the > 60 years age groups, the sensitivity was 100 % and positive predictive value was also 100%. It indicated that 100 % study population in this age group had breast cancer in the present study. Hence, Breast-i could be considered as a first line screening tool for breast cancer after 40 years of age.

Discussion

The most prevalent cancer in the world is breast cancer. Compared to older women, women who are childbearing age experience rapid breast cancer progression. Lack of knowledge is to blame for the rise in mortality [8]. The goal of the current study was to use the breast-i-LED machine to screen for breast lesions. If a lesion was found, it was further investigated, and the outcomes were compared. The main tenet of breast cancer management is early diagnosis, which

often improves the survival outcome. Chemotherapy, radiation, and recently developed biologicals (human monoclonal antibody) are only a few of the non-surgical treatment options accessible [9]. Early detection thereby enhances and offers prompt access to treatment. Before any symptoms in women manifest, screening is conducted. It comprises different types of screening mammography, fully digital mammography, computer-aided detection software, clinical breast exams, breast self-exams, magnetic resonance imaging (MRI), and ultrasound. [10]. But these methods are not entirely accessible because of budgetary limitations and a lack of knowledge.

Breast-i-LED offers a visual representation of the breast. In a dimly lit chamber, the entire breast, including the nipples, is examined with the machine firmly pushed against the breast. The breast typically has complete transillumination. The results were classified as either favourable or negative. Positive results show the existence of darker patches, while negative results can show no breast abnormalities at all. The way that this machine operates is dependent on the amount of light that red blood cells absorb per unit volume of breast tissue. A typical, healthy breast has a uniform red colour and clearly visible black vein structure. However, angiogenesis associated with cancer will result in a black spot. [11]

The mean age of the study participants was 34 ± 1.2 years. This is because the study was skewed towards screening younger women as we wanted to determine the efficacy of the Breast-i in this group who would not use mammography services due to dense breast tissue. The majority of the participants were between the age of 34-37 years (42%) which was similar to an African study where the mean age was 34 to 41 years.

A study done among 150 females in Iraq which compared the results of clinical breast examination, mammography, ultrasound, and fine needle aspiration cytology (FNAC) as the gold standard for sensitivity and specificity. The study findings include Breast cancer in 24% of the cases, positive finding in 80.56% of the study population who were True Positive, negative findings in 19.44% who were false negative respectively. FNAC done revealed benign pathology in 73.72% among them. Of those, negative findings were recorded using the device in 53.47% who were True Negative, while the remaining 46.53% the device yielded false positive findings. The author concluded that there was a significant accuracy of detecting palpable malignant breast lumps, while there was a high false positive detection rate and the significantly low specificity in excluding malignancy preclude its use as a screening tool for breast cancer [12]. Another study done in Iran in 2013 on 500 women showed that the efficacy of Breast light in detection of breast changes as domestic apparatus was appropriate. However it recommended further studies to evaluate the Breast light efficacy and accuracy in detection of breast lesions [13].

Breast-i-LED is an adjunct tool for looking into insides of suspicious lumps found during clinical breast examination. Initially breast light was used for screening but due to its drawbacks including inability to detect small lesions, heat generation so Breast-i was devised to overcome these challenges. We found that the Breast-i breast exam positivity was greater than previous study [14]. In a clinical use

a higher positivity rate is more acceptable in screening. These devices are low cost with user friendly technology requires minimal training to identify asymptomatic women. This when combined with clinical breast examination helps in triaging patients who needs further evaluation. In a study done by Mango D et al, I Breast Exam and clinical breast examination when used together, reported sensitivity for suspicious masses would improve, but specificity would decrease. They also found better sensitivity and specificity for masses which are suspicious in non dense breasts as compared to dense breasts [15]. Xu and colleagues reported results of breast-i exam were not influenced by breast density [16]. The sensitivity decreases in clinical breast examination and breast-i exam to detect smaller lesions less than 2 cm. various studies reported the same [17,18]. In our study Breast-i was able to screening the abnormality in the breast with 100 % sensitivity and 50 % specificity in the age groups of 41-60 and > 60 years age groups. The diagnostic accuracy of breast-i compared with FNAC/Trucut biopsy was 81.25% at >40 years age group. Thus the study findings reveal high sensitivity supporting the use of Breast-i as an additional screening tool along with CBE and mammography.

Limitation

The study was done considering a small population which could be considered a limitation and most importantly as the diagnosis is also dependent on the physician's experiences there is a chance of observer bias in the study which can be ruled out by increasing the study samples and by blinding or by checking interrater reliability of observers diagnosis.

Conclusion

Breast-i-LED can be used readily to screen women for breast cancer. It has shown high positive predictive value and sensitivity. In locations where clinical breast examination is unavailable, this device might be used and patients can be referred early for management.

Declaration of patient consent:

The authors certify that they have obtained patient consent forms. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil

Conflicts of Interest

There are no conflicts of Interest.

Authors' contributions

All authors have read and agreed to the final manuscript.

References

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin*. 2021;71:209–249
2. International Agency for Research on Cancer. India Source: Globocan 2020.
3. Ferlay J, Colombet M, Soerjomataram I, Mathers C, Parkin DM, Piñeros M, Znaor A, Bray F. Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods. *Int J Cancer* 2019;144(8):1941-53.
4. Oestreicher N, Lehman CD, Seger DJ, Buist DS, White E. The incremental contribution of clinical breast examination to invasive cancer detection in a mammography screening program. *AJR Am J Roentgenol* 2005;184:428-32.
5. Kuhl CK, Schrading S, Leutner CC, Morakkabati-Spitz N, Wardelmann E, Fimmers R, et al. Mammography, breast ultrasound, and magnetic resonance imaging for surveillance of women at high familial risk for breast cancer. *J Clin Oncol* 2005;23:8469-76.
6. Research (IJSR) IJ of S and. Accuracy of Hopelight (Mammolight) Imaging in Detection of Breast Cancer. *Int J Sci Res IJSR* [Internet]. [cited 2020 Jun 22]; Available from: https://www.ijsr.net/get_abstract.php?paper_id=ART20176232
7. Ahmed A, Zahid I, Ladiwala ZFR, Sheikh R, Memon AS. Breast self-examination awareness and practices in young women in developing countries: A survey of female students in Karachi, Pakistan. *J Educ Health Promot*. 2018;7:90.
8. Sun Y-S, Zhao Z, Yang Z-N, Xu F, Lu H-J, Zhu Z-Y, et al. Risk Factors and Preventions of Breast Cancer. *Int J BiolSci* [Internet]. 2017 Nov 1 [cited 2020 Aug 22];13(11):1387–97. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5715522/>
9. Godavarty A, Rodriguez S, Jung Y-J, Gonzalez S. Optical imaging for breast cancer prescreening. *Breast Cancer Targets Ther* [Internet]. 2015 [cited 2020 Jun 26];7:193. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4516032/>
10. Jacob TC, Penn NE. The Need and Value of Breast Self-examination. *J Natl Med Assoc*. 1988 Jul;80(7):777–87. WHO | Breast cancer: prevention and control [Internet]. WHO. World Health Organization; [cited 2020 May 27]. Available from: <http://www.who.int/cancer/detection/breastcancer/en/>
11. Research (IJSR) IJ of S and. Accuracy of Hopelight (Mammolight) Imaging in Detection of Breast Cancer. *Int J Sci Res IJSR* [Internet]. [cited 2020 Jun 22]; Available from: https://www.ijsr.net/get_abstract.php?paper_id=ART20176232
12. Shiryazdi SM, Kargar S, Nasaj HT, Neamatzadeh H, Ghasemi N. The accuracy of Breastlight in detection of breast lesions. *Indian J Cancer* [Internet]. 2015 Jan 10 [cited 2020 Aug 22];52(4):513. Available from: <http://www.indianjcancer.com/article.asp?issn=0019-509X;year=2015;volume=52;issue=4;spage=513;epage=516;aulast=Shiryazdi;type=0>
13. Cacciamani GE, Shakir A, Tafuri A, Gill K, Han J, Ahmadi N, et al. Best practices in near-infrared fluorescence imaging with indocyanine green (NIRF/ICG)-guided

- robotic urologic surgery: a systematic review-based expert consensus. *World J Urol* [Internet]. 2020 Apr 1 [cited 2020 Aug 22];38(4):883–96. Available from: <https://doi.org/10.1007/s00345-019-02870-z>
14. Khandelwal R Health worker led breast examination in rural India using electro-mechanical hand-held breast palpation device. *J Cancer Prev Curr Res*. 2018; 9: 138-141
 15. Mango, Victoria & Olasehinde, Olalekan & Omisore, Adeleye & Wuraola, Funmilola & Famurewa, Olusola & Sevilimedu, Varadan & Knapp, Gregory & Steinberg, Evan & Akinmaye, Promise & Adewoyin, Boluwatife & Romanoff, Anya & Castle, Philip & Alatise, Olusegun & Kingham, T. (2022). The iBreastExam versus clinical breast examination for breast evaluation in high risk and symptomatic Nigerian women: a prospective study. *The Lancet Global Health*. 10. e555-e563. 10.1016/S2214-109X(22)00030-4.
 16. Xu X, Chung Y, Brooks AD, Shih WH, Shih WY. Development of array piezoelectric fingers towards in vivo breast tumour detection. *Rev Sci Instrum*. 2016; 87:124301
 17. Clanahan JM, Reddy S, Broach RB et al. Clinical utility of a hand-held scanner for breast cancer early detection and patient triage. *JCO Glob Oncol*. 2020; 6: 27-34
 18. Broach RB, Geha R, Englander BS, DeLaCruz L, Thrash H, Brooks AD. A cost-effective handheld breast scanner for use in low-resource environments: a validation study. *World J Surg Oncol*. 2016; 14: 277
 19. Ocasio-Villa F, Morales-Torres L, Velez-Medina N, Cubano LA, Orengo JC, Martinez EB. Evaluation of The Pink Luminous Breast LED-Based Technology Device as a Screening Tool for the Early Detection of Breast Abnormalities. *Frontiers in Medicine*. 2021;8.
 20. Suryasa, I. W., Rodríguez-Gámez, M., & Koldoris, T. (2021). The COVID-19 pandemic. *International Journal of Health Sciences*, 5(2), vi-ix. <https://doi.org/10.53730/ijhs.v5n2.2937>.