



Comparative analysis of automated breast volume scanner (ABVS) combined with conventional hand-held ultrasound and mammography in female breast cancer detection

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Objective and background: This study aimed to compare the diagnostic value of an automated breast volume scanner (ABVS) combined with conventional hand-held ultrasound and mammography in detecting female breast cancer. Early detection is vital in improving patient outcomes for this prevalent disease.

Methods: Seventy-eight suspicious breast lesions from 60 patients were examined between August 2019 and July 2020. Each patient underwent ABVS, conventional hand-held ultrasound, and mammography. Diagnostic values, including coincidence rate, sensitivity, specificity, positive predictive value, and negative predictive value, were calculated using histopathology results as the “gold standard.”

Results: Histopathology confirmed 55 malignant (70.51%) and 23 benign lesions (29.48%). ABVS combined with conventional hand-held ultrasound identified 56 malignant (52 confirmed, 4 benign) and 22 benign nodules (3 confirmed, 19 benign). Mammography detected 48 malignant (45 confirmed, 3 benign) and 30 benign nodules (10 confirmed, 20 benign). ABVS combined with conventional hand-held ultrasound had a sensitivity of 94.5%, specificity of 82.6%, positive predictive value of 92.9%, and negative predictive value of 86.4%. Mammography showed a sensitivity of 81.8%, specificity of 87.0%, positive predictive value of 93.8%, and negative predictive value of 66.7%.

Conclusion: ABVS combined with conventional hand-held ultrasound showed high diagnostic value in detecting female breast cancer. The “convergence sign” in the coronal section played a significant role. It slightly outperformed mammography and offered advantages in terms of cost, convenience, comfort, and absence of radiation. Further promotion and implementation are supported.

Keywords: Automated Breast Volume Scanner (ABVS), Conventional hand-held ultrasound, mammography, Female breast cancer, Convergence sign

Introduction

Breast cancer is a significant health concern for women, with an increasing incidence and younger trend in recent years^[1]. In Western developed countries, the incidence of breast cancer has been steadily increasing in female malignant tumours, making it the leading cause of death related to malignant tumours in

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HIGHLIGHTS

- Automated breast volume scanner and hand-held ultrasound are highly effective in detecting breast cancer, with a significant role played by the “convergence sign.”
- They outperform mammography, offering higher sensitivity and advantages like cost-effectiveness and patient comfort.
- The study recommends the wider use of automated breast volume scanner and hand-held ultrasound in clinical practice for breast cancer detection.
- Their diagnostic accuracy and patient benefits make them valuable tools in early breast cancer detection.

middle-aged and elderly women^[2]. In China, female patients with breast cancer is also increasing due to the development of social and environmental factors. The incidence of breast cancer in China was still increasing at a rate of about 3.5% per year from 2010 to 2013, which is higher than the global average^[3].

The early detection of breast cancer can reduce mortality rates, improve survival rates, and improve prognosis and quality of life for breast cancer patients. Imaging examinations, such as ordinary hand-held ultrasound, mammography, breast ultrasound automatic volume imaging (ABVS), computed tomography (CT)

examination, and nuclear magnetic resonance, are essential tools for breast cancer detection. However, these methods have their advantages and disadvantages in clinical application. Mammography gained popularity early due to its good contrast and ability to display lesions with calcification, particularly for the timely diagnosis of micro-calcification lesions. However, mammography examination has its limitations, such as decreased sensitivity when breast glands are denser, and difficulty in making detailed assessments of breast lesions' extent and location^[4].

Organized breast volume imaging ABVS is a new three-dimensional ultrasound diagnostic technology that has been increasingly accepted by patients with breast diseases. It has higher reproducibility and less dependence on operator manipulation, collects standard views of the whole breast volume, and has high reliability in detecting the size and location of lesions in dense breasts^[5]. This technology is relatively more accurate in evaluating breast cancer than ordinary hand-held ultrasound^[6].

This study combined automated breast volume ultrasound ABVS with ordinary hand-held ultrasound and conducted a comparative analysis using mammography. The most common manifestation of breast cancer is breast nodules, which can be benign or malignant. Early accurate judgment of benign and malignant breast nodules can reduce medical treatment waste and unnecessary panic for patients. Ultrasound and mammography are the two most widely used examinations in breast diseases, but their advantages and disadvantages in interpreting benign and malignant breast nodules remain unclear^[7].

Taking pathological diagnosis results as the gold standard, this study analyzed and calculated the coincidence rate, sensitivity, specificity, negative predictive value, and positive predictive value of two methods of automated breast volume imaging ABVS combined with conventional hand-held ultrasound and mammography for breast nodules. The comparison of the advantages and disadvantages of ABVS combined with conventional hand-held ultrasound and mammography in diagnosing breast cancer is crucial for improving patient outcomes and reducing the burden of medical treatment.

Materials and method

Study Design

This retrospective observational study with a cross-sectional design was carried out with a total of 60 outpatients and inpatients from August 2019 to July 2020 in a tertiary care centre in China (Fig. 1). Ethical approval for conducting the study was taken from the medical ethics committee (approval number: NM-LL-2019-06-03-1). All the participants were selected in the consecutive series. The work is reported in line with the Standard for Reporting of Diagnostic Accuracy Studies (STARD)^[8].

Inclusion criteria

Participants must have intact skin, tolerate pressure, be women aged 40–75, have suspicious nodules found by ultrasonography or mammography, have the nodules for the first time, and agree to undergo an operation or puncture biopsy for histopathological results.

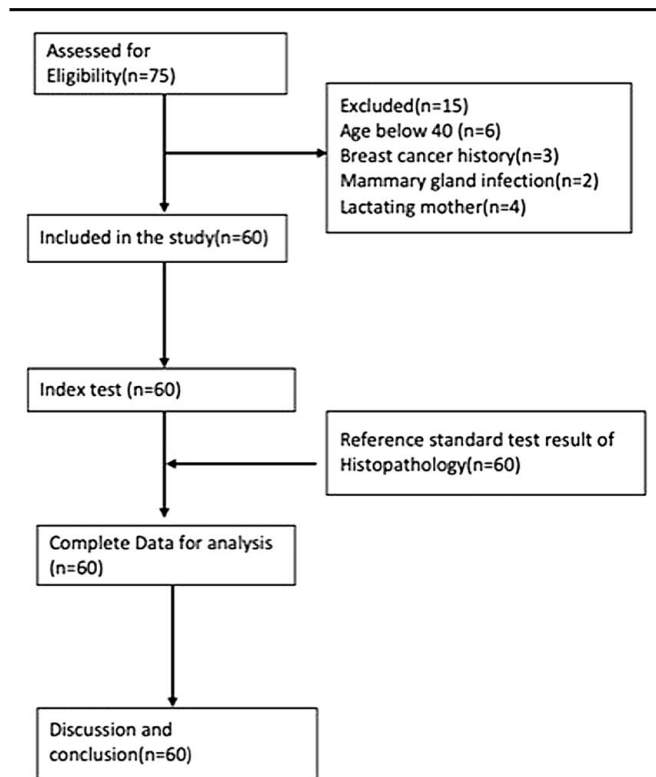


Figure 1. STARD flow diagram of the participants.

Exclusion criteria

The study excluded patients with mammary gland infection, implantation failure, lactation mammary gland, females under 40, breast cancer history, abnormal coagulation function, severe liver and kidney insufficiency, or respiratory and circulatory failure.

Examination methods

A hand-held ultrasound probe was used to examine female patients using linear array probe 9L4 for bilateral breasts, focusing on longitudinal, transverse, and fan-shaped sections. Colour Doppler flow imaging was used to detect nodules, while pulse Doppler sampling measured peak systolic velocity and resistive index. Ultrasound images were collected based on diagnostic criteria and nodule characteristics, and the results were recorded.

The ABVS probe was used to examine the bilateral breasts of female patients using a Colour Doppler ultrasound diagnostic instrument. The probe was equipped with a 14L5BV probe and a special image processing workstation. The patient was placed in supine or lateral positions, and the images were scanned in medial, lateral, and anteroposterior positions. Data from scanning is transmitted to a three-dimensional reconstruction system for continuous offline reading, requiring observation and description of lesions, including location, size, shape, direction, and convergence sign. Nodule images were classified according to the North American Radiology Society's diagnostic classification standard. The combination of ABVS and conventional hand-held ultrasound defines benign nodules as having a regular shape,

uniform internal echo, clear boundary, and normal surrounding gland echo (Fig. 2). Malignant tumours were hypoechoic with uneven internal echo, irregular shape, unclear boundary, and “crab foot” shape changes (Fig. 3). Some tumours showed calcification and abundant arterial blood flow signals with high speed and resistance. The coronal images of ABVS exhibited a characteristic “convergence sign” (Fig. 4).

The molybdenum target photography examination was conducted using a digital mammography instrument and image acquisition system from GE Company. Professional technicians in the hospital’s imaging department conducted the examination, using various body positions and an automatic exposure control mode^[9]. The collected images were analyzed and the associated pleomorphic microcalcifications, architectural distortion, skin thickening and nipple retraction, and presence or absence of axillary lymph nodes were recorded. The nodule images were classified according to the North American Radiology Society’s diagnostic classification standard, and relevant results were recorded.

The ultrasound, ABVS, and mammography images of enrolled patients were then classified by BI-RADS according to the North American Radiology Society’s diagnostic classification standard^[10]. The classification system includes

- Class 0 (incomplete data).
- Class 1 (negative, without obvious abnormal performance).
- Class 2 (benign lesions).
- Type 3 (may be benign lesions, may be malignant degree < 2%).
- Type 4 (suspicious malignant tumour, degree of malignancy 2–95%).
- Type 5 (highly suspected malignant tumour, possibility of malignancy more than 95%), and
- Grade 6 (malignant tumour confirmed by pathology).



Figure 2. Benign nodule by hand-held ultrasound.

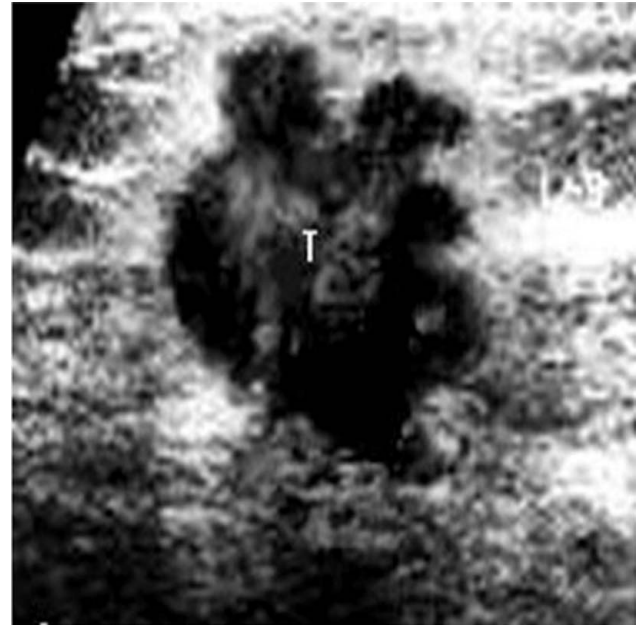


Figure 3. Malignant nodule by hand-held ultrasound.

The study found that BI-RADS 2-3 nodules were classified as benign lesions and BI-RADS 4-6 nodules as malignant lesions.

The imaging findings were compared with histopathological findings, which were the gold standard for determining whether the lesions were benign or malignant. The histopathological reports, provided by a post-graduate consultant pathologist with at least 6 years of experience, served as the reference standard. These reports contained the definitive diagnosis of whether the suspicious lesions were benign or malignant based on the tumour size, grade, margin, and nuclear grade. The researcher recorded the imaging and histopathological findings along with demographic data in a proforma. Clinical information was withheld from the technician, operator, radiologist, and pathologist to prevent potential bias. All physicians conducting the procedure

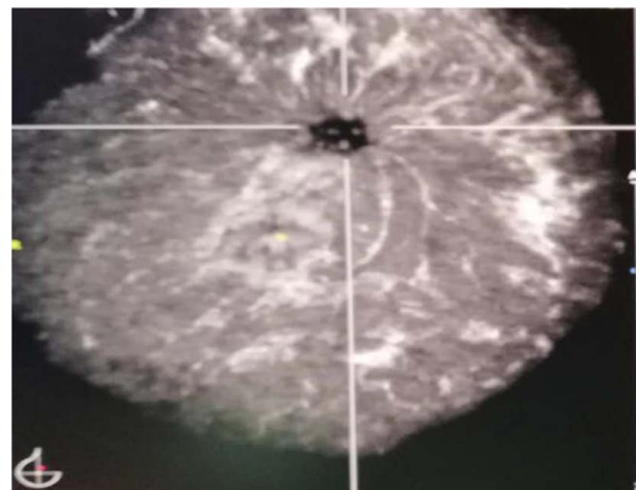


Figure 4. Convergence sign of Automated breast volume scan study.

were kept unaware of the findings from the other imaging modality. There were no noticeable adverse effects observed in the patients during the radiological imaging or histopathological examination.

We reviewed indeterminate cases and repeated tests to obtain conclusive findings. We sought expert consultation from senior radiologists and pathologists to gain valuable insights. To ensure study validity and reliability, we proactively followed up with patients to collect missing data and verify clinical outcomes. We conducted a comprehensive re-evaluation of imaging and pathology reports, cross-referencing with other sources, to minimize errors and avoid missing cases impacting study outcomes.

Statistical analysis

The personal information and data of all the patients were sorted out and entered into the computer to create the relevant database. SPSS 21.0 was used for statistical analysis. The measurement data were expressed by $x \pm s$; the counting data were analyzed by χ^2 test. The test results were statistically significant with *P* less than 0.05.

Sensitivity, Specificity, Positive predictive value, and Negative predictive value for combined ABVS and conventional hand-held ultrasound and mammography were calculated in addition to the coincidence rate for ABVS and hand-held ultrasound.

The formula used for the relevant data is as follows:

Coincidence rate = (true positive + true negative)/(false positive + false negative).

Sensitivity = true positive/true positive + false negative.

Specificity = true negative/true negative + false positive.

Positive predictive value = true positive/true positive + false positive.

Negative predictive value = true negative/true negative + false negative.

Results

This study involved 60 female patients aged between 40 and 75 years, with a majority falling within the 40–50 age range. The most frequent presenting complaint was palpable breast lumps (Table 1). Among the 78 breast nodules evaluated in these female patients, 23 were diagnosed as benign tumours, such as Fibroadenoma, Adenosis, Intraductal papilloma, and Plasma cell mastitis, while 55 nodules were identified as malignant tumours,

including Invasive ductal carcinoma, Ductal carcinoma in situ, Mucinous carcinoma, and Medullary carcinoma. Out of the 78 nodules examined, the combination of ABVS and conventional hand-held ultrasound identified 56 as malignant (52 confirmed by pathology) and 22 as benign (3 confirmed by pathology). The results were compared to pathological findings.

Out of the 78 nodules examined, 48 were malignant in mammography (45 confirmed by pathology) and 30 were benign (10 confirmed by pathology). Mammography detected malignant lesions with irregular shapes, a “burr sign” on the edge (Fig. 5), and various types of calcifications.

The study found that the combination of automated breast volume imaging ABVS and conventional hand-held ultrasound accurately diagnosed 71 out of 78 breast nodules (52 malignant, 19 benign), with a coincidence rate of 91.3%.

Mammography detected 65 breast nodules (45 malignant, 20 benign) consistent with a pathological diagnosis with a coincidence rate of 83.3% including 3 false positives and 10 false negatives.

The sensitivity of ultrasound examination with ABVS is greater than that of mammography (*P*=0.039), and there is no significant statistical difference in specificity, positive predictive value, and negative predictive value (*p* values are 0.659, 0.571, and 0.105, respectively). The sensitivity and negative predictive value of ultrasonography with ABVS was better than using the “convergence sign” alone (*P*=0.002, 0.013), and the specificity and positive predictive value were not significantly different from using the “convergence sign” alone (*p* values are 0.711 and 0.490 respectively); Compared with mammographic examination and convergence sign, there was no significant statistical difference in sensitivity, specificity, positive predictive value, and negative predictive value (*p* values were 0.258, 0.441, 0.406, 0.327) (Table 2).

Table 1
Clinico-demographic profile of patients with suspicious breast lesions.

Characteristics	Number, <i>n</i> (%)
Age	
40–50 year	36 (60)
50–59 year	20 (33.33)
60–69 year	3 (5)
70–75 year	1 (1.67)
Presenting complaints	
Palpable breast mass	48 (80)
Focal breast pain	9 (15)
Nipple discharge	2 (3)
Axillary lump	1 (2)

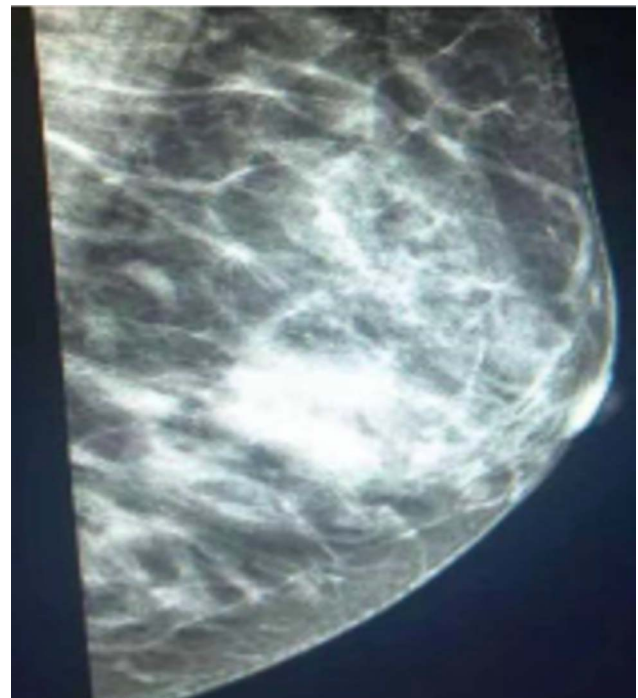


Figure 5. Burr sign of mammography.

Table 2
Comparison of diagnostic value of ultrasound with ABVS, mammography, and “convergence sign” of Coronal image.

Type	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Ultrasound with ABVS	94.5%	82.6%	92.9%	86.4%
Mammography examination	81.8%	87.0%	93.8%	66.7%
Convergence sign	72.7%	78.3%	88.9%	54.5%

ABVS, automated breast volume scanner.

A comparison of the coincidence rate of ABVS with conventional hand-held ultrasound and mammography shows a significant difference ($\chi^2 = 2.064, P = 0.152$) (Table 3).

Discussion

Breast cancer has become a major global health concern, with high mortality rates among women^[11]. Studies show that breast cancer accounts for a significant portion of new malignant tumours worldwide, and its incidence has been rising rapidly, particularly in China. The incidence of breast cancer in China is increasing at a rate higher than the global average, with a younger age of onset compared to Western countries^[12,13]. Early detection and diagnosis are crucial for better prognosis and outcomes in breast cancer patients.

Imaging techniques have gained significant importance in breast cancer screening. This study focused on the classification of breast nodules based on the BI-RADS standard, where BI-RADS 2-3 nodules were considered benign and BI-RADS 4-6 nodules were classified as malignant. The study aimed to compare the diagnostic performance of automated breast volume imaging ABVS combined with conventional hand-held ultrasound and mammography in detecting breast malignant nodules. The evaluation parameters included coincidence rate, sensitivity, specificity, negative predictive value, and positive predictive value.

The findings of this study contribute to the understanding of the application value of ABVS combined with ultrasound and mammography in diagnosing breast cancer. By analyzing the breast cancer signs detected through these imaging techniques, the study provides insights into their diagnostic accuracy and potential roles in clinical practice. Early detection, accurate diagnosis, and timely treatment of breast cancer are crucial for improving patient outcomes, and the continuous development of medical imaging technology plays an increasingly prominent role in achieving these goals.

Table 3
Comparison of coincidence rate of ABVS combined with conventional hand-held ultrasound and mammography.

Type of examination	Consistent with pathological findings	
	Agree with	Disagree
ABVS combined with hand-held ultrasound	71	7
Mammography examination	65	13

ABVS, automated breast volume scanner.

The diagnostic value of breast ultrasound automated breast volume imaging (ABVS) combined with conventional hand-held ultrasound for breast cancer

In recent years, breast ultrasound automated breast volume imaging ABVS has gained acceptance in clinical practice as a new method for breast examination. It allows three-dimensional volume imaging of the breast, reducing operator dependence and improving repeatability. The fusion of hand-held ultrasound and ABVS demonstrates elevated sensitivity in the early detection of cancer, particularly in patients with dense breast tissue and those who are asymptomatic^[14]. However, there is no consensus on the detection and diagnostic capabilities of ABVS^[15].

This study aimed to evaluate the diagnostic performance of ABVS combined with conventional hand-held ultrasound. The results showed a coincidence rate of 91.3%, sensitivity of 94.5%, specificity of 82.6%, positive predictive value of 92.9%, and negative predictive value of 86.4% for breast cancer diagnosis. Although these values indicate high diagnostic accuracy, other studies have reported slightly higher sensitivity and specificity for ABVS^[16].

The discrepancy in results could be attributed to the classification of benign and malignant nodules. This study classified BI-RADS 4a lesions as malignant, whereas other studies considered them benign. Including BI-RADS 4a lesions in the malignant group has clinical relevance as many patients opt for biopsy or surgical resection despite the low possibility of malignancy. The BI-RADS classification method facilitates communication between imaging doctors and clinicians.

ABVS provides clear coronal section images, compensating for the limitations of conventional hand-held ultrasound and improving the diagnostic rate of breast cancer. The “convergence sign” observed in the coronal section of ABVS reflects the relationship between lesions and surrounding soft tissues. The sensitivity, specificity, positive predictive value, and negative predictive value of the “convergence sign” were 72.7%, 78.3%, 88.9%, and 54.5%, respectively. However, the subjective nature of imaging and the lack of a standardized definition for the “convergence sign” may affect its sensitivity and specificity.

The low negative predictive value of the “convergence sign” could be due to early-stage breast cancer presenting only as irregular boundary hypoechoic sonograms without invading surrounding tissues. Additionally, benign lesions like breast tissue hyperplasia may also exhibit the “convergence sign,” reducing its diagnostic accuracy.

In conclusion, ABVS combined with conventional hand-held ultrasound shows promising diagnostic capabilities for breast cancer. The study emphasizes the importance of standardized classifications and highlights the potential of the “convergence sign” in improving diagnostic accuracy. However, further research is needed to establish consistent criteria and refine the performance of ABVS in breast cancer diagnosis.

The diagnostic value of mammography in breast cancer

Mammography is a widely used imaging method for breast cancer screening due to its simplicity, speed, cost-effectiveness, and high sensitivity. It has contributed to a significant reduction in breast cancer mortality rates in countries like the United States^[17]. Other studies have also shown that mammography can better improve the risk of death in women with breast cancer^[18]. However, mammography has limitations, particularly in cases of dense breast tissue and severe breast hyperplasia, where its sensitivity decreases and the risk of missed diagnoses increases. In a study, mammography demonstrated a coincidence rate of 83.3%, sensitivity of 81.8%, specificity of 87.0%, positive predictive value of 93.8%, and negative predictive value of 66.7%. Several cases were found to be inconsistent with histopathological results, including false positive and false negative results. Non-calcified soft tissue lesions, especially in patients with dense breasts, showed lower sensitivity, leading to missed diagnoses.

Comparison of diagnostic value of ABVS combined with conventional hand-held ultrasound and mammography

Various studies have investigated the diagnostic value of ultrasound and mammography in breast cancer detection, but there is still controversy surrounding their exact diagnostic capabilities, possibly due to different study classifications. In this study, ABVS combined with conventional hand-held ultrasound demonstrated better sensitivity than mammography ($P < 0.05$) in diagnosing breast cancer, while specificity, positive predictive value, and negative predictive value were not significantly different ($P > 0.05$). Mammography is known for its ability to detect microcalcifications, resulting in higher sensitivity in some previous studies. However, the introduction of ABVS with coronal section imaging has further improved the diagnosis of microcalcifications^[19]. This may be one of the reasons why the combination of ABVS and conventional hand-held ultrasound exceeds mammography. Additionally, the “convergence sign” in the coronal section of ABVS played an important role in breast cancer diagnosis. However, it showed lower sensitivity and negative predictive value compared to overall ultrasound evaluation ($P < 0.05$). The specificity and positive predictive value were similar between the two groups ($P > 0.05$). The “convergence sign” contributes to the superiority of ABVS combined with conventional hand-held ultrasound over mammography.

This study has limitations due to its retrospective design, potential biases, and single-centre setting. Convenient patient sampling may introduce selection bias, and the sample size may affect statistical power and precision. Additionally, the absence of a direct head-to-head comparison between ABVS, hand-held ultrasound, and mammography limits the ability to draw definitive conclusions about their diagnostic accuracy.

In a research study conducted by Brunette *et al.*, it was demonstrated that the combination of ABVS and hand-held ultrasound exhibited superior diagnostic accuracy compared to mammography, with statistically significant results for detection of subclinical lesions^[20]. Nonetheless, it has limitations, such as operator dependency, potential false positives, cost factors, limited specificity, and the requirement for further diagnostic procedures.

Conclusion

The combination of ABVS and conventional hand-held ultrasound has a high diagnostic value for breast cancer, with the “convergence sign” in the coronal section playing an important role. ABVS combined with conventional hand-held ultrasound showed slightly better results than mammography in this study. Moreover, ultrasound examination outperformed mammography in terms of economy, convenience, comfort, and absence of radiation. Therefore, it is recommended to further promote and implement the use of ABVS combined with conventional hand-held ultrasound in clinical practice for the detection of breast cancer, considering its diagnostic accuracy and patient benefits.

Ethical approval

We have conducted an ethical approval base on the Declaration of Helsinki with registration research at the Medical Ethics Committee of Affiliated hospital of Inner Mongolia University for the Nationalities with reference number of NM-LL-2019-06-03-1.

Consent

Written informed consent was obtained from the patient for the publication of this case report and the accompanying images. A copy of the written consent is available for review by the Editor-in-chief of this journal on request.

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Author contributions

A.S.: conceptualization, as mentor and reviewer for this original article and for data interpretation. J.T.L.: conceptualization and reviewer for this case. B.S.: reviewer and data interpretation. S.S.: contributed in performing literature review and editing. S.K.: contributed in performing literature review and editing. All authors have read and approved the manuscript.

Conflicts of interest disclosure

The authors declare that there is no conflicts of interest regarding the publication of this article.

Research registration unique identifying number (UIN)

1. Name of the registry: researchregistry.com.
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Guarantor

Shailendra Katwal is the person in charge of the publication of our manuscript.

Data availability statement

Data Sharing is not applicable to this article.

Provenance and peer review

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