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Validation of cost-effective model for breast self-examination

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Introduction: The incidence of breast cancer is increasing in India; it predominantly affects women in their 30s and 40s. The disease burden is very high given the high incidence of triple-negative disease in a large portion of the population. Early detection can save lives and aid in breast conservation surgery. Breast self-examination (BSE) is a valid tool for early breast cancer detection. If performed with the help of a simulation model that resembles a given culture and tradition, it can result in good outcomes from screening programs. We designed and validated an Indian model for BSE and reported the feasibility of this model.

Materials and methods: We designed an Indian model for the BSE based on the cultural mindset of Indian women. The design was finalized, and the model was constructed. It was then compared with preexisting international models and validated by in-depth interviews with validation experts from various fields involved in breast cancer management. Minor design revisions were made, followed by testing and re-testing. Finally, it was ready for public use.

Results: The in-depth interview was conducted using a validated modified animation multimedia questionnaire. The majority of the validation experts had used stimulation models before, and all stated that it could help teach women about BSE, and it was comparable with other preexisting internationally validated models (91.33 ± 4.98%).

Conclusion: Using a breast model, women can learn to detect breast cancer as early as possible, and this can lead to good outcomes. We designed the model using easily available, cheap, and safe materials to keep it as realistic and useful as possible. The Indian BSE model can be used by Indian women to learn to detect breast lumps early. It is easily reproducible and cost-effective.

Keywords: animation video, breast cancer, breast self-examination, simulation models

Introduction

Breast cancer is the most common cancer among women worldwide and is one of the leading causes of cancer-related deaths in women today[1]. However, breast cancer awareness is poor in low-income countries (a mere 7.3% of women in Kashmir) as has been reported by Malik *et al*.[2] Consequently, the percentage of women performing regular BSE is still more varied between developed and developing countries. There are no uniform guidelines available in India for breast cancer screening because of the varying standards of medical care provided according to income level. Therefore, increasing the awareness of this disease among women is imperative. The best way forward is to involve them as active participants in detecting the disease and raising awareness of breast cancer by means as simple as a BSE[3]. This paper aims to help educate women on the importance of early detection of breast cancer and early presentation to healthcare centers to ensure a high chance of a complete cure.

HIGHLIGHTS

- Breast self-examination (BSE) is still a useful tool in developing countries.
- Simulation models are useful, however, may be costly.
- We have developed a cost-effective model which can be made easily.

A substantial amount of research has been conducted on the factors influencing the behavior of women regarding performing BSEs. A few studies have shown that BSEs can help in early detection of breast cancer and, thus, decrease the risk of mortality. In a developing country such as India, many factors play a role in the utilization of BSE as a tool for screening[1]. One of the most important factors that can promote BSEs is the terror management theory. This theory explains that when we unconsciously think of death, we try to empower ourselves and a behavioral change with the intention to engage in life-saving activities occurs (e.g. performing BSEs gives women an opportunity to empower themselves by taking charge of their health)[4,5]. Indeed, 90% of all breast lumps are detected by women who perform regular BSEs. Although 80% of breast lumps are not cancerous, serious malignant changes can be detected early, thus improving survival rates. In this scenario, the steps of a BSE, the need to perform a BSE, and the probable

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outcomes of a BSE should be explained to women so that they can perform BSEs regularly and correctly.

Methodologies can be explained using specific tools. A breast simulation model is one such tool that can help impart effective and useful information on BSE to women. New simulators available in the market are made of materials that provide human breast-like sensation and facilitate the identification of signs of breast tumors, including skin dimpling, redness, and lumps in the breast, suggestive of breast cyst/fibroadenoma and/or tumors. The appearance and texture of these life-sized models facilitate life-like clinical training. In campaigns aiming to increase awareness about breast cancer and BSEs, the use of learning aids and simulation devices can result in long-term efficiency and overall adherence to screening protocols[6,7].

Dey *et al*.[8] confirmed the observations that shyness, fear, and posteriority among Indian women are major behavioral barriers that prevent them from seeking professional help. Unfortunately, the myth that investigations like fine needle aspiration cytology and tru-cut biopsy cause the spread of cancer in the rest of the body is upheld in our society. Previous deaths in families due to breast cancer are stigmatized so much that most people believe that breast cancer is not curable; therefore, performing a BSE or participating in screening programs is not considered worthwhile.

This ambivalence shown by women in prioritizing their own health and social and behavioral hurdles must be addressed.

Hence, we aimed to formulate a method to help reduce the stigma associated with breast cancer in our society. An Indian breast simulation model for BSE was developed with the intent of catering to the needs of Indian women. We prepared a breast simulation model using commonly available materials and named it the "SGPGI Indian Model." This model was then compared with other validated models and the efficacy of our model was tested. This research was designed for and aimed at consumer needs – a BSE simulator for Indian women and its use for teaching Indian women the concept of BSE, thereby propagating this method of screening and increasing awareness of breast cancer.

Materials and methods

This hospital-based validation study was conducted in the Department of Endocrine Surgery and Breast Surgery at a tertiary care hospital in North India. We designed an Indian breast simulation model in accordance with Indian culture to make it appealing to our population. In our Indian model, both breast mounds are clothed, so it is aligned with the cultural mindset of Indian women. The torso was that of a mannequin available in model shops, and the breast mounds were made of sponge and foam covered with cloth. The nipple was modeled using purse-string sutures placed over the cloth. The left breast mound was like a normal breast. In the right breast mound, we inserted a torn cricket ball with a cork to simulate a hard tumor in the upper outer quadrant, which is the most common site of breast cancer[9]. Our team of validation experts comprised of a breast and endocrine surgeon, a medical oncologist, a radiation oncologist, and a model designer. Once the first model design was made, we conducted in-depth interviews with the validation experts who were then asked to complete modified multimedia questionnaires. The data from the questionnaire and their feedback was utilized to revise the model. Once the model was revised as per advice from validation experts, it was again re-tested. The Indian model was found comparable in terms of appearance, texture, and utility, with the other two previously validated models from the UK and Germany, and was then released for public use[8]. Data analysis was performed by a statistician. The ethics committee approved the study, which was the first step in the validation of our model (Figures 1–3).

Step by step methodology applied for validation of the Indian BSE model is as follows:

(1) Potential problems of the BSE simulation model for Indian women identified.
(2) Data collection on requirements for model preparation done.
(3) Product design for the model made based on the potential problems identified in step 1.
(4) Model design made and validated by other healthcare professionals (validation experts).
(5) Model revision done based on feedback received by validation experts.
(6) Final model design ready.
(7) Final model re-tested and validated by the same validation experts.
(8) Indian model ready for public use.

Statistical analysis

Descriptive statistics of the quantitative variables are presented as mean ± SD, while categorical data are presented as frequencies (%). The independent-samples *t*-test was used to compare the distributions, whereas Fisher's exact test was used to compare the proportions between the groups. Statistical significance was set at *P*-value less than 0.05. The Statistical Package for Social Sciences, version 23 was used for data analysis.

Results

An in-depth interview was conducted using a validated, modified animation multimedia questionnaire. After validation of the design, the model was revised and re-tested.

Most of the validation experts (80%) had used BSE simulation models before. Overall, 100% agreed that this Indian model would help educate women about BSE. They also rated this model as comparable with other existing models from UK and Germany (91.33 ± 4.98%) (Table 1). There was a statistically significant difference between the years of experience of male and female radiation oncologists ($P = 0.006$).

Discussion

Confucius said, "I hear and forget, I see, and remember, I do, and I understand." – This is the concept behind our model. This means that once a woman is encouraged to perform a BSE herself, she will understand the correct methodology and its importance.

We first gathered information regarding our model and created this model from materials that are easily available so that other centers can easily replicate it. The materials are cheap, durable, realistic, safe, and like those used in other validated models[10].

We want Indian women to be comfortable performing BSEs. The women felt embarrassed to examine the unclothed breast mounds in the existing model; hence, we decided to clothe our model in line with traditional Indian values. The most common

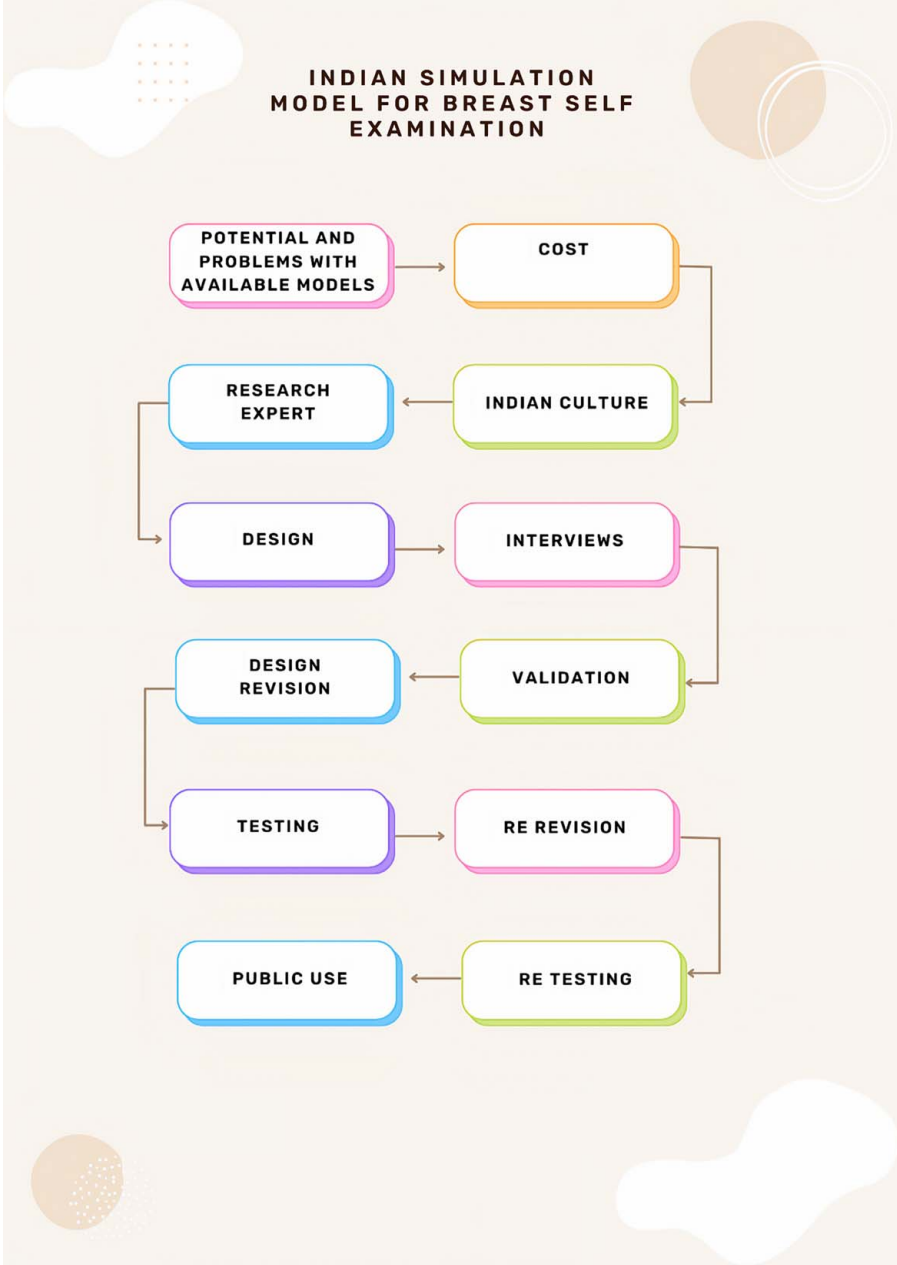

Figure 1. Validation of Indian model of breast self-examination.

site for breast cancer is the upper outer quadrant hence in our model, a hard tumor was placed in the same quadrant of the right breast.

Once the model designer was confident about the structure and anatomy of the breast, it was validated with the help of experts. The experts from different fields were satisfied with the structure and feel of the model; however, we initially used a pebble to simulate the breast lump, which was later changed to a cricket ball with a cork, based on expert advice. This change ensured that the tumor was hard, with irregular edges, and did not move.

This simulation of real-life scenarios provided adequate knowledge to help Indian woman easily detect a lump measuring 1 cm. This simulation is much better than the knowledge gathered by lectures, books, or pamphlets alone[11,12] because it enhances the learning process for these women in a controlled and safe environment[13]. Repeated examinations are needed to help women enhance their lump-detection skills. The German and English models cost INR 15 000 and 1 00 000, respectively. In comparison, the Indian model costs INR 1500 only. The time taken to create this model was only 3–5 days. In our previous studies, we found that simulation models helped the users better understanding the issue in question than other forms of information[14].

BSE helps women be aware of the appearance and nature of their breasts. Any changes noted by a woman during BSE can prompt her to report to a healthcare provider. The American

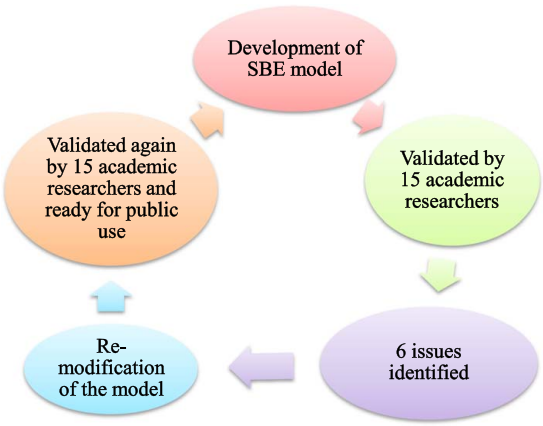

Figure 2. Flowchart of validation and revision of Indian model for breast self-examination.

cancer society does not recommend BSE as a screening tool for breast cancer as it is not associated with decreased mortality independently. In the western part of the world, annual screening mammography is widely available, and it has increased the awareness of the western women to breast cancer detection[15]. Moreover, majority of the population in the developed countries is insured so health concerns are not a burden to them.

In developing countries like India, no separate guidelines for breast cancer screening exist. Access to mammography for our women is a challenge. Majority of our women belong to low socio-economic strata, have less education, and do not seek care upon feeling a breast lump. This is attributed to their unawareness that what the lump represents, stigma of being rejected by the community and her partner, potential fear of loss of the breast, and the major obstacle being the prevailing taboo of not discussing breast cancer topic openly, and disbelief of existence of any effective therapy for the disease[16].

It us this disbelief among our women which needs to be erased and the best way to do is to take baby steps. Our screening program should include mammography and BSE and primary healthcare facilities should be mobilized to get BSE awareness at the doorstep.

BSE has been found to be the most reasonable and feasible approach in early detection and reduction of breast cancer mortality in India and other developing countries[15,16]. Studies from India suggested BSE can be used as a tool of creating breast health awareness among women and trained female health workers can play a promising role in disseminating this knowledge among women to carry out BSE[17,18].

In this study, the Indian simulation model was well accepted by the validation experts. They were regarded as useful tools for learning about BSE and spreading this information to lay women. Simulation models provide the necessary tactile input; however, the breast surgeons and their teams need to emphasize the right method of BSE using the simulation models.

We found that most Indian women were not aware of BSE except if any family member had suffered from breast cancer[14,19] and so a combination of both animation video and simulation model may provide better results. Here, where the interaction time between the patient and the consultant is suboptimal[20], it may be problematic for surgeons to teach BSE to women, which takes 12–15 min. Therefore, such a simulation model and the involvement of breast nurses[21–25] could be of great help in increasing the understanding of various aspects of BSE.

The issues surrounding breast cancer are different in developing countries compared with high-income nations. BSE could enable women to approach the healthcare system early, resulting in better outcomes[26–30]. In low-resource settings, simulation models in accordance with the culture of the women could be useful[31].

In the Indian context, we believe that the tactile sensation of the tumor in simulation models can help women better understand what a breast lump feels like than written or verbal explanations. Early detection is an important factor in the success of breast cancer treatment. The earlier the breast cancer is diagnosed, the more easily and successfully it can be treated, and the Indian simulation model for BSE has been designed to meet this important aim of breast cancer screening campaigns.

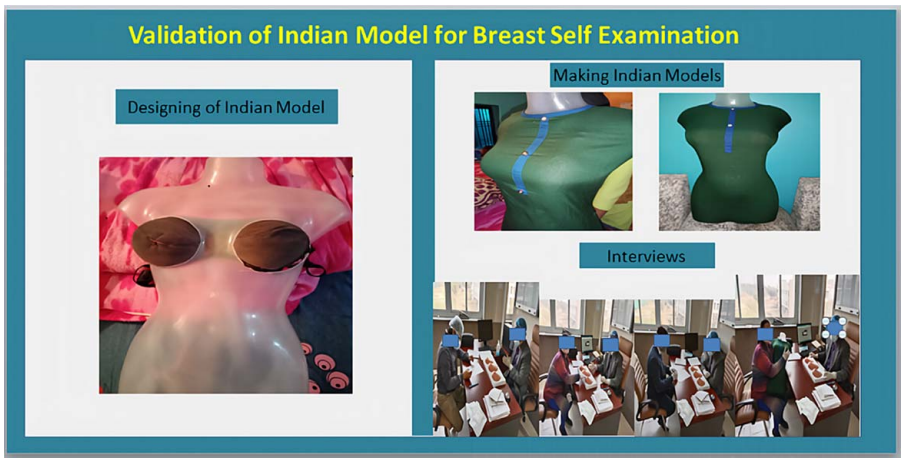

Figure 3. Design of Indian model of breast self-examination and interviews.

Table 1

Characteristics of the researchers (*N* = 15)

Variables	Total (*N* = 15)	Male (*n* = 7)	Female (*n* = 8)	*P*
Type of researchers [*n* (%)]				
Breast and endocrine surgeon	8 (53.3)	4 (50)	4 (50)	0.999
Medical oncologist	2 (13.3)	1 (50)	1 (50)	0.999
Radiation oncologist	5 (13.3)	2 (40)	3 (60)	0.526
Years of experience (mean ± SD)				
Breast and endocrine surgeon	6.17 ± 2.2	7.32 ± 3.4	5.01 ± 2.6	0.160
Medical oncologist	7.5 ± 0.56	7.1 ± 0	7.9 ± 0	–
Radiation oncologist	17.38 ± 6.2	22.36 ± 3.5	12.40 ± 4.8	0.006
Time taken for the interview (mean ± SD) (min)				
Breast and endocrine surgeon	20.67 ± 6.9	19.35 ± 6.5	21.98 ± 7.5	0.484
Medical oncologist	26.26 ± 0.90	25.62 ± 0	26.9 ± 0	–
Radiation oncologist	23.3 ± 3.7	24.20 ± 3.9	22.40 ± 3.6	0.370
Validation questions				
Have you used any simulation models before? [*n*/*N* (%)]	12/15 (80)	6/8 (75)	6/7 (85.7)	0.878
Do you think it would help educate women on breast cancer self-examination [*n*/*N* (%)]	15/15 (100)	7/7 (100)	8/8 (100)	0.999
In comparison to the first model, how would you rate the India model (0–100)? (mean ± SD)	91.69 ± 4.98	90.63 ± 5.23	92.74 ± 4.69	0.425

Independent sample *t*-test/χ^2 test was used.
Significance at $P < 0.05$.

Ethical approval

The ethics committee approved the study (Department Ethics Committee No. PGI/2021/3/emp-118).

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Presentation

A part of this manuscript was presented as a poster by Sarrah Idrees at the 49th World Congress of Surgery at Vienna, Austria in August 2022.

Authors' contribution

S.M. and S.I. contributed to the conception and design of the study; did the analysis and interpretation of data; drafted the article. S.M., S.I., and P.M. did the acquisition of data. All authors revised the article critically for important intellectual content and also the final approval of the version to be submitted.

Conflicts of interest disclosure

The authors declare that they have no financial conflict of interest with regard to the content of this report.

Research registration unique identifying number (UIN)

CTRI/2021/03/032057.

Guarantor

Sabaretnam Mayilvaganan.

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