Comparative analysis of effectiveness of digital breast tomosynthesis vis-à-vis digital mammography in India

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Abstract
Breast cancer is an important public health concern in India. Over the last ten years, breast cancer has been rising steadily. Age adjusted prevalence rate is as high as 25.8 per 100,000 women and mortality 12.7 per 100,000 women. As per National Cancer Registry Programme, 25% to 32% of all female cancers in the leading Indian urban centers are of breast cancer.[1] In order to enhance screening efficiency in the area of breast cancer, various technologies are required. One such innovation is Digital Breast Tomosynthesis, which is an important screening tool for breast cancer. Digital Breast Tomosynthesis is a method of imaging the breast in three dimensions which provides high resolution results. It’s been only used at three places in India. There are multiple barriers in its usage across India. This study aims at finding these barriers as well as solutions to it. The study not only restricts here but aims at spreading awareness regarding its application and usefulness. Lastly, the paper aims to differentiate its effectiveness to Digital Mammography in Indian healthcare domain.

Keywords: Breast Cancer, Digital Breast Tomosynthesis, Digital Mammography, Specificity, Sensitivity, Screening, Cost of installation, Cost per patient.

Introduction
Breast cancer, a malignant tumor specific to the human breast. It is the result of an atypical growth of cells in the breast that can metastasize to other body parts, causing a systematic breakdown of body processes and fatality. Though females are the prime victim of breast cancer, males can also develop the malignancy. However, there are certain risk factors specific to the condition, such as ageing, heredity, genes, radiation exposure, obesity, delayed pregnancy and alcohol. As per National Cancer Registry Programme, 25% to 32% of all female cancers in the leading Indian urban centres are of breast cancer. The prominent symptoms and signs of breast cancer may include- Formation of a thick piece of mass (lump) in the infected breast or just below the armpit, constant pain in the infected region, ranging from mild to severe, the breast skin developing pits and redness, the infected nipple(s) carrying rashes, blood discharge from the nipple of the infected breast, a deep-set or upturned nipple, a drastic anomaly in the breast shape or size, the skin of the nipple with effects like peeling, flaking or scaling. Diagnostic facilities for breast cancer are Digital Mammography, Digital Breast Tomosynthesis, MR Mammography, Scintimammography and PET MRI. The most widely used diagnostic tool is Digital Mammography. Digital mammography, also known as full-field digital mammography (FFDM), is a system in which the X-ray film is replaced by solid-state detectors that convert X-rays into electrical signals.² The other technique that is being less widely used in India is Digital Breast Tomosynthesis. Each Digital Breast Tomosynthesis acquisition consists of 9-25 separate projections that allows reconstruction of multiple planes in the breast, focusing each plane. It provides clearer lesion margins than 2D in non-fatty breasts.³ In comparison to 2D digital mammography, DBT detects more breast cancers (increased sensitivity). DBT has decreased recall rates (improved specificity) compared to 2D mammography. The study aimed at identifying the barriers for its decreased use in India, which includes limited availability of mammography and well experienced radiologists. Many symptomatic women present to surgeons, oncologists, gynecologists and they are referred to various breast imagining techniques. Utilization of breast imaging is judged by the beliefs of the clinician and quality of breast imaging services available to them and thus, breast imaging does not form a major part of radiology practice and hence this results in the shortage of dedicated breast radiologists. The output and contribution of breast imaging in diagnostic setting lacks Quality Assurance and results in poor quality of services. Therefore, a systematic approach is the key to standardize and evolve diagnostic breast imaging which can be achieved with regular conferences, CMEs, workshops, fellowships and training programs.
Objectives
1. To describe the application and usefulness of Digital Breast Tomosynthesis in screening of invasive Breast Cancer vis-à-vis Digital Mammography.
2. To identify the barriers in the usage of Digital Breast Tomosynthesis and finding solutions to overcome it in India.

Materials and Methods
The study is a purely Descriptive Study with primary objective of understanding the application and usefulness of Digital Breast Tomosynthesis and secondary objective of differentiating the working of Digital Breast Tomosynthesis with Digital Mammography. We searched through Google Scholar, PubMed for relevant studies using combinations of following search terms “Digital Breast Tomosynthesis, Digital Mammography, Sensitivity, and Specificity, Cost-effective.”
“..."A thorough literature search was carried out to find relevant reviews and articles. Study designs included randomized controlled trials (RCTs), observational studies, and systematic reviews published from 2008 to January 2019; protocols, nonsystematic reviews, commentaries and letters or editorials were excluded.

Study inclusion
Total of 15 unique studies were checked at full text reading. Descriptions of studies for exclusion were:
1. No breast study
2. High risk profile
3. No abstract available
4. No prospective study
5. Not reporting digital mammography result
6. No full text available

Overview of method studies
Out of 15 studies 4 reported sensitivity and specificity, 2 studies represented cancer detection rate

Findings

| Criteria                  | Digital Breast Tomosynthesis | Digital Mammography |
|---------------------------|------------------------------|---------------------|
| Time of screening         | 10 mins                      | 15 mins             |
| Painful procedure         | No                           | Slightly painful    |
| Cost of installation      | $39,94,000-40,00,000          | $65,00,000-50,00,000|
| Cost per patient          | $130                         | $349                |
| Specificity               | 79%                          | 72%                 |
| Sensitivity               | 90%                          | 89%                 |

Source: T. M. Svahn et al., “Breast tomosynthesis and digital mammography: A comparison of diagnostic accuracy,” Br J Radiol 2012;85:1019-74.

Data Interpretation
On comparing tomosynthesis and mammography, this study finds that while the time taken to screen a patient using mammography is 15 min, tomosynthesis takes around 10 mins which is lesser. Mammography founds to be bit painful while tomo is completely painless. While mammography costs around $349 per patient, tomosynthesis can reduce the costing by one third. The results of tomosynthesis are more reliable as it scored high on both sensitivity and specificity than mammography. Hence on the basis of above results, we can say that tomosynthesis is a better choice for patients as it is a painless process which gives more accurate results in shorter time vis-à-vis mammography. tomosynthesis is also cheaper to install than mammography as the cost of installation can be reduced by approx 22% thus making it a more viable option for hospitals as well.

Result
Distinguish between digital breast tomosynthesis and digital mammography
Sensitivity of Digital breast tomosynthesis was 90% being higher than that of digital mammography which was 89%. specificity of digital breast tomosynthesis was 79% which is slightly higher than that of digital mammography which was 72%. DBT with /without DM gave better result for CDR with a ratio of 1.12 compared to DM alone. The time for investigation was 5 minutes less for DBT as compared to DM. Patient satisfaction would be more for DBT being cost effective and less painful as compared to DM. Even the cost of installation is 1/3 times less than that of DM.
It was analyzed t there are many causes that delay screening in Indian women that varies from availability and accessibility for healthcare facility, various stigma and low knowledge related to breast cancer. As there is no organized population based screening programme in India and DM resource intensive process thus it’s not an ideal in interest of social strata, with limited manpower, untrained worker for a large population is a burden for the diseased person. So, there are several pilot studies going on for checking the barrier and challenges in breast cancer screening and awareness. Out of which one is BISI conducted study which we reviewed and some of the points were highlighted as:
1. Limited availability of screening tool
2. Less experienced radiologist
3. Variable trends for referral of breast cancer
4. Non – uniform quality
5. Less follow-ups
So, there is need of pan – India level of digital screening of breast cancer with multiple collaboration of NGO, industry, policy maker, surgeon, oncologist and others who can contribute in awareness, providing access and help in managing services for a noble cause.

So we suggest some steps that can help to remove barrier in path of screening breast cancer
1. Several training programs with online lecture and hands on should be given for proper learning and getting experience from latest technology to the professionals.
2. More centres with public private partnerships should be step-up for screening under standardized curriculum and examination protocol.
3. Health ministry could be suggested to induce laws to ensure mandatory accreditation, quality assurance and setting up new centre up to lower level of society
4. Setting up online screening portal for breast cancer that includes sign, symptoms, steps to identify, treatment and related centers, method of preventions in every vernacular language.
5. Identify 5 major centre for breast imaging in India, which can further develop their satellite clinics through which various camps, workshop can be done and simantenously suggesting government to fund the screening of breast cancer under various ongoing schemes for women welfare.

Discussion
Wide implementation of tomosynthesis and mammography as a tool for breast cancer detection, we found it necessary to advise its implementation for community welfare. It was found that CDR was higher in tomosynthesis than conventional mammography. The total cost of screening is relatively lesser which is associated with improving morbidity and mortality ratios at community level. Review of 15 studies which compared accuracy on CDR, specificity, time, sensitivity of DBT and DM in women. Where CDR improved when DBT is used so almost all review of literature that distinguishes between DBT and DM in breast cancer detection give a firm alternative for breast cancer screening.

Studies that were reviewed and taken into consideration were heterogeneous in nature. Although aiming to investigate accuracy of DBT in breast cancer screening and taking it into consideration as a screening tool.

Breast imaging in India in present scenario stands on a footprint that developed countries had 0 year ago. So we hope that it would not take 30 years more for proper screening and detection of breast cancer. As per our advice that various organization should affiliate with major established societies in world like EUSOBI so that they can guide you better and take the work at a higher pace and can government and society help the woman in general awareness and guiding their mother, sister, wife and daughters to be educated and aware about why and how breast cancer occur, in what ways it can be treated under what schemes it can be funded for needy and how can you prevent it in early stage.

“A real man is the one who espect and protect their woman in every horizon “

Limitation of our studies
Less literature review can be done
Some studies included only 2 groups on basis of breast density
Preparation of images and its slicing in DBT is 47% longer than DM.

Conclusion
DBT is an alternative to DM due to its potential of early CDR, decreased amount of unnecessary imaging, cost factor sensitivity and specificity comparatively more than DM where as more studies with long term follow-up and screening are necessary for a defining conclusion on whether improvement in cancer detection and potentially on breast cancer mortality.

Latest technology and firm guidelines are major factor needed to be considered for proper screening of breast cancer. It should also be looked into that entire replication of western model should not be adopted as the demographic and social background varies. Some more challenges in imaging of breast in India include women at advanced stage of cancer, inadequate imaging facilities and manpower and no screening is practiced in an independent super specialty.

BISI had identified that several areas are there to work upon like better coordination and sharing of professional knowledge, latest equipment promotion and continuous trainings and interaction with healthcare worker at community level, improvement in public awareness time bound duty and responsibility should be released by professional, worker, policy maker and organization to develop environment with less incidence of breast cancer thus more steps need to be setup and hard work to be done so that a success in a noble cause at a faster rate and aiming in reducing down burden of healthcare expenditure.
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Abbreviations
BC – breast cancer
CDR - cancer detection rate
DBT- digital breast tomosynthesis
DM – digital mammography
BISI- breast imaging society (India)

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