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Diagnostic Accuracy of Automated breast ultrasound as an adjunct test for breast cancer screening: a systematic review

Jassim, G; Al Zayani, F; Dsilva, S.

Corresponding author:
Ghufran Jassim

gjassim@rcsi-mub.com

Author Affiliation:
RCSI Bahrain.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 October 2025 and was last updated on 28 October 2025.

INTRODUCTION

Review question / Objective The objective is to assess the diagnostic accuracy of automated breast ultrasonography combined with mammography versus mammography alone or in combination with handheld ultrasound for breast cancer screening in women.

Rationale There is growing evidence regarding the use of adjunct modalities in mammography, especially in women with dense breasts, and accumulating evidence suggests that women with dense breasts are underserved by screening with mammography alone. Furthermore, the technology is rapidly evolving, with new radiographic modalities being introduced into the market. Therefore, there is a need to evaluate and combine evidence that will be translated into a recommendation within clinical guidelines.
A Previous systematic review investigated the use of ultrasound as an adjunct to mammography in women at average risk; however, it did not include studies with sequential U/S following negative mammography and did not clarify which ultrasound modality is superior [27]. Specifically, it is unclear whether the use of new modalities such as 3D automated ultrasonography or 3D tomographic ultrasound as adjunct screening tools in women at average risk is superior to handheld ultrasound or mammography alone, which corresponds to a reduction in mortality and morbidity (the ultimate goal of any screening program) or to an increase in screening-related harm.
Lastly, the review included all women of average risk defined as those who have a lifetime risk of less than 15% whereas in this systematic review, we will specifically focus on trials conducted in a screening setting rather than a diagnostic setting, as our aim is to assess the effectiveness of interventions in asymptomatic populations typically targeted by screening programs.
Therefore, there is a need to combine the evidence to inform future guidelines and recommendations.

This review aimed to assess the diagnostic accuracy of automated breast ultrasonography combined with mammography versus mammography alone or in combination with handheld ultrasound for breast cancer screening in women.

Condition being studied Worldwide, female breast cancer is the most prevalent cancer with 7.8 million women diagnosed alive as of 2020. In the same year, there were 2.3 million new cases of breast cancer and 685 000 deaths globally.
Worldwide, the gold standard screening method for breast cancer is mammography with high sensitivity reaching up to 85%. However, its sensitivity decreases significantly to between 47.8 and 64.4% with higher breast density owing to the dense breast tissue masking the lesion, leading to misdiagnosis. Therefore, it has been recently advocated that screening with ultrasound as an adjunct to mammography in dense breasts is as beneficial as contrast-enhanced MRI in extremely dense breasts. The standard supplemental breast screening technique is hand-held whole-breast ultrasound (HHUS). However, in 2012, the Food and Drug Administration (FDA) approved automated breast ultrasound (ABUS), which has been widely used as a supplemental screening tool for breast cancer [14, 15]. Another emerging technique is whole-breast 3-dimensional tomographic imaging (UST), which obtains quantitative tomograms of the speed of sound in the entire breast. It represents a breakthrough and holds promise as a method to evaluate dense breasts without ionizing radiation since it was approved by the FDA in 2021. However, the evidence was not combined in a systematic review to evaluate the effectiveness and clinical accuracy of the newest modalities of ultrasonography, such as ABUS or UST, compared with standard HHBUS as a supplemental screening tool for breast cancer in women.

METHODS

Search strategy A comprehensive search strategy was implemented in PubMed, Embase, and Cochrane Library. Citation tracking and grey literature sources were also explored to reduce the risk of publication bias. The final search was completed in May 2025.
The search combined controlled vocabulary (MeSH/Emtree terms) and free-text keywords across four conceptual domains: breast neoplasms, mass screening, ultrasound modalities (ABUS, handheld ultrasound, and ultrasonography), and mammography, with breast density as a modifying factor. Boolean operators ("AND", "OR") were employed to opti-mise sensitivity. An illustrative PubMed search string was used as follows:
("Breast Neoplasms"[MeSH Terms] OR "Breast Neoplasms"[Title/Abstract] OR "breast cancer" OR "breast carcinoma")AND ("Mass Screening"[MeSH Terms] OR "Mass Screen-ing"[Title/Abstract] OR "screening" OR "detection")AND ("Ultrasonography"[MeSH Terms] OR "automated ultrasound" OR "ABUS" OR "handheld ultrasound" OR "ultra-sound" OR "automated breast ultrasound")AND ("Mammography"[MeSH Terms] OR "Mammography"[Title/Abstract] OR "mammogram" OR "mammographic")AND ("Breast Density"[MeSH Terms] OR "breast density").Database filters were applied to limit retrieval to studies published in 2000 and beyond, and given that ABUS was FDA-approved in 2012, we chose the starting date to be a dec-ade earlier.
We manually searched the reference lists of all the included studies, pertinent reviews, and background articles on this topic to identify any relevant citations that our search might have missed. Multiple reports from the same study were collated and reported as one unit.

Participant or population Women between the ages of 40 and 75 years who had not previously undergone breast cancer screening and participated in a breast cancer screening program (population-based or opportunistic). We also included studies that assessed women with negative mammo-gram results who subsequently underwent additional ultrasound evaluation or studies that included women with breast density only presenting for routine breast screening. Furthermore, we included studies in which women were recalled for further ultrasound assessment for the same reason, as these follow-up procedures are considered an integral component of the screening process.

Intervention The index test involves automated breast ultrasound (ABUS), including an Automated Breast Volume Scanner (ABVS) which is a specific type of ABUS, or ultrasound tomography (UST). All 3D images were used sequentially or simultaneously as screening tests with mammography versus mammography alone, or in combination with handheld ultra-sound for breast cancer screening in women.

Comparator Any form of mammography screening (e.g. one view, two views, digital, tomosynthesis (three-dimensional (3D)-mammography), combination of 2D- and 3D-mammography) with additional breast automated ultrasonography or ultrasound tomography compared to

mammography screening alone or with handheld breast ultrasonography.

Study designs to be included Prospective or retrospective, randomised, non-randomised controlled, or non-controlled study conducted in a screening context (population-based or opportunistic).

Eligibility criteria Same as PICO section.

Information sources A comprehensive search strategy was implemented in electronic databases such as PubMed, Embase, and Cochrane Library and trial registers. Citation tracking and grey literature sources were also explored to reduce the risk of publication bias. The final search was completed in May 2025.

Main outcome(s) The outcomes included the sensitivity/specificity, cancer detection rate (CDR), recall, pre-dictive values, and workflow metrics.

Data management Structured data-extraction forms were designed and used to gather pertinent information from the included articles. This includes the characteristics of the study population, set-tings, index tests, comparators, study designs, and outcomes.

Quality assessment / Risk of bias analysis Two authors independently assessed the risk of bias using QUADAS-2 the Quality As-sessment of Diagnostic Studies) tool, which is specifically designed to evaluate diagnostic accuracy studies. This tool evaluates four key domains: 1. patient selection; 2. Index test; 3. reference standards and 4. Flow and timing. The first three domains were assessed for applicability. For each domain, the reviewers provided a judgment of the risk of bias (low, high, or unclear) accompanied by justification based on the information reported in the study. Any disagreements between reviewers were resolved through discussion.

Strategy of data synthesis We summarised the characteristics of included studies narratively and extracted data re-lated to diagnostic accuracy of the test from the included studies and provided a narrative synthesis where appropriate. When sufficient data were available from studies with simi-lar designs and contexts, we calculated the pooled estimates of sensitivity and specificity to quantify the overall diagnostic performance and ability of the test to accurately identify true positives and true negatives. When only the percentages were reported, we recon-structed the counts from the denominators. For zero cells, we used a continuity correction of 0.5. When several readers reported the results, we used the consensus read (or, if not available, the primary analysis read) to avoid unit-of-analysis errors.

Subgroup analysis A subgroup analysis will be performed, if appropriate, to explore potential sources of heterogeneity. Subgroups will be defined based on key factors such as the type of participants (e.g., screening vs. diagnostic populations) and the type of index test used (e.g., automated breast ultrasound vs. ultrasound tomography), to determine whether these variables influence diagnostic accuracy estimates.

Sensitivity analysis A sensitivity analysis will be conducted, where appropriate, to assess the robustness of the pooled estimates. This analysis will be restricted to high-quality studies with a low risk of bias and sufficient methodological and clinical homogeneity, in order to evaluate whether study quality influences the overall diagnostic accuracy outcomes.

Language restriction No language restrictions.

Country(ies) involved Bahrain.

Keywords breast density; screening; automated breast ultrasound; handheld ultrasound; mammography; diagnostic accuracy.

Dissemination plans The dissemination plan includes publication of the study findings in a Q1, high-impact, peer-reviewed international journal relevant to diagnostic imaging or cancer screening. In addition, results will be presented at regional and international scientific conferences to reach researchers, clinicians, and policymakers. This will ensure wide dissemination of the evidence and support translation of findings into screening practice and policy.High impact factor, Q1 journals and conferences.

Contributions of each author

Author 1 - Ghufran Jassim - GJ and FZ contributed to planning, conducting, and reporting of the work described in this article. SD cleared any disagreement and contributed to the final reading and editing of the manuscript. SD performed the search strategy and contributed to the editing of the paper.
Email: gjassim@rcsi-mub.com
Author 2 - Fahad AlZayani - GJ and FZ contributed to planning, conducting, and reporting of the work described in this article. SD cleared any disagreement and contributed to the final reading and editing of the manuscript. SD performed the

search strategy and contributed to the editing of the paper.
Email: fahadrkz@agu.edu.bh
Author 3 - Suchita Dsilva - GJ and FZ contributed to planning, conducting, and reporting of the work described in this article. SD cleared any disagreement and contributed to the final reading and editing of the manuscript. SD performed the search strategy and contributed to the editing of the paper.
Email: sdsilva@rcsi-mub.com