

ARTIFICIAL INTELLIGENCE IN AUTOMATED BREAST ULTRASOUND: A CRITICAL REVIEW OF DIAGNOSTIC ACCURACY, CLINICAL UTILITY, AND CURRENT EVIDENCE

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Abstract

Automated Breast Ultrasound (ABUS) is an established adjunctive breast-imaging technique, particularly relevant to women with dense breasts. Artificial intelligence (AI), including computer-aided detection and deep-learning approaches, is increasingly being investigated to improve lesion detection, characterization, reader consistency, and workflow. This critical review examines evidence published from January 2015 through August 2026, distinguishing studies that directly evaluate ABUS from broader breast-ultrasound AI studies. The evidence base demonstrates that ABUS can provide clinically useful supplemental detection, while AI-assisted interpretation may improve diagnostic discrimination and reduce reading time, particularly for less-experienced readers. However, the available evidence remains heterogeneous: studies differ in population, lesion- versus patient-level analysis, reference standards, breast-density distribution, AI role, and external validation. Importantly, several frequently cited AI studies concern handheld breast ultrasound or mammographic density classification rather than ABUS and therefore should not be treated as direct evidence for AI-ABUS performance. Current evidence supports AI-ABUS as a promising adjunct rather than a replacement for radiologist interpretation. Prospective, multicenter, multivendor, externally validated studies with transparent reporting and clinically relevant outcomes are required before routine implementation can be recommended.

INTRODUCTION

Breast cancer remains a major global health burden, and early detection is central to improving outcomes.¹ Mammography remains the principal screening modality, but its

sensitivity is reduced in women with dense breast tissue, in whom overlapping fibroglandular tissue can mask small or subtle lesions.² This limitation has driven sustained interest in supplemental imaging modalities

including handheld and automated ultrasound that can be added to mammography for women with dense breasts.³

Automated Breast Ultrasound (ABUS) provides automated whole-breast volumetric acquisition and multiplanar reconstruction, reducing some of the operator dependence associated with handheld ultrasound (HHUS);⁴ its role is primarily adjunctive, particularly in dense breasts.⁵ Early comparative work demonstrated the incremental diagnostic value of adding whole-breast ultrasound to mammography,⁶ in a study of 4,419 women with dense breasts, Kelly et al. reported that breast cancer detection nearly doubled from 23 to 46 cancers identified across 6,425 paired studies⁶ when automated whole-breast ultrasound (AWBU) was added to mammography, raising diagnostic yield from 3.6 to 7.2 cancers per 1,000 examinations, with a comparable positive predictive value for biopsy recommendation (39.0% for mammography versus 38.4% for AWBU).^{6,7} Subsequent single-center and multicenter studies reported sensitivities for ABUS-based screening or diagnosis ranging from approximately 83% to 92%, with specificity around 93% in the largest multicenter non-inferiority cohort.⁸ More recently, the UK BRAID randomised controlled trial directly compared ABUS with abbreviated MRI and contrast-enhanced mammography as supplemental imaging in 9,361 women with dense breasts and a negative screening mammogram; in the interim analysis of 6,305 women who completed supplemental imaging, cancer detection rates per 1,000 examinations were 4.2 for ABUS, 17.4 for abbreviated MRI, and 19.2 for contrast-enhanced mammography, compared with 8.4 for the contemporaneous mammography-only cohort with ABUS detecting significantly fewer cancers than abbreviated MRI ($p=0.047$).⁹ Taken together, these data frame ABUS as a clinically useful but comparatively modest supplemental modality relative to MRI or contrast-enhanced mammography, motivating interest in whether AI-based interpretation can improve its diagnostic yield.¹⁰ AI has introduced additional opportunities for automated lesion detection, classification, and decision support across medical imaging,¹¹ including oncologic image analysis and AI-assisted mammography. Early

institutional experience with ABUS implementation has highlighted both workflow benefits and interpretation challenges that AI-based tools are intended to address.¹² However, evidence labelled as “AI breast ultrasound” is not synonymous with “AI-ABUS.” Some studies use ABUS specifically, whereas others use handheld ultrasound, mammography, or synthetic tomosynthesis images. A clinically meaningful critical review therefore needs to separate direct ABUS evidence from indirect evidence, because performance obtained on one imaging platform cannot automatically be generalized to another.

2. METHODOLOGY

This article was conducted as a critical review rather than a systematic review or meta-analysis. Literature was searched across PubMed/MEDLINE, Embase, relevant Nature/Scientific Reports records, and Google Scholar for publications from January 2015 through August 2026. Search concepts included “Automated Breast Ultrasound,” “ABUS,” “automated whole breast ultrasound,” “Artificial Intelligence,” “deep learning,” “computer-aided detection,” “CADx,” “diagnostic accuracy,” and “breast cancer screening.” Studies were considered relevant when they reported clinical or diagnostic information concerning ABUS, AI-assisted ABUS, or closely related breast-ultrasound AI applications. Prospective and retrospective clinical studies, multicenter studies, and systematic reviews/meta-analyses were considered; case reports and conference abstracts without extractable clinical information were not used as principal evidence. Because this is a critical review, no pooled effect estimate was newly calculated by the present authors; the numerical results reported in the tables are taken from the cited studies or reviews. As a methodological principle, studies using handheld breast ultrasound, mammography/tomosynthesis, or general breast-ultrasound AI are not presented as direct evidence of AI-ABUS performance. They are retained in Table 2 as indirect or contextual evidence where they inform the broader feasibility of AI in breast imaging.

3. TECHNICAL ASPECTS OF ABUS

3.1 Image Acquisition and Reconstruction

ABUS systems use an automated high-frequency transducer to acquire volumetric breast data. The acquired volume can be reconstructed in axial, sagittal, and coronal planes.^{4,13} The coronal plane provides an additional representation that may assist lesion detection and characterization.¹⁴

3.2 Advantages over Handheld Ultrasound (HHUS)

ABUS standardizes acquisition and reduces operator dependence compared with HHUS. Whole-breast coverage and multiplanar review can support reproducible interpretation and follow-up.¹⁵ Nevertheless, ABUS does not

eliminate all artifacts or interpretation burden, and axillary assessment remains limited compared with targeted HHUS.

4. RESULTS

4.1 Direct ABUS Evidence

The direct ABUS evidence demonstrates substantial variability in reported diagnostic performance. Earlier comparative cohorts established the role of ABUS as an adjunct to mammography or as an alternative whole-breast ultrasound acquisition method. More recent studies have evaluated AI-CAD specifically in ABUS and have reported improvements in reader discrimination. The key direct evidence is summarized in Table 1.

Table 1. Direct clinical evidence for ABUS and AI-assisted ABUS (2016–2026).

Study (year)	Setting / sample	AI technology	Key reported performance	Comparator / outcome	Design
Wilczek et al. (2016) ¹⁶	Sweden; 1,671 women	Not AI-based (conventional ABUS)	Sensitivity ~83% for ABUS added to mammography; specificity not separately reported as this study's primary comparative endpoint was incremental cancer detection	ABUS added to mammography in heterogeneously /extremely dense breasts	Prospective, single-center
Vourtsis & Kachulis (2018) ¹⁷	Greece; 1,886 women	Not AI-based (conventional ABUS)	Sensitivity ~95% for lesion visualization; the study's primary endpoint was BI-RADS characterization agreement rather than diagnostic specificity	3D ABUS vs HHUS, lesion visualization and characterization	Prospective comparative
Xin et al. (2021) ¹⁸	China; 5 hospitals; 1,947 women	Not AI-based (conventional ABUS)	Sensitivity 91.8%; specificity 92.9%	ABUS vs HHUS/mammography, non-inferiority endpoint	Multicenter non-inferiority
Lee et al. (2022) ¹⁹	South Korea; 846 women	Commercial CAD marks	Sensitivity 60.0%; specificity 59.0%; PPV 0.9%	CAD in screening ABUS; false-positive burden characterized	Retrospective
Tan et al. (2023) ²⁰	Netherlands/China; 430 paired DM-ABUS cases, predominately	Multimodal AI (AI-DM + AI-ABUS)	AUC 0.865 for AI-multimodal vs 0.832 for AI-DM alone (p=0.026) and 0.841 for AI-ABUS alone (p=0.041); at maximum Youden index, sensitivity 79.4%, specificity 91.2%	Combined ABUS+ mammography AI vs individual modalities	Retrospective, clinical AI study

	ntly dense breasts				
Kwon et al. (2024) ²¹	South Korea; 262 lesions / 231 women	AI-based CAD for ABUS	Radiologist AUC improved from 0.870 to 0.919 with AI-aided reading (p=0.001)	Histopathology-verified lesions; reader performance with vs without AI	Retrospective
Kwon et al. (2026) ²²	South Korea; 1,683 women / 2,904 screening	No AI; supplemental ABUS	ABUS + DM sensitivity 100%; specificity 95.0%; cancer detection rate 9.0/1,000 vs 7.9/1,000 with DM alone	Supplemental ABUS in nondense breasts	Retrospective, two centers
Jassim et al. (2026) ³	Multinational; 18 studies, >20,000 screening	Systematic review/meta-analysis	Pooled ABUS-vs-HHUS sensitivity 0.90; specificity 0.89	Supplemental ABUS/UST in mammographic screening	Systematic review/meta-analysis

4.2 Critical Synthesis

The direct ABUS evidence supports clinical utility but does not justify a single summary estimate of AI-ABUS accuracy. Non-AI ABUS studies show that performance varies with population, comparator, breast density, and reference standard. The 2026 systematic review/meta-analysis found pooled ABUS-versus-HHUS sensitivity of 0.90 and specificity of 0.89, while noting substantial heterogeneity and that only two of 18 included studies were at overall low risk of bias.²³ The same review found that adding ABUS to mammography increased sensitivity by 6–35 percentage points but was associated with higher recall and modestly lower specificity; increased detection should therefore not be interpreted as an unconditional improvement in screening benefit.³ For AI specifically, the strongest direct

ABUS evidence in the present review is the Kwon et al. study, in which AI-assisted interpretation improved AUC from 0.870 to 0.919.²¹ The Tan et al. multimodal study reinforces this trend: combining AI-based ABUS and mammography (AUC 0.865) outperformed either AI-DM (AUC 0.832) or AI-ABUS (AUC 0.841) alone, achieving 79.4% sensitivity and 91.2% specificity at the optimal operating point.²⁰ Conversely, the earlier Lee et al. CAD study illustrates the opposite side of the evidence: although CAD was clinically evaluated, sensitivity and specificity were modest and PPV was very low, demonstrating the false-positive burden that can accompany early CAD implementations.¹⁹ These findings argue against describing AI-ABUS as uniformly improving all diagnostic metrics.

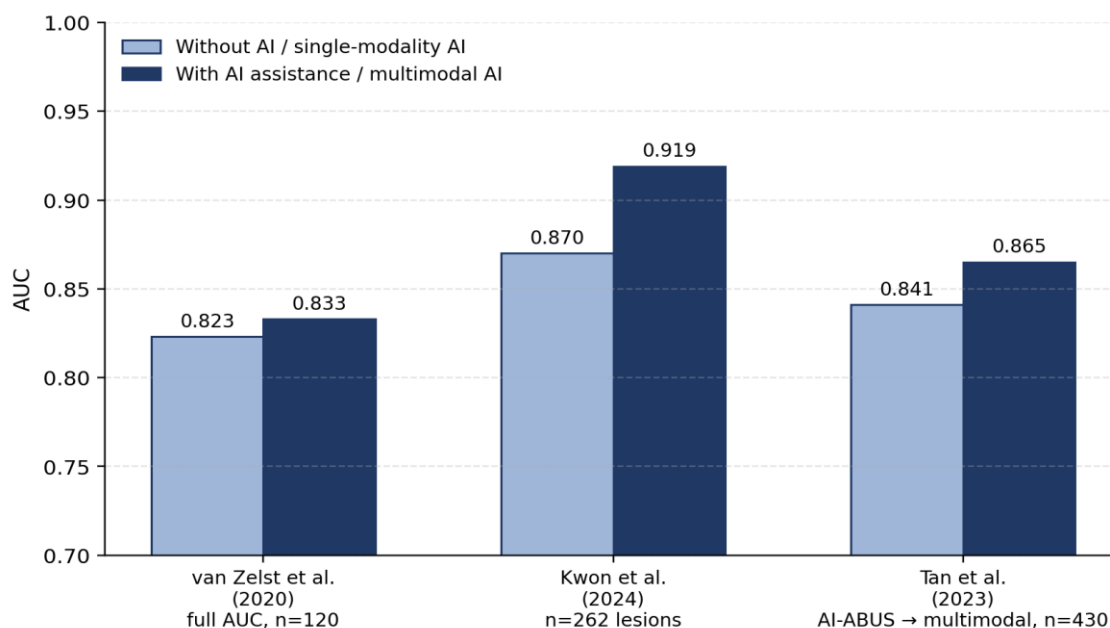


Figure 1. AUC before and after AI assistance in the three direct ABUS-AI studies in this review that report AUC (van Zelst et al. 2020, Kwon et al. 2024, Tan et al. 2023). All three show a consistent, if modest-to-substantial, improvement with AI assistance.

4.3 Indirect and Contextual AI Evidence

Several influential studies concern breast ultrasound AI but do not specifically establish AI-ABUS performance. They remain relevant to

the field but should be interpreted as indirect evidence. Table 2 deliberately separates these studies from direct ABUS evidence.

Table 2. AI evidence relevant to breast ultrasound, with explicit distinction from direct ABUS evidence.

Study (year)	Modality / scope	Sample	AI approach	Reported outcome	Clinical relevance	Evidence status
Van Zelst et al. (2020) ²⁴	3D ABUS	120 women; 8 radiologists	CAD software (finding validation)	Partial AUC (80–100% specificity range) improved from 0.126 to 0.142 (p=0.037); full AUC 0.823 vs 0.833 (not significant)	Supports feasibility of CAD validation in ABUS	Direct ABUS
Tan et al. (2023) ²⁰	3D ABUS + mammography	430 paired cases, predominantly dense breasts	Multimodal AI	AUC 0.865 (multimodal) vs 0.832 (AI-DM) and 0.841 (AI-ABUS); sensitivity 79.4%, specificity 91.2% at optimal threshold	Supports multimodal AI combining ABUS and mammography	Direct ABUS
Kwon et al. (2024) ²¹	ABUS	262 lesions / 231 women	AI-CAD	AUC 0.870 → 0.919 with AI-aided reading	Direct evidence for	Direct ABUS

					reader assistance	
Lee et al. (2022) ¹⁹	ABUS	846 women	Commercial CAD	Sensitivity 60.0%; specificity 59.0%; PPV 0.9%	Shows false-positive limitations of early CAD	Direct ABUS
Sexauer et al. (2023) ²⁵	Mammographic/tomosynthesis density classification	1,665 patients; 4,605 images; test set 460 images / 380 patients	Deep convolutional neural network	Sensitivity 80.4%; specificity 89.3%; accuracy 89.6% for ACR A/B vs C/D density	Relevant to automated density assessment, not lesion malignancy on ABUS	Indirect, not ABUS
Xiang et al. (2023) ²⁶	Breast ultrasound (multivendor, multicenter)	Internal and three external hospital test sets	Deep-learning diagnostic assistance	Internal AUC 0.94 (95% CI 0.92–0.95); external AUCs 0.92, 0.91 and 0.96 across three hospitals; AI assistance improved AUC for novice readers	Supports external generalizability of breast-US AI across vendors and sites	Indirect, not ABUS-specific
Tsuyuzaki et al. (2025) ²⁷	Breast ultrasound	171 masses (92 benign, 79 malignant)	BU-CAD / AI-CADx	AI sensitivity 91.1%; specificity 92.4%; AUC 0.948; AI improved AUC for less-experienced radiologists and reduced reading time	Strong evidence for AI-assisted breast-US diagnosis	Indirect unless ABUS acquisition confirmed
Yin et al. (2025) ²⁸	Handheld breast ultrasound	4,998 patients; 1,410 test set	MobileNet-v2 deep-learning model	AUC 0.924; accuracy 87.3%	Demonstrates AI performance on breast-US images generally	Indirect, not ABUS
Shen et al. (2025) ²⁹	AI-assisted breast ultrasound screening	Population-based Chinese screening cohort	AI-assisted ultrasound	Prospective, clustered, controlled, population-based design; reported as effective for AI-assisted screening implementation	High-value prospective evidence for clinical implementation of AI-US	Indirect, not ABUS-specific
Ochoa et al. (2026) ³⁰	Comprehensive breast ultrasound, low-resource setting	VSI-B cohort	DenseNet + majority voting	100% detection sensitivity; 93.6% detection specificity; 83%	Demonstrates feasibility in low-resource settings	Indirect unless ABUS acquisition

				classification specificity	without a sonographer or radiologist	confirmed
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4.4 Variables Recommended for Standardized Reporting

Future ABUS-AI diagnostic studies should report: population size at patient and lesion levels; breast-density distribution; age and screening/symptomatic status; acquisition system and vendor; AI model/vendor and version; training, validation, and external-test datasets; reference standard; reader experience and blinding; threshold/BI-RADS definition; sensitivity, specificity, PPV, NPV, accuracy, and AUC with 95% confidence intervals; patient-level versus lesion-level analysis; reading time; recall and biopsy outcomes; and whether AI is used as a standalone reader, concurrent reader, or second reader. Reporting these variables is

necessary for meaningful external validation and future meta-analysis.

4.5 Study Design and Reporting Characteristics of Direct ABUS Evidence

Table 3 summarizes design-level characteristics of the direct ABUS studies in Table 1. This is a descriptive summary of design and validation features as reported in the source publications, not a formal risk-of-bias assessment (e.g., QUADAS-2),³¹ which was outside the scope of this narrative review. Most direct AI-ABUS evidence originates from retrospective, single-center studies, and independent multivendor external validation is rarely reported.

Table 3. Study design and reporting characteristics of direct ABUS evidence.

Study (year)	Design	Sample size	Center(s)	AI component	External multicenter validation reported
Wilczek et al. (2016) ¹⁶	Prospective	1,671 women	Single-center	None (conventional ABUS)	Not reported
Vourtsis & Kachulis (2018) ¹⁷	Prospective comparative	1,886 women	Not specified in extracted data	None (conventional ABUS)	Not reported
Xin et al. (2021) ¹⁸	Multicenter non-inferiority	1,947 women	5 hospitals	None (conventional ABUS)	Yes
Lee et al. (2022) ¹⁹	Retrospective	846 women	Not specified in extracted data	Commercial CAD	No
Tan et al. (2023) ²⁰	Retrospective, clinical AI study	430 paired DM-ABUS cases	Multi-site (Netherlands/China)	Multimodal AI (AI-DM + AI-ABUS)	Partial (multi-site development; independent external test not fully specified)
Kwon et al. (2024) ²¹	Retrospective	231 women / 262 lesions	Single-center	AI-based CAD	No

Kwon et al. (2026) ²²	Retrospective	1,683 women / 2,904 pairs	Two centers	None (conventional supplemental ABUS)	Two-center only
Jassim et al. (2026) ³	Systematic review / meta-analysis	18 studies; >20,000 episodes	Multinational (review-level)	Not applicable (review of ABUS vs HHUS)	Not applicable

5. AI INTEGRATION IN ABUS

5.1 Computer-Aided Detection (CAD)

CAD in ABUS is intended to flag suspicious regions and support radiologists. The 2022 Korean study demonstrates that early CAD may carry a substantial false-positive burden (PPV 0.9%),³² whereas the 2024 Kwon study provides stronger evidence that newer AI-CAD can improve reader AUC.²¹ These studies should therefore be interpreted as evidence of technological evolution rather than proof that all CAD systems provide equivalent benefit.

5.2 Deep Learning and Reader Assistance

Deep-learning systems can perform detection, classification, segmentation, or decision support. The most clinically meaningful endpoint is not simply standalone algorithm accuracy; it is whether AI improves patient-level diagnostic decisions, recall, biopsy selection, reading time, and downstream outcomes when used by radiologists. The 2025 Tsuyuzaki study is particularly relevant to this reader-assistance question, but because it concerns breast ultrasound generally, its results should not be labelled as direct AI-ABUS evidence without confirmation of the acquisition modality.²⁷

5.3 Breast Density and Related AI Tasks

Automated density classification is a related but distinct AI task. Sexauer et al.²⁵ reported 80.4% sensitivity, 89.3% specificity, and 89.6% accuracy for differentiating ACR A/B from C/D density using synthetic 2D tomosynthesis images. These results are useful context for automated breast-imaging workflows but should not be presented as evidence of AI lesion classification on ABUS.

6. CLINICAL APPLICATIONS

6.1 Screening in Dense Breasts

The strongest established clinical role of ABUS is as a supplemental screening modality, particularly in women with dense breasts. The 2026 meta-analysis found increased sensitivity and cancer detection when ABUS was added to mammography, but also higher recall and modest specificity loss. Clinical benefit should therefore be framed as a balance between additional cancer detection and additional false-positive assessment rather than as sensitivity improvement alone.

6.2 Monitoring Treatment Response

Beyond screening, ABUS has been explored as a tool for monitoring response to neoadjuvant systemic therapy, leveraging its reproducible, operator-independent volumetric acquisition to track lesion size, morphology, and vascularity across serial examinations. This application remains at an earlier stage of evidence development than screening; available reports are drawn largely from small, single-center feasibility series rather than adequately powered comparative studies. Well-designed prospective studies benchmarking ABUS-based response assessment against established reference modalities including contrast-enhanced breast MRI and conventional handheld ultrasound are needed before ABUS-based treatment-response monitoring can be regarded as validated for routine clinical decision-making.

6.3 Second-Look Imaging

ABUS-derived volumetric datasets may also assist second-look correlation for lesions initially identified on MRI, supporting localization for subsequent targeted handheld ultrasound or image-guided biopsy. Direct comparative evidence establishing diagnostic equivalence between ABUS-based second-look imaging and

conventional MRI-directed second-look ultrasound is currently limited. Until dedicated comparative studies are available, this application should be regarded as an emerging adjunctive use of ABUS rather than an established alternative to MRI-correlated targeted ultrasound.

7. CHALLENGES AND LIMITATIONS

7.1 False Positives and Workflow

AI assistance can reduce reading time but may also increase false-positive prompts. The 0.9% PPV reported for the early CAD cohort illustrates the importance of evaluating downstream consequences rather than relying only on sensitivity or AUC.

7.2 Image Artifacts and Limited Axillary Evaluation

ABUS can be affected by acquisition artifacts and typically provides limited axillary coverage. Additional targeted imaging may therefore remain necessary when axillary assessment is clinically indicated.

7.3 Heterogeneity and Generalizability

The principal limitation of the current evidence is heterogeneity. Studies vary in acquisition platform, population density, reference standard, reader experience, outcome definition, and whether the AI system is standalone or reader-assisted. The 2026 meta-analysis reported substantial heterogeneity and found that only two of 18 included studies had an overall low risk of bias. AI-ABUS evidence is also geographically concentrated, making external validation across vendors, populations, and healthcare systems essential.

7.4 Reporting and Methodological Bias

A further limitation of this review is that it is a critical/narrative review and did not use a registered systematic-review protocol, duplicate independent screening, or formal quantitative synthesis; consequently, its findings should not be read as implying exhaustive systematic identification of all available studies. Publication bias, selective reporting, spectrum bias, and verification bias should also be considered when interpreting the existing literature.

7.5 Ethical and Legal Considerations

AI deployment raises questions concerning algorithmic bias, transparency, cybersecurity, liability, human oversight, and performance drift after deployment. Clinical adoption should require clear responsibility for final interpretation and prospective monitoring of performance across relevant patient groups.

8. FUTURE PERSPECTIVES

Priority areas include prospective multicenter and multivendor validation; external testing on geographically and demographically diverse populations; reader studies with predefined endpoints; evaluation of recall, biopsy, and reading-time outcomes; transparent reporting of training and test-set separation; calibration and threshold analysis; and prospective assessment of AI-assisted workflows. The field should also distinguish clearly between algorithm-level accuracy and clinical utility a high AUC alone does not establish improved patient outcomes. Table 4 consolidates the evidence gaps identified throughout this review into specific research.

Table 4. Summary of evidence gaps and research recommendations.

Identified evidence gap	Research recommendation
Heterogeneous reference standards, outcome definitions, and lesion- vs patient-level reporting across studies	Adopt standardized reporting of sensitivity, specificity, PPV, NPV, and AUC with 95% CIs, and specify the level of analysis (lesion vs patient)
Most direct AI-ABUS studies are retrospective and single-center	Prioritize prospective study designs with predefined endpoints and independent test sets
Limited multivendor, multicenter external validation	Conduct prospective multicenter, multivendor validation studies across diverse healthcare settings

Early CAD systems show a high false-positive burden (e.g., PPV 0.9%)	Report downstream clinical outcomes (recall rate, biopsy yield, PPV) in addition to AUC and sensitivity
Sparse comparative evidence for non-screening applications (treatment-response monitoring, second-look imaging)	Conduct dedicated comparative studies against established reference modalities (contrast-enhanced MRI, targeted HHUS)
Evidence base is geographically concentrated (predominantly East Asia and Europe)	Include demographically and geographically diverse validation cohorts to support generalizability
Inconsistent reporting of how AI is deployed (standalone, concurrent, or second reader)	Explicitly state the AI deployment model and reader workflow in study methods

9. CONCLUSION

ABUS is a valuable adjunct to mammography, particularly for women with dense breasts, and AI is a promising tool for improving lesion detection, diagnostic discrimination, and reading efficiency. However, the evidence does not support treating all breast-ultrasound AI studies as AI-ABUS evidence. Direct ABUS studies show encouraging improvements with newer AI-CAD systems, but important limitations remain, including false positives, study heterogeneity, limited external validation, and inconsistent reporting. AI-enhanced ABUS should therefore currently be regarded as an adjunct to expert interpretation rather than a replacement for established clinical assessment. Well-designed prospective, multivendor, externally validated studies with patient-centered outcomes are needed before widespread routine implementation.

LIST OF ABBREVIATIONS

ABUS, Automated Breast Ultrasound; AI, Artificial Intelligence; AUC, Area Under the receiver operating characteristic Curve; BI-RADS, Breast Imaging Reporting and Data System; CAD, Computer-Aided Detection; CADx, Computer-Aided Diagnosis; CI, Confidence Interval; DCNN, Deep Convolutional Neural Network; DM, Digital Mammography; HHUS, Handheld Ultrasound; MRI, Magnetic Resonance Imaging; NPV, Negative Predictive Value; PPV, Positive Predictive Value.

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