RESEARCH ARTICLE

Prospective evaluation of Tactile Breast examination by Visually Impaired for early detection of breast cancer in Indian women

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Abstract

Introduction: Breast cancer is the most common cancer in women around the world, including India. The peak incidence in India is occurring between the ages of 45 -49 years. The solution to problem lies in early detection. The two important methodologies are tactile examination and radiological assessment in form of Mammography. This study explores the concept of enabling and training visually impaired women known as Medical Tactile Examiners with enhanced tactile sense to perform Tactile Breast Examination (TBE) for early detection of Breast Cancer.

Material & Method: A total 1338 women were enrolled. Tactile Breast Examination included intensive and meticulous examination of every cm of breast by three different touch pressures using specialized strips to guide the visually impaired. It was preceded by recording information around lifestyle habits, pregnancy, lactation, menstruation, family history, etc. The radiological assessment included Ultrasound for women less than 40 years and Mammogram for 40 years and above. Data generated was statistically analyzed.

Results: 2.6% of 1338 women were doing routine breast screening; 16% had Body Mass Index > 30; 3% were into substance abuse; 7% experienced menstrual irregularities; 16% were nulliparous; 15% of the parous women had insufficient lactation. 5% had family history of Hereditary Breast and Ovarian Cancer and 4% had previous history of Breast Cancer. Tactile Breast Examination findings were normal in 756/1338 (56.5%), amongst which 8/756 (1%) had radiology reports with BIRADS 4 (suspicious for malignancy) findings. Medical Tactile Examiners during the process of TBE identified palpable breast alterations in 582/1338 (43.5%) of the cases, amongst which 29/582 (5%) were identified as BIRADS 4. The statistical analysis suggests Tactile Breast Examination having a high sensitivity (78.3%) and a very high negative predictive value (98.9%)

Conclusion: The process of Tactile Breast Examination by visually impaired appears apt for breast screening as it detects almost any aberration both benign and malignant in breast which is amenable to human touch and misses out in just 1% changes which can be malignant. It has the potential to become vocational avenue for visually impaired women.

INTRODUCTION

Breast cancer is the most common cancer in the female population across the globe. According to Globocan 2020[1], Breast Cancer component is 26.3 % of all cancers in the female population. Around 1,80,000 new cases are reported in India every year. The important fact of concern is that still 90,000 women die of breast cancer in India. This makes it 50% (1,80,000/90,000) mortality rate. When compared to western population i.e., those women living in the United Kingdom (UK) or United States of America (USA), the mortality rate in India is significantly higher[2].

Breast Cancer in India, affects much younger women. According to National Cancer Registry Programme (NCRP) 2010 – 2012, '5-year age distribution among different cancer registries across India, showed a peak incidence between 45 and 49 years and in north eastern India the peak is seen in the age bracket of 35 - 40 years[3]. Majority of women in India present when the cancer has reached advanced stage, according to Bhattacharya et al[4] 60% to 70% of all patients with breast cancer in the USA are diagnosed with stage 1 disease. In India, only approximately 1%to 8% of Indian women present with stage 1 disease. It is estimated that 10% of women in the USA present with stage IV disease. In India this number rises to approximately 24% stage IV presentation and 29% to 52% of stage III presentation[5]. There is progressive decrease in 5year survival as the stage of presentation advances[6],

The solution to the breast cancer problem lies in early detection of breast cancer by evolving effective screening methods/protocols. The two important methodologies of screening are tactile examination and radiological assessment. Mammogram is an established radiological screening methodology in the developed world. Its role s still indeterminate in Indian setting[7-8]. It has the following limitations:

1.   Being resource intensive, it requires large financial investment to set up a Mammogram facility.

2.   It requires highly trained manpower to perform mammography and analyze it.

3.   There is limited effectiveness of this methodology in screening women in the younger agegroup[9-10].

The Tactile methods are of two types (i) Self-Breast examination (SBE) and (ii) Clinical Breast Examination (CBE). SBE is being aware of one's own breast. It involves regular inspection and tactile examination to identify a new lump/swelling/change in the breast. According to Aggarwal et al[11] SBE is a desirable change in behavior of females in India. This will help in early detection and control of Breast Cancer. SBE is a simple methodology. It has limited acceptability due to lackof proper knowledge and confidence. Whether practicing breast Self-Breast Examination actually helps to reduce the mortality from breast cancer **is still unclear**. The US Preventive Health Services Task Force[12] has concluded that "there is too little evidence to either recommend or discourage breast self-examination".

Clinical Breast Examination (CBE) involves scheduled tactile examination by clinician or trained personnel to identify a new lump/swelling/change in the breast. It has been proven by Dinshaw etal[13] that CBE is an effective methodology for Breast Cancer Screening especially in the younger age group. Substantial efforts are being put in to increase the trained manpower to perform CBE and increase the awareness among women to undergo scheduled CBE.

In an attempt to find solution to the problem of lack of early detection of breast cancer, the present study explores the concept of enabling and training visually impaired women known as Medical Tactile Examiners (MTE) and to use their inherently enhanced tactile sense to perform breast examination described as Tactile Breast Examination (TBE) for early detection of Breast Cancer. According to Goldreich et al[14-15], tactile acuity is enhanced in blindness. The women with special abilities are trained through a standardized registered discovering hands ® training program. This concept was developed by a German Doctor, Dr Frank Hoffman[16]. It has been successful in Germany and Austria. The study by Dr Lux et al conducted at Erlangen[17] (Germany) suggested that the predictive value for a suspicious breast lesion in CBEs performed by MTEs in patients without prior surgery was similar to that of physician-conducted CBEs.

OBJECTIVE OF THE STUDY
The objective of the study is to understand the role of Tactile Breast Examination by visually impaired in early detection of breast cancer.

MATERIAL & METHODS
After giving informed consent, 1500 women from Gurugram (suburb of Delhi; capital of India) between the age groups of 30 to 70 years belonging to middle and upper middle class strata of society chose at random to participate in the study between 2019 and 2020. Due to the commencement of the COVID-19 Pandemic, the research was closed in March 2020. A total of 1338 participants were examined. The woman underwent a TBE by an MTE, followed by a radiological screening test appropriate for her age.

Figure 1: Process of Data Collection
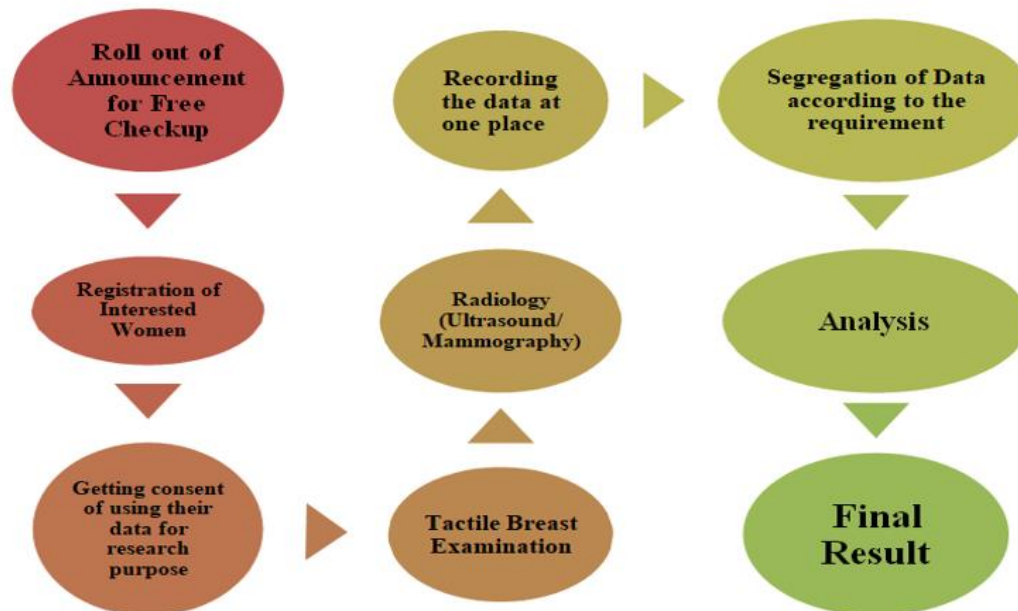
The research study was conducted at CK Birla Hospital, Gurgaon. The protocols were approved by the Ethical Committee of CK Birla Hospital. The process of TBE includes

1. Recording history

   1.1. **General History**- Height, Weight, Physical Activity status (as determined by question), Intake of alcohol and nicotine

   1.2. **History of Pregnancy**- No. of pregnancies, No, of child births, Age at first child birth and Duration of breastfeeding

   1.3. **Menstruation History**- Age at onset of menstruation, last menstruation, menstrual cycle duration, menstrual bleeding duration, any kind of irregularity in the menstruation and any complaints regarding the menstruation period

   1.4. **Menopause History**- Age or year of attaining menopause, Menopausal Symptoms and Details of current

Hormone Replacement medication (if any).

   1.5. **Medication Details**- Hormone Containing Contraceptives (current and/or past), Any other medicines (for BP, Thyroid, Diabetes and Antidepressant)

   1.6. **Medical Cancer Checkups**- Recording of last Cancer Screening, Last Ultrasound/ Sonography and Last Mammography

   1.7. **Any Finding from the above checkup**- Malignant, Benign, Ovarian Cancer

   1.8. **Self-Findings**- Breast Self-Examination (skin changes, erythema, changes in the nipples, secretion, any discomfort)

   1.9. **Details of History of Cancer in the family**- Nature of cancer and patient's relationship with the family member

   1.10. **Details of any surgeries**- Breast

conserving, Ablation/Mastectomy, Axillary Dissection,Breast Implant, Breast Lifting, Breast Reduction

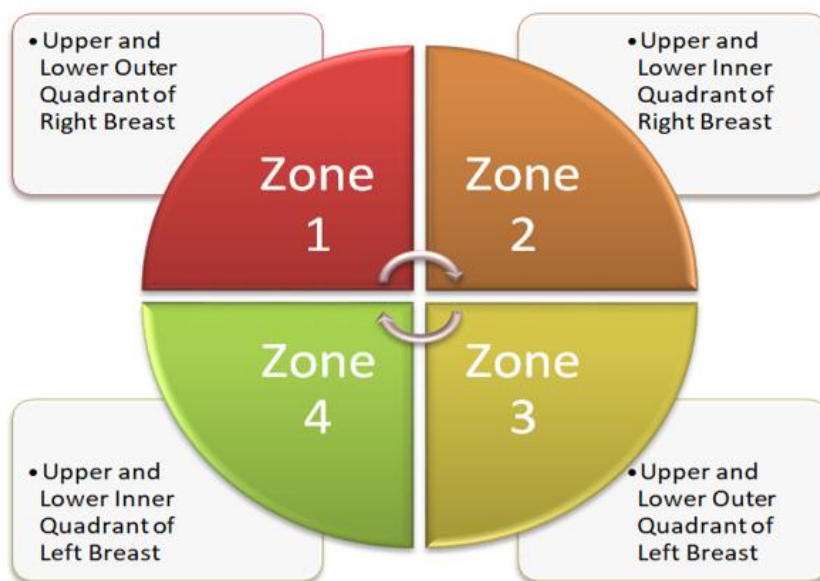1.11. **Therapies**- Radiotherapy, Chemotherapy and Anti-hormonal Therapy

2. **Process of TBE: The process of TBE is divided into following steps-**

2.1. **Position 1: Sitting Position** – In this position, the patient sits on the examination bed (back of knees should be in contact with the bed). The MTE checks the cervical lymph nodes, supraclavicular and infraclavicular lymph nodes, and axillary lymph nodes, temperature of both breasts (by using back of the palm) and changes on the skin of both breasts. MTEs also apply pressure on the breast to check any half-filled cyst which is hard to identify in the lying position.

2.2. **Application of DOCOS** - DOCOS (Documentation and Orientation System) is a braille tapepatented by discovering hands® and is used by MTEs to divide the breast into 4 zones.

Figure 2: Details of Zones and Quadrants

- Upper and Lower Outer Quadrant of Right Breast — Zone 1
- Upper and Lower Inner Quadrant of Right Breast — Zone 2
- Upper and Lower Inner Quadrant of Left Breast — Zone 4
- Upper and Lower Outer Quadrant of Left Breast — Zone 3

2.3.**Palpation**- MTEs checks both breasts in their area and depth extent with special considerationof the retromammary region. MTEs do the waltz movement (1-2-3-4-5-6) and apply 3 different pressures (4-subcutaneous, 5-medial, 6-thorax). The palpation is done in the following sequence-

- Zone 1- Position 2: Left-half Lateral Position
- Zone 2- Position 3: Supine Position
- Zone 3- Position 4: Right-half Lateral Position
- Zone 4- Position 5: Supine Position

2.4.**Checking of Retro mammary region**- While removing the DOCOS, MTEs palpate

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the area covered under the DOCOS and nipple area to check for any secretions.

3. Recording of findings by MTE

 3.1. **Skin Findings**- Peau d orange, Indentations, Eczema, Changes in Nipples

 3.2. **Other Abnormalities**- Asymmetries between the breasts, Temperature differences and anyother abnormalities

 3.3. **Lymph Nodes**- Movability and Consistency of Cervical lymph nodes, Supraclavicular & Infraclavicular lymph nodes and Axillary lymph nodes.

 3.4. **Description of findings**- The findings are explained under 7 heading which are as follows:

- **Location**- In x and y axis
- **Size**- In cm and ½ cm
- **Form**- Shape of the abnormalities (round, oval, angular, oblong, irregular)
- **Consistency**- In terms of thickness of the abnormalities (soft, soft pressed, elastictough, rough)
- **Surface Structure**- Description of surface of the abnormalities (even, uneven)
- **Displacement of the environment**- In terms of movability of the abnormalities(easy to move, not very flexible, not displaceable)
- **Demarcation/ Delineation against the surroundings**- Description of relationshipwith the surroundings (well demarcated, little definable, badly distinguishable)
- **Location in the Tissue**- In terms of depth in the breast tissue

(subcutaneous,medial, thorax)

The above examination on an average takes 30-45 minutes. The process of TBE was done by MTE under the supervision of medical personnel (gynecologist or radiologist or oncologist). The TBE results were categorized as

- Negative: MTE did not feel anything
- Positive: MTE reported palpable findings. They were further categorized into
- Definitive Lumps: MTE reported well defined lesions
- Vague Palpable findings: MTE reported palpable findings, but they did not feel aswell-defined lumps.

For statistical analysis both the definitive and vague palpable lesions reported were taken as positive TBE.

The radiological screening was decided as per the woman's age.

- Women less than 40 years underwent Ultrasound of Breast
- Women of 40 years or above underwent Mammogram. In those women having higher breast density on mammogram, it was supplemented with ultrasound.

The radiological findings were divided into BIRADS categories. The Breast Imaging Reporting and Data System (BI-RADS) were developed by the American College of Radiology (ACR) to reduce variation in the radiologists' descriptions of findings used for diagnosis. BI-RADS includes[18]:

 i. A standard lexicon to describe anatomical features present in breast imaging (Table 1).

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ii. A classification system designed to categorize by likelihood of malignancy, independently to each breast (Table 1).

Table 1: Description of BI-RADS assessment categories[18]:

BI-RADS Category	Final Assessment meaning	Likelihood of Breast Cancer
0	Need Additional imaging evaluation and/or prior imaging for comparison	Not Applicable
1	Negative	Negligible
2	Benign Finding	Negligible
3	Probably benign finding	<2%
4	Suggestive of abnormalities	23-34%
5	Highly suggestive of malignancy	>=95%
6	Malignancy confirmed by biopsy	100%

Statistical Analysis was carried out comparing TBE findings with the radiological BIRADS category.

RESULTS

The data of 1338 women collected between March 2019 and March 2020, was recorded as under.

1. Table 2 presents the following:

    1.1. The study group had a 40% under-40 population.

    1.2. Premenopausal or perimenopausal women made up 74% of the sample.

    1.3. Around 16% of women had a BMI of more than 30 and fewer than half of sample exercised regularly.

    1.4. 39% (520/1328) of women had undergone some breast screening (either CBE or Ultrasound or Mammogram), with only 2.6% (36/520) doing so on a regular basis.

Table 2. Details of 1338 women with respect to different variables

S. No.	Situation	Criteria	Numbers
1	Age of the participants	Age < 40 years	540
		Age >= 40 years	798
2	Menstruation Stage	Pre/ Peri Menopause	995
		Post Menopause	343
3	Body Mass Index (BMI)	BMI < 25	673
		BMI = 25-30	447
		BMI > 30	218
4	Physical Activity	Regular	661
		Irregular	677
5	Previous Screening for Breast Cancer	Yes	520
	Frequency	Regular	36
		Irregular	484
		Never	818

2. Using Table 3 as a reference, the following can be deduced:

2.1. 2% had experienced early menarche in the past while 7% had irregular menstruation.

2.2. 3% of the female population used addictive substances like alcohol and cigarettes.

2.3. Approximately 16% of the overall sample was nulliparous, while 15% of the parouswomen had a history of insufficient breastfeeding.

Table 3. Details with respect to the different variable

S. No.	Situation	Criteria	Numbers
1	Smoking	Regular	45
		Irregular/Never	1293
2	Alcohol consumption	Regular	37
		Irregular/Never	1301
3	Menarche Age	Age <= 11 years (EarlyMenarche)	27
		Age > 11 years	1310
4	Menstrual Cycle	Regular	928
		Irregular	75
5	Pregnancy Status	Nulliparous	208
		Para (<=2)	999
		Para (>=3)	137
6	Lactation Period	< 4 months	168
		>= 4 months	962

3. The following can be derived using Table 4 as a guide:

    3.1. Breast cancer survivors made up 4% of the total sample size.

    3.2. A total of 35 women and 28 women each shared a history of breast and/or ovarian cancer in first-degree and second-degree family members respectively.

3.3. Approximately 5% of the population required genetic counselling for breast cancer.

3.4. Only axillary (armpit) lymph nodes were seen in 5/1338 (0.3%) of the women.

3.5. 31/1338 (2.3%) patients showed synchronous lymph node enlargement and breast alterations

Table 4. Details with respect to the given situation

S. No.	Situation	Criteria	Numbers
1	Personal Breast Cancer History	Yes	56
		No	1282
2	Hereditary Breast and Ovarian Cancer (HBOC)	1st Degree	35
		2nd Degree	28
3	Finding in Lymph Nodes	Only Lymph Nodes	5
		Only Breast Lump (Defined Lumps)	493
		Only Breast Lump (Vague Findings)	208
		Lymph Nodes and Breast Lump (Defined Lumps)	21
		Lymph Nodes and Breast Lump (Vague Findings)	10

4. The following can be derived using Table 5 and Graph 1 & 2:

    4.1. TBE findings were normal in 756/1338 (56.5%) of the population, indicating that MTE was unable to identify any change. During radiological assessment of TBE normal women, 693/756 (91.5%) had a BIRADS score of 2 or below, 55/756 (7%) had BIRADS 3, and 8/756 (1%) had BIRADS 4.
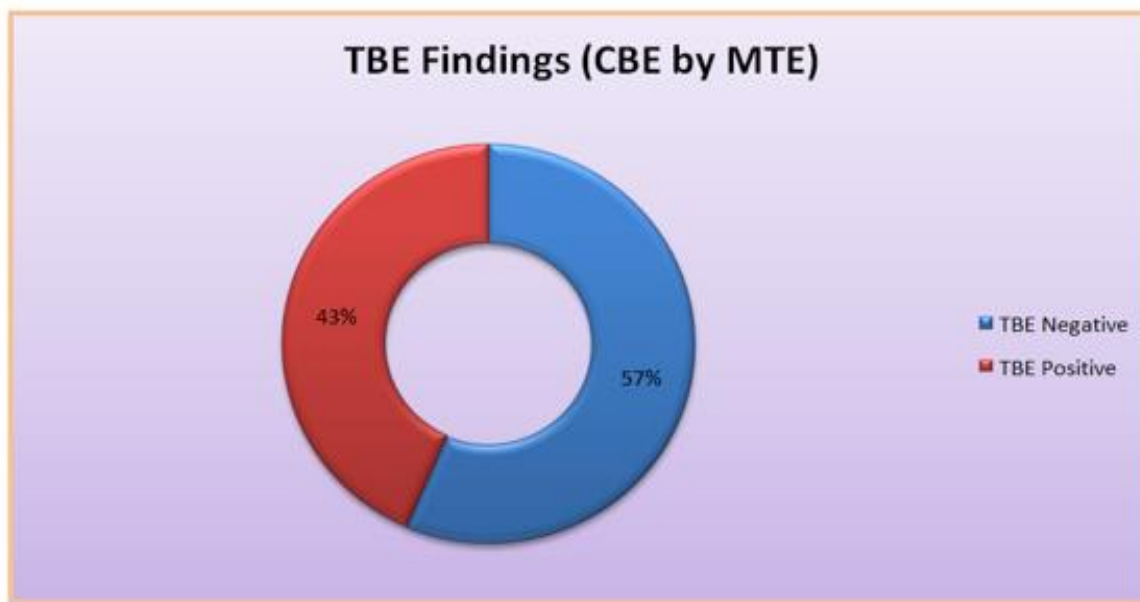
4.2. TBE was positive in 582/1338 (43.5%) of the cases, indicating that MTE identified breast alterations. During radiological assessment of TBE positive women, 449/582 (77%) of the lesions had a BIRADS score of 2 or less, 104/582 (17.8%) had BIRADS 3, and 29/582 (5%) were BIRADS 4 lesions.

Table 5. Details of findings

S. No.	MTE Report	Radiology Report	Numbers
1	MTE Negative	BIRADS 0	58
		BIRADS Negative (1 or 2)	635
		BIRADS Equivocal (3)	55
		BIRADS Positive (4 and above)	8
2	MTE Positive	BIRADS 0	37
		BIRADS Negative (1 or 2)	412
		BIRADS Equivocal (3)	104
		BIRADS Positive (4 and above)	29

Graph 1: TBE Findings (CBE by MTE)

TBE Findings (CBE by MTE)

43% — TBE Positive
57% — TBE Negative

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Graph 2: TBE Finding in correlation with Radiology Finding

TBE Finding in correlation with Radiology Finding

	BIRADS 0	BIRADS Negative (1 or 2)	BIRADS Equivocal (3)	BIRADS Positive (4 and above)
TBE Negative= 756	58	635	55	8
TBE Positive= 582	37	412	104	29
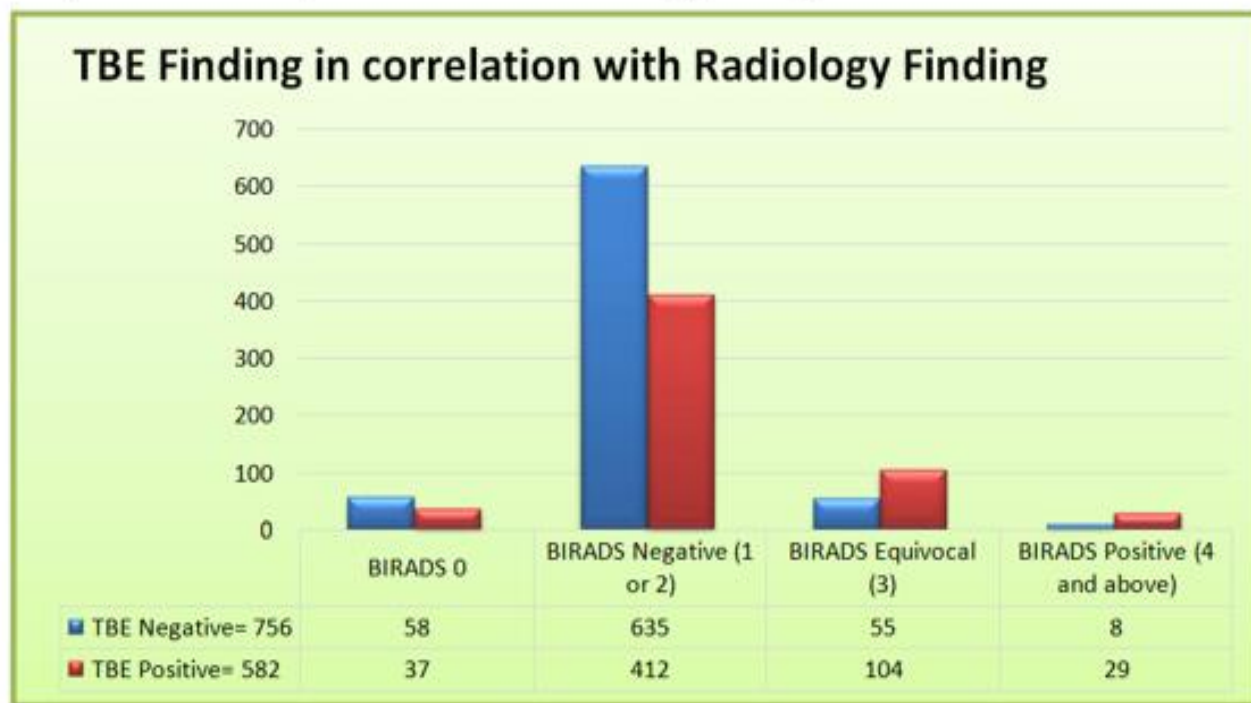
DISCUSSION

The study comprises of middle-income women living in urban settings in India. 74% (995) of women involved in the screening process were in either pre-menopausal or perimenopausal stages. A total of 40% (540) of the entire study group were under the age of 40, while 38% (520/1338) women had undergone following breast screening, such as a CBE, ultrasound, or mammogram. These findings indicate a strong desire among younger pre/perimenopausal women to learn about methods for detecting breast cancer early. They are nolonger afraid to bring up the issue of breast cancer.

The fact that only 2.6 % of our study population appears to follow breast cancer screening on a routine basis indicates a lack of awareness about the proper methodologies for breast cancer screening, as well as a lack of confidence or apprehension about the overall effectiveness and adverse effects of the known methodologies. According to the 2019-21 National Family Health Survey (NFHS)[19] data, just 1.2 % of Indian women in urban areas really choose Breast Screening.

A recent study by Gupta et al[20] observed that Indian women, regardless of their socioeconomic oreducational status, possess low cancer literacy when it refers to breast cancer risk factors. To enhance cancer literacy in India, there is an urgent need for national and state-wide awareness programs that involve different stakeholders from society and the health system.

The process of Tactile Breast Examination (TBE) is a step towards increasing the Breast Cancer literacy. It involves assessment of

certain factors influencing the occurrence of Breast Cancer. As documented in results Tables 2 & 3 the prevalence of raised BMI, substance abuse, early menarche, irregular menstruation, nulliparity, inadequate lactation was recorded. There is lot of evidence[21-31] explaining the role each of the abovementioned factors play influencing the incidence of breast cancer. In due course process of TBE may become the source of data on which population based primordial prevention decisions/policies can be based.

In our research population, 4% of the women had a history of breast cancer. After surviving a breast cancer, women have a two to sixfold increase in the likelihood of acquiring a second breast cancer in the contralateral breast[32-33]. A 4 % breast cancer survivor population indicates a high prevalence of illness and an increasing necessity for women to include breast cancer screening intotheir lifestyle.

There is a certain subtype of breast cancer that has a genetic propensity and runs in families. According to Bernard et al, women with breast cancer in their first-degree family had a twofold increase in chance of having the disease, with a significant increase in risk among women with a first-degree relative diagnosed before age of 50 years as compared to after age of 50 years[34-35]. In general, 15 to 20% of the total breast cancer is considered familial[36-37]. In northern India, 5% of women in thegeneral population have a documented familial history, indicating a relatively high incidence of hereditary/ familial breast cancer. More resources should be invested in identifying women with family susceptibility so that early intervention in the form of intense surveillance and correctly timed risk-reducing surgery may be done to save valuable lives, according to our findings.

With no notable alterations in the breast, 0.3% (5/1338) of the group showed isolated axillary lymph node enlargement. On imaging, none of the isolated axillary lymph nodes were determined to be abnormal. It is consistent with breast cancer biology, since the total percentage of occultprimary breast cancer in axillary lymph nodes is less than 1%[38].

The data around the role of CBE in Screening for Breast cancer remains inconclusive. According to ACOG[39], CBE may be administered to asymptomatic, average-risk women; however, the extra advantages of CBE remain unknown. A recent ACS systematic review[40] identified no research that established a link between CBE and mortality. Three studies in the systematic review revealed that CBE in conjunction with mammography had a significant false-positive rate, with around 55 false-positive test findings for every one instance of cancer detected. According to Fenton et al[41], an anomaly was detected on screening CBE in just one of every five breast cancer patients (sensitivity = 21.6%; 95 % confidence interval [CI] = 18.1% to 25.6%). CBE misses four out of every five instances. As a result, CBE has yet to be proven as a viable modality for screening breast cancer. It also has a high false positivity rate and misses a substantial number of cases (80%), putting a spin on its effectiveness and reliability. According to Hoff

et al[42], full field digital mammography too misses around 30% of interval cancers.

In our study, 56.5% of women were reported to be normal following TBE. When reviewed with radiology, more than 90% were labelled as BIRADS 2 or less, 7% of cases radiology suggested BIRADS 3 alterations, and just 1% of normal TBE reports were BIRADS 4. Labelling BIRADS 4 as suspicious of malignancy, 1 % false negative rate of TBE is highly appreciable.

TBE observed changes in around 43% of the study group. The majority of TBE alterations were benign, including fibroadenomas, fibrocystic abnormalities, and increased fibro

glandular tissue. It is the 5% who, after additional confirmation by radiography, were found to be highly suggestive of malignancy, i.e., a BIRADS 4 lesion.

Malvia et al[43] claim that in Delhi, the age adjusted incidence rate of breast cancer is 4%. 2.7 percent of our research sample, which consisted of urban random women from the Delhi NCR, had BIRADS-4 lesions, which are strongly indicative of malignancy. This number shows that the study group has an extremely high prevalence of breast cancer. TBE looks to be an excellent tool for spotting suspicious lesions. TBE identified 29 out of 37 under BIRADS-4 category.

Table 6. True Positive and True Negative

TBE	True Negative	False Negative	Total
Negative	748	8	756
	True Positive	False Positive	
Positive	29	553	582
			1338

Sensitivity = True positive/ (True positive + False Negative) * 100 = 78.3%
Negative predictive value = True Negative/ (True Negative + False Negative) * 100 = 98.9%

According to the statistical study, TBE has a high sensitivity and a very high negative predictive value for identifying suspicious lesions in the breast.

TBE's significance in early diagnosis of breast cancer is defined by its high sensitivity and very strong negative predictive value[44]. TBE will assist in finding alterations in the breast that require additional assessment, and those women who come out normal following TBE have a very high chance that the cancer was not overlooked.

Although only 1 in 20 alterations observed in TBE are very suggestive for malignancy, this is better than 1 in 55 in CBE[40] Furthermore, just one suspicious alteration will be overlooked after TBE, implying that TBE is far more accurate than CBE[40]. It illustrates the value of a visually impaired trained woman's heightened tactile sense in identifying such a malignant disease of breast cancer over normal vision medical personnel.

According to this study, visually impaired women's high levels of innate touch and focus play a significant role in their ability to detect even the slightest abnormalities in the breast. As a result,the training is enabling more blind women across the nation to lead independent lives through a new type of profession as an MTE.

CONCLUSION

The Indian women have increasingly become more concerned about the rising incidence of Breast Cancer. They are not sure/confident about the methodology to be adopted for detecting this disease early which leads to increase in chances of cure.

This study evaluated the use of enhanced tactile sense of trained visually impaired women (MTE)for detecting Breast lesions by palpation. The methodology shows very promising results, MTE is able to detect palpatory findings in more than 40% women and 5% of these harbor changes which are suspicious for malignant process. More importantly those who were labeled normal only 1% was the probability of missing a malignant process.

During the process of Tactile Breast Examination (TBE), the MTE does an elaborative history taking. This increases Breast Cancer awareness and has provides valuable insights on Indian woman, especially their BMI, exercise routine, habit of substance abuse, menstrual habits, parity and lactation. Also, it records the prevalence of strong family history and breast cancer survivors in the study population.

The process of TBE can play a very important role in Early detection of breast cancer. As a methodology it is very apt for screening as it detects almost any aberration both benign and malignant in breast which is amenable to human touch and misses out in just 1% changes which can be malignant. This will also generate a decent vocational avenue for visually impaired women.
'*It is probably for the first time that differently abled can perform something better than us who are enabled.*'

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Conflicts of Interest Statement:
None

LIMITATIONS OF THE STUDY
1. There were only 2 MTEs available for the screenings.
2. MTEs were allowed to use the standardized screening technique of discovering hand®.
3. Selection of study population: self-selected (through word-of-mouth and advertisement)
4. The study population was from Delhi NCR (National Capital Region).
5. Consent Form was mandatory. It was made in English and Hindi.

6. Excluding women aging less than 18 years.
7. Excluding pregnant and lactating women.
8. Excluding women who underwent only one method of screening.
9. Limitations of TBE:
9.1. The breast to be examined is too big
9.2. The breast tissue is too dense (mastopathic)
9.3. The breast to be examined cannot be reliably assessed by previous treatments. Eg. Radiogenic tissue changes
9.4. Extensive scarring (previous operation)
9.5. The breast to be examined is too sensitive to pain (pronounced mastodynia)
9.6. The presence of fresh effects (eg., mastitis, hematoma, diagnostic procedure such astissue punching).

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