Section: Radiology

Systematic Review

DIGITAL BREAST TOMOSYNTHESIS VS. CONVENTIONAL MAMMOGRAPHY FOR BREAST CANCER SCREENING IN DENSE BREASTS: A SYSTEMATIC REVIEW

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Abstract

Background: Improved breast cancer screening is needed for women with dense breasts, as traditional mammography screening is frequently hindered by dense breast tissue. This systematic review aims to compare the effectiveness of Digital breast tomosynthesis (DBT) versus conventional mammography for breast cancer screening in women with dense breasts, focusing on outcomes such as cancer detection rates, recall rates, and radiation exposure. **Materials and Methods:** A systematic review was conducted by searching PubMed and Google Scholar to identify randomized controlled trials (RCTs) published in English that compared digital breast tomosynthesis (DBT) with conventional mammography for breast cancer screening in women with dense breasts, as classified by BI-RADS density categories. Studies were included if they reported breast cancer detection rates as an outcome. Non-RCTs, studies not in English, and those not focused on dense breasts were excluded. The risk of bias was assessed using the revised Cochrane risk-of-bias tool for randomized trials (RoB 1). **Result:** Five RCTs (n = 161,182 women) met the inclusion criteria. DBT was associated with a higher cancer detection rate than conventional mammography, particularly in women with extremely dense breasts. The impact of DBT on recall rates was mixed; some studies found lower recall rates with DBT, while others found no significant difference. **Conclusion:** Our findings suggest that DBT may be a valuable tool for improving breast cancer screening outcomes in women with dense breasts due to its ability to overcome the limitations of traditional mammography.

INTRODUCTION

Early detection of breast cancer through screening is crucial for reducing mortality rates, and mammography is a key tool for this purpose.[1] However, the presence of dense breast tissue poses a significant challenge.[2] Dense breasts not only increase the risk of developing breast cancer but also reduce the sensitivity of mammograms by obscuring tumors. It has been noted that 15-30% of cancers may be missed due to the masking effect of dense tissue, highlighting the limitations of conventional mammography in this population.[3] Digital breast tomosynthesis (DBT) has emerged as a promising advancement over conventional digital mammography (DM).[4] By acquiring low-dose images of the breast from multiple angles and reconstructing thin slices to create a quasi-3D view, DBT reduces tissue overlap, enhancing tumor visibility.

Mammography is an established method for breast cancer screening, contributing to reduced mortality, but it has well-documented limitations. Mammographic density, defined by the amount of fibroglandular tissue in the breast, is an independent risk factor for breast cancer.[5] Breasts are categorized into different density levels, such as heterogeneously dense and extremely dense, with higher density categories posing a greater challenge for accurate screening. Dense breast tissue reduces the sensitivity of 2D mammography, with studies showing that it can be as low as 30-45% in women with dense breasts.[6] The overlapping tissue can obscure tumors, resulting in false negatives, or create false positives, leading to unnecessary recalls.[7] Interval cancers, which are cancers that present symptomatically after a negative screening exam and before the next scheduled screen, are more common in women with dense breasts due to these limitations.[8] These factors

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underscore the urgent need for improved screening methods for women with dense breasts.

Digital Breast Tomosynthesis (DBT) is a technological advancement that addresses some of the limitations of 2D mammography. DBT uses low-dose x-ray images of the breast taken at multiple angles to reconstruct thin slices of the breast, providing a quasi-3D view.[9,10] This process reduces tissue superimposition, potentially making tumors more visible. Synthetic 2D mammography (s2D), a 2D image created from DBT data, helps to reduce radiation exposure when used in conjunction with DBT.[11] DBT has been implemented in many centers, either as a replacement for or as an adjunct to conventional mammography.[12] The potential advantages of DBT include increased cancer detection rates, reduced recall rates, and improved visualization of tumors. While these benefits are promising, the evidence base is still evolving.[13] Questions remain about its performance in diverse breast densities and real-world screening settings.

The effectiveness of DBT in women with dense breasts is still a subject of ongoing debate, with varying results reported in existing literature.[6,14,15] Some studies indicate that DBT improves screening outcomes by increasing cancer detection and reducing recall rates compared with digital mammography alone.[4] However, these findings are not consistent across all studies, and the magnitude of the benefits may vary. Some research suggests that the reduction in false-positive rates may not be sustained with continued screening.[5,8,14] There is a need to synthesize the available evidence to gain a clear understanding of DBT's role in screening women with dense breasts, with specific questions about how its cancer detection rate, recall rate, sensitivity, and specificity compare to DM, and whether it reduces false positive results. Therefore, this systematic review aims to compare the effectiveness of DBT versus conventional DM for breast cancer screening in women with dense breasts, focusing on key outcomes such as cancer detection rate, recall rates, sensitivity, and specificity, to inform evidence-based screening strategies.

MATERIALS AND METHODS

Eligibility Criteria: The eligibility criteria for this systematic review were defined to ensure that only the most relevant and methodologically sound studies were included, adhering to the PRISMA 2020 guidelines. The review followed a PICO framework: Population (P) – women with dense breasts undergoing breast cancer screening, defined by BI-RADS density categories; Intervention (I) – digital breast tomosynthesis (DBT); Comparison (C) – conventional mammography (DM); Outcomes (O) – breast cancer detection rates, recall rates, sensitivity, and specificity. Studies were included if they were RCTs, published in English, and met these criteria. Studies that did not meet these criteria were excluded. This approach ensured that only the most relevant and methodologically sound studies were included in the synthesis. This systematic review was not prospectively registered in a public registry. The protocol was developed internally and adhered to PRISMA 2020 guidelines to ensure a systematic and reproducible approach.

Literature search and selection: A comprehensive search of the literature was conducted to identify all relevant studies in PubMed and Google Scholar. The search strategies employed a combination of keywords and MeSH terms related to the PICO elements, using Boolean operators (AND, OR, NOT) to combine search terms. Specific keywords included "digital breast tomosynthesis", "DBT", "3D mammography", "mammography", "conventional mammography", "2D mammography", "breast cancer", "breast neoplasms", "breast tumors", "dense breasts", "mammographic density", and "screening". MeSH terms included "Mammography", "Tomography, X-Ray Computed", "Breast Neoplasms", and "Early Detection of Cancer". The search strategy was tailored for each database, as exemplified by the search string used in PubMed. For Google Scholar, additional terms such as "randomized controlled trial", "RCT", "randomised controlled trial", "random allocation", and "clinical trial" were used to target appropriate studies.

Pubmed Search Strategy (last searched on Jan 20, 2025)

("digital breast tomosynthesis"[Title/Abstract] OR "DBT"[Title/Abstract] OR "3D mammography"[Title/Abstract] OR "tomosynthesis"[Title/Abstract])
AND
("mammography"[Title/Abstract] OR "conventional mammography"[Title/Abstract] OR "2D mammography"[Title/Abstract])
AND
("breast cancer"[Title/Abstract] OR "breast neoplasms"[MeSH Terms] OR "breast carcinoma"[Title/Abstract] OR "breast tumors"[Title/Abstract])
AND
("dense breasts"[Title/Abstract] OR "breast density"[Title/Abstract] OR "high breast density"[Title/Abstract])

Google Scholar Search Strategy (last searched on Jan 20, 2025)

"digital breast tomosynthesis" OR "DBT" OR "3D mammography" OR "tomosynthesis"
AND
"mammography" OR "conventional mammography" OR "2D mammography"
AND
"breast cancer" OR "breast neoplasms" OR "breast carcinoma" OR "breast tumors"
AND
"dense breasts" OR "breast density" OR "high breast density"
AND

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("randomized controlled trial" OR "RCT" OR "randomised controlled trial" OR "random allocation" OR "clinical trial")

The initial search yielded 312 records from PubMed and 2740 records from Google Scholar, for a total of 3052 records. After the removal of 270 duplicate records, 2782 records remained. These records were then screened by title and abstract, resulting in 2748 records being excluded as they did not meet the eligibility criteria. 34 records were assessed for full-text retrieval. After full text screening, 29 were excluded leaving 5 studies meeting the inclusion criteria for the review [Figure 1].

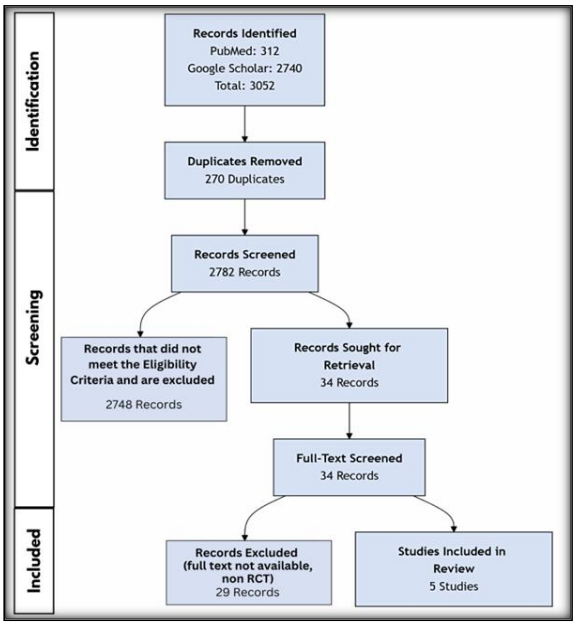

Figure 1: PRISMA flow diagram of the study selection process

To assess the risk of bias in the included randomized controlled trials (RCTs), we utilized the revised Cochrane risk-of-bias tool for randomized trials (RoB 1), which evaluates bias across five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Two reviewers independently applied the RoB 1 tool to each study, ensuring a thorough and objective evaluation of potential biases. In cases where the reviewers reached differing conclusions, they resolved these discrepancies through discussion to achieve consensus. If a disagreement persisted, a third reviewer was consulted to provide an independent judgment. No automation tools were used in this process, as the nuanced nature of the assessments required manual, context-specific judgments. This approach ensured a rigorous and reliable evaluation of the risk of bias in each included study.

RESULTS

Characteristics of the studies

The five included RCTs involved a total of 161,182 women. The studies were conducted in various settings and used different protocols for DBT and DM. Key characteristics of the included studies are summarized below:

- Siminiak et al. (2022): This study, conducted in Poland, included 402 women recalled from breast cancer screening and compared the diagnostic performance of contrast-enhanced mammography (CEM) and DBT. The study concluded that CEM and DBT showed similar diagnostic accuracy.[16]
- Aase et al. (2018): This trial, conducted in Bergen, Norway, randomized 14,274 women to either DBT or DM for breast cancer screening. This study had an interim analysis of performance indicators and found that DBT had a lower recall rate than DM, although it took longer to read.[9]
- Pattacini et al. (2018): This study in Reggio Emilia, Italy, compared DM plus DBT versus DM alone in breast cancer screening and showed that DBT plus DM detected 90% more cancers with similar recall rates in a population previously screened with DM. The study included 9,049 women in the experimental arm and 9,150 women in the control arm.[11]
- Weigel et al. (2022): This multicentre German study (TOSYMA trial) randomized 99,689 women to DBT plus synthesized mammography (SM) or DM. It found higher invasive cancer detection rates with DBT plus SM than DM in dense breasts, especially in extremely dense breasts.[17]
- Moshina et al. (2020): This study, also from the To-Be trial in Bergen, Norway, focused on comparing screening outcomes using automated breast density measurements and included 28,749 women. It reported lower recall rates for women with non-dense breasts using DBT+SM, and an increase in adjusted relative risk of recall and screen detected cancer with denser breasts for DBT+SM but not DM.[18]

Table 1: Characteristics of included studies.

Study	Location	Study Design	Sample Size	Intervention	Comparator	Key Outcomes
Siminiak et al. (2022)	Poznań, Poland	Randomized controlled trial	402	Contrast enhanced mammography (CEM)	Digital breast tomosynthesis (DBT)	Both CEM and DBT demonstrated high diagnostic performance, and none of them was found to be superior

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Aase et al. (2018)	Bergen, Norway	Randomized controlled trial	14,274	Digital breast tomosynthesis (DBT)	Digital mammography (DM)	DBT had significantly lower recall rate than DM; longer reading time for DBT; no difference in radiation dose
Pattacini et al. (2018)	Reggio Emilia, Italy	Randomized controlled trial	18,199	Digital mammography plus tomosynthesis (DBT+DM)	Digital Mammography (DM)	DBT+DM detected 90% more cancers than DM, with similar recall rates; higher detection may have a beneficial impact on cancer prognosis
Weigel et al. (2022)	Germany	Randomized controlled trial	99,558	Digital breast tomosynthesis plus synthesized mammography (DBT+SM)	Digital Mammography (DM)	Higher invasive cancer detection rates with DBT+SM than DM, especially in dense breasts
Moshina et al. (2020)	Bergen, Norway	Randomized controlled trial	28,749	Digital breast tomosynthesis with synthetic 2D mammography (DBT+SM)	Digital mammography (DM)	Detailed analysis of cancer characteristics by breast density (VDG 1-4); False-positive findings and screen detected cancers are available in the source

Risk of Bias Assessment

The risk of bias within individual studies was assessed using the revised Cochrane risk-of-bias tool for randomized trials (RoB 1).

- Selection Bias: All five trials were randomized, which generally reduces selection bias. However, in the Pattacini et al. study, 37% of eligible women refused to participate, which could introduce a selection bias.[11]
- Performance Bias: The studies of Siminiak et al, Pattacini et al, and Weigel et al did not mention blinding of the intervention, meaning a high risk of performance bias. In the To-Be trial, the radiologists had a training session for DBT.[11,16,17] The outcome assessor was not necessarily blinded to the intervention for these studies. This could influence the outcome assessment.
- Detection Bias: Detection bias was considered moderate in most studies, as it's difficult to blind radiologists to the imaging modality. However, the Moshina et al. study used an automated software for breast density measurements which could lower the detection bias.[18]
- Attrition Bias: Attrition bias was low in most of the studies, with a small number of patients being excluded due to missing information or dropouts.
- Reporting Bias: There was potential for reporting bias due to selective reporting of results in some studies. Some studies, for example, did not report all outcomes originally planned, while others highlighted only positive findings, particularly when reporting on the detection of breast cancer, instead of interval cancers.[16]

Table 2: Risk of Bias Assessment of the included studies, using ROB 1 tool

Study	Selection Bias	Performance Bias	Detection Bias	Attrition Bias	Reporting Bias	Overall Risk of Bias
Siminiak et al. (2022)	Low	Moderate	Moderate	Low	Moderate	Moderate
Aase et al. (2018)	Low	Moderate	Moderate	Low	Low	Low
Pattacini et al. (2018)	Moderate	High	Moderate	Low	Moderate	Moderate
Weigel et al. (2022)	Low	High	Moderate	Low	Moderate	Moderate
Moshina et al. (2020)	Low	Low	Low	Low	Moderate	Low

Narrative Synthesis

This systematic review evaluates the comparative effectiveness of digital breast tomosynthesis (DBT), with or without synthesized mammography (SM), and contrast-enhanced mammography (CEM) against standard digital mammography (DM) for breast cancer screening, with a particular emphasis on women with dense breasts. The evidence from five randomized controlled trials (RCTs)—Aase et al., Pattacini et al., Weigel et al., Moshina et al., and Siminiak et al.—demonstrates a consistent trend of improved cancer detection with DBT-based

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modalities over DM alone.[9,11,16–18] This enhancement is especially evident in dense breast tissue, where DBT's three-dimensional imaging reduces the obscuring effect of overlapping structures, a limitation inherent to conventional DM. The studies collectively suggest that combining DBT with SM amplifies this benefit, particularly for detecting invasive cancers in women with extremely dense breasts, aligning with the review's focus on optimizing screening outcomes in this population.

The impact of DBT on recall rates, however, reveals variability across the trials. Some evidence points to a reduction in recalls with DBT, attributed to improved specificity and fewer false positives, while other findings indicate no significant difference compared to DM. This inconsistency may reflect differences in study design, population characteristics, or interpretive protocols, highlighting an area requiring further investigation to refine DBT's application in screening programs. Beyond detection and recall, practical considerations such as reading times and radiation exposure are noteworthy. DBT tends to increase reading times, potentially affecting workflow efficiency, yet maintains radiation doses comparable to DM, supporting its feasibility as a screening tool from a safety perspective.

The inclusion of the Siminiak et al. trial introduces an additional dimension by comparing CEM with DBT, suggesting comparable diagnostic performance between these modalities.[16] This finding positions CEM as a potential alternative, particularly in contexts where DBT is less accessible or where contrast enhancement could provide supplementary diagnostic value. Collectively, these results indicate that DBT, especially when paired with SM, offers a robust screening option for women with dense breasts, enhancing cancer detection without compromising radiation safety. However, the mixed outcomes for recall rates and the operational challenges posed by longer reading times underscore the need for ongoing research to optimize its integration into routine practice.

DISCUSSION

This systematic review assesses the effectiveness of Digital Breast Tomosynthesis (DBT) versus conventional digital mammography (DM) for breast cancer screening in women with dense breasts. The results, drawn from five randomized controlled trials (RCTs), indicate that DBT, especially when paired with synthesized mammography (SM), enhances cancer detection rates (CDR) in this population. This improvement is particularly evident in detecting invasive cancers among women with extremely dense breasts (BI-RADS category D), as seen in trials like TOSYMA and the Reggio Emilia Tomosynthesis trial.[11,17] However, the effect on recall rates varies, with some studies (e.g., the Bergen trial) showing reductions, while others (e.g., Pattacini et al. and Maxwell et al.) report no significant change compared to DM.[9,11,19] These findings suggest DBT offers a diagnostic advantage over DM, primarily by mitigating the masking effect of dense tissue, though its impact on screening efficiency remains less consistent.

When placed in the broader context, these results align with other systematic reviews and meta-analyses. For instance, Marinovich et al. in 2018 found that DBT increases CDR compared to DM, particularly in dense breasts, a conclusion echoed by Gao et al.[4,20] However, the inconsistency in recall rate reductions mirrors observations in the study by Pace et al, which suggests that DBT's benefits in reducing false positives may diminish over time.[5] Additionally, Lin et al. noted that DBT's improved detection comes with practical trade-offs, such as increased reading times, a challenge also identified in our included studies.[2] These comparisons highlight that while DBT's diagnostic superiority is widely supported, its operational implications warrant further scrutiny.

Limitations

The evidence synthesized here has notable limitations. Variability in breast density classification, DBT equipment, and reading protocols, complicates the generalizability of the findings. Moreover, the absence of long-term data on critical outcomes like interval cancer rates and mortality limits our understanding of DBT's ultimate impact, as noted by Marinovich et al.[20] Single-center studies within the review further constrain external validity. These factors suggest caution in extrapolating the results across diverse screening settings.

The review process itself is not without flaws. Restricting the search to English-language publications may have excluded relevant non-English studies, potentially introducing selection bias. Additionally, by focusing solely on RCTs to ensure high-quality evidence, we may have overlooked valuable real-world insights from observational studies.

CONCLUSION

In conclusion, this systematic review suggests that DBT, particularly when combined with SM, offers a superior alternative to conventional DM for breast cancer screening in women with dense breasts due to improved cancer detection, without significantly increasing radiation exposure. It is also important to consider the potential for synthetic mammography to reduce the radiation dose. However, further research is needed, including trials with longer-term follow-up, to fully understand the impact of DBT on long-term clinical outcomes and to address the limitations identified in this review. Further research should also explore the diagnostic benefits of CEM compared to DBT.

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