Efficiency And Impact Factors of Anatomical Intelligence For Breast And Hand-Held Ultrasound In Lesion Screening: A Pilot Study

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Abstract

Objective: To investigate the efficiency and impact factors of anatomical intelligence for breast (AI-Breast) and hand-held ultrasound (HHUS) in lesion screening.

Methods: A total of 172 outpatient women were randomly selected, underwent AI-Breast ultrasound (Group AI) once and HHUS twice. HHUS was performed by breast image radiologists (Group A) and general radiologists (Group B). For the AI-Breast examination, a trained technician performed the whole-breast scan and data acquisition, while other general radiologists performed image interpretation. The examination time and lesion detection rate were recorded. The impact factors for breast lesion screening, including breast cup size, lesion number (LN), and benign or malignant lesions were analyzed.

Results: Scan times of Groups AI, A, and B were 262.15 ± 40.4 s, 237.5 ± 110.3 s, 281.2 ± 86.1 s, respectively. The scan time of Group AI was significantly higher than Group A ($P < 0.01$), but was slightly lower than Group B ($P > 0.05$). The detection rates of Group AI, A, and B were $92.8 \pm 17.0\%$, $95.0 \pm 13.6\%$, and $85.0 \pm 22.9\%$, respectively. Comparable lesion detection rates were observed in Group AI and Group A ($P > 0.05$), but a significantly lower lesion detection rate was observed in Group B compared to the other two (both $P < 0.05$). Regarding missed diagnosis rates of malignant lesions, comparable performance was observed in Group AI, Group A, and Group B (8% vs. 4% vs. 14%, all $P > 0.05$). We found a strong linear correlation between scan time and cup size in Group AI ($r = 0.745$). No impacts of cup size and LN were found on the lesion detection rate in Group AI ($P > 0.05$).

Conclusions: The screening efficiency of AI-Breast ultrasound was comparable to that of a breast image radiologist and superior to that of the general radiologist. AI-Breast ultrasound may be used as a potential approach for breast cancer screening.

Introduction

Breast cancer is the leading malignant tumor to severely threat female health worldwide, accounting for 11.7% of the new cases of cancer in 2020. In particular, mortality rates are higher in developing countries [1]. Early detection and diagnosis of breast cancer is critical, so standardized screening is of great importance. Asian women have relatively small and dense breasts; in China, half of those aged 45-65 are classified as dense type [2, 3]. This category has a 4-6 folds increased risk of breast cancer than women with non-dense breasts. Mammography, a classic screening tool, has limitations on dense breasts; thus, screening sensitivity is reduced in China [4]. Moreover, according to the national registry, the breast cancer detection rate is less than 1% [5]. In the past 20 years, the prevalence of this disease has increased by 3-5% every year, much faster than the average increase rate of 0.5% worldwide [6].

Conventional hand-held ultrasound (HHUS) is a preferred approach for the screening of breast cancer in Chinese women [7]. The accuracy and efficiency of the screening is related to the experience of the radiologist [8, 9]. On the other hand, anatomical intelligence for breast (AI-Breast) is a new ultrasound method [10] that makes the scan process visual. AI-Breast uses a magnetic positioning device and

separates real-time scan and interpretation diagnosis. This study aimed to explore the value of AI-Breast in breast lesion detection and the possibility of its use for breast cancer screening, while comparing it to HHUS.

Materials And Methods

A single-center study was carried out in the Affiliated Hangzhou First People's Hospital, School of Medicine, Zhejiang University, from February to April 2021. The project was approved by the Ethics Committee of the hospital [No. HZFPHLL2020089]. For this study, all patients signed informed consent and accepted the use of their image data.

Study participants and study design

A total of 172 female patients, aged 18-80 years, were enrolled at the Breast Department. They presented breast pain, lumps (initial diagnosis or reexamination), nipple discharge, or abnormal imaging findings. Patients who met the inclusion criteria were 1) about to undergo surgery or needle biopsy for breast lesions; 2) Included in a long-term follow-up for breast lesions (≥ 2 years) and had complete data. The exclusion criteria listed those with cardiac pacemaker implantation, previous total mastectomy, breast implantation, or in lactation and pregnancy.

All patients received AI-Breast ultrasound scan once and HHUS twice. The AI-Breast ultrasound group (Group AI) included two general radiologists that interpreted the images (5-8 years of experience in ultrasound diagnosis, C.C, and H.J) and one technician (short training in breast scan).

HHUS was performed by breast image radiologists (Group A) or general radiologists (Group B). The radiologists in Group A had 8-10 years of experience in breast ultrasound (X.X and Y.J) while those in Group B had a 5 to 8-year expertise in ultrasound diagnosis (L.F and J.J).

AI-Breast ultrasound

A color ultrasound instrument (Philips EPIQ5) equipped with a variable-frequency probe (eL18-4) was used. This technology comprised a frequency range of 2-22 MHz, a receivable magnetic field signal, and a AI-Breast magnetic positioning device mattress.

In Group AI, the technician conducted the scanning as follows: the patient took a supine position with arms raised above the head, and the targeted breast was raised by appropriate lateral rotation. Triangular support behind the examined side helped fix the position and place the breast into an effective magnetic field. The scan area was determined through locating the nipple and the lower, inner, and outer margin of the breast. To ensure clearness in the images, a relatively uniform and alternating up-down scan mode was selected, with at least a 1/3 overlap between every two scans. A bilateral double breast examination was performed. During the exploration, the breast surface marks were filled with green thick lines. Complete filling meant that the examination of a unilateral breast was finished. The technician in the

Group A performed a whole-breast scanning according to the standards and recorded the time of scanning completion.

Subsequently, the breast data were saved in video by the technician, imported into a computer, and interpreted using professional software by the radiologists. The time of interpretation, and lesion number (LN) and location were recorded.

HHUS examination

The previously described Philips EPIQ5 instrument equipped with the eL18-4 probe was employed. Examinations in Groups A and B began with patients taking a supine position and fully exposing their chest. A comprehensive breast scanning was performed radially or alternating up and down, left and right. During the examination, the images were saved and the number and specific location of the lesions were recorded.

Number and categorization of breast lesions

Breast lesion detection and patient clinical data were analyzed in the three groups. If the LN was the same in the three groups, there was no controversy. If the LN was different, two radiologists in Group A reviewed the AI-Breast image information and saved 2D ultrasound images to make a judgment. If necessary, patients were called for reexamination.

Criteria for benign and malignant breast lesions: 1) lesions with BI-RADS categories 4 and above were confirmed as benign or malignant by surgery or puncture; 2) lesions with BI-RADS 3 and below were confirmed by surgery. In the cases where no surgery nor puncture was conducted, all lesions were followed up for at least 2 years (≥ 2 times). Ultrasound images of the last 2 years were reviewed. No significant change in the size and ultrasound characteristics of the lesions was judged benign. Lastly, 10% of patients were randomly selected for MRI to exclude false positives.

Statistical analysis

The MedCal software was used for statistical analyses. Measurement data were expressed as mean $\pm$ SD. Differences in measurement data between two groups were analyzed by the Mann-Whitney test, with $P < 0.05$ termed as statistical significance. Differences in measurement data between multiple groups were analyzed by the Anova test, with $P \leq 0.05$ indicating a significant difference between at least two groups. Further evaluations included the use of Spearman's correlation, with $|P| = 0.7$, $0.7 > |P| > 0.4$, and $|P| < 0.4$ indicating high, weak and no significant linear correlation, respectively.

Results

Participant characteristics

A total of 172 patients were enrolled, with an average age of 41.3 years old ($SD \pm 13.3$). Breast cups A, B, C, and D and above accounted for 26%, 40%, 27%, and 7%, respectively. LN values of 0, 1, 2, and 3 and more were distributed as present in the 8%, 23%, 19%, and 50%, respectively, of the patients (Table 1).

In this study, 15 cases had no lesions confirmed by ultrasound during the follow-up, while the remaining 157 women had a total of 555 lesions. Of them, 132 women underwent surgery or puncture and counted a total of 163 lesions that were: 1) malignant (N=51): 36 lesions of invasive breast carcinoma (non-special type, NST), 6 lesions of ductal carcinoma in situ(DCIS), 3 lesions of mucinous carcinoma, 5 lesions of papillary carcinoma, and 1 lesion of adenoid cystic carcinoma; and 2) benign (N=112): 81 lesions of fibroadenomas, 4 lesions of inflammatory lesions, 6 lesions of intraductal papillomas, 18 lesions of adenopathy, 1 lesion of lipoma and 2 lesions of fat calcified nodules. There were 392 lesions without pathological results. Of them, 70 lesions were confirmed as benign by MRI. The remaining 322 lesions were confirmed as benign by ultrasound in the follow-up (Table 1).

Table 1
Basic characteristics of enrolled patients

Group	Enrolled cases (n=172)	Benign (n=128)	Malignant (n=44)
Lesion number			
0	15(8%)	15(12%)	0(0%)
1	41(23%)	18(14%)	23(52%)
2	32(19%)	23(18%)	9(20%)
3	28(16%)	22(17%)	6(14%)
4	19(11%)	15(12%)	4(9%)
≥ 5	37(23%)	35(27%)	2(5%)
Breast cup size			
A	44(26%)	32(25%)	12(27%)
B	69(40%)	54(42%)	15(34%)
C	47(27%)	34(27%)	13(30%)
D and above	12(7%)	8(6%)	4(9%)

Examination time with AI-Breast and HHUS

Scan times of Groups A, B, and AI were 237.5 ± 110.3 s(T_A), 281.2 ± 86.1 s(T_B), and 262.15 ± 40.4 s ($T_{AI \text{ scan}}$), respectively. Group AI interpretation time was 225.6 ± 43.6 s ($T_{AI \text{ interpretation}}$). T_A was significantly shorter than T_B and $T_{AI \text{ scan}}$ (Both $P < 0.05$), and $T_{AI \text{ scan}}$ was relatively shorter than T_B ($P = 0.057$) (Fig. 1).

In the non-lesion groups, the scan times were 173.7 ± 34.9 s (T_A), 217.5 ± 50.6 s (T_B), and 239.5 ± 30.5 s ($T_{AI \text{ scan}}$), while $T_{AI \text{ interpretation}}$ was 193.7 ± 34.1 s. For those with LN 1-5, times were 223.5 ± 75.9 s (T_A), 275.8 ± 77.4 s (T_B), 259.8 ± 35.4 s ($T_{AI \text{ scan}}$), and 223.7 ± 38.8 s ($T_{AI \text{ interpretation}}$). In the LN ≥ 5 cases, times were 340.6 ± 190.9 s (T_A), 342.6 ± 106.1 s (T_B), 286.3 ± 55.7 s ($T_{AI \text{ scan}}$), and 251.1 ± 56.1 s ($T_{AI \text{ interpretation}}$). The scan times of patients with lesions were significantly longer than those of patients without lesions. In particular, Groups A and B had a positive linear correlation between the scan time and the LN ($r_a = 0.512$, $r_b = 0.397$). The scan time in Group AI did not correlate with LN ($r_{AI \text{ scan}} = 0.156$). When LN was 1-5, there was no statistical significance ($P > 0.05$) (Table 2 and 4).

Furthermore, scan times significantly increased with breast size in the three groups. In particular, $T_{AI \text{ scan}}$ had a positive linear correlation with breast size ($r_{AI \text{ scan}} = 0.745$) (Table 2 and 4). On the other hand, the scan times of benign cases from Group A and group B were significantly longer than those of malignant cases ($P < 0.05$). $T_{AI \text{ scan}}$ did not correlate with benign or malignant lesions, and there were no significant differences ($P = 0.688$) (Table 2 and 4).

Lesion detection rate with AI-Breast and HHUS

In this study, the average detection rates of breast lesions were: Group A ($95.0 \pm 13.6\%$), Group AI ($92.8 \pm 17.0\%$) and Group B ($85.0 \pm 22.9\%$). No statistical significance was noted between Group AI and Group A ($P = 0.367$). However, differences were found when comparing Group A and Group AI, respectively, with Group B (both $P < 0.05$).

Detection rates in Group A and Group AI did not correlate with LN, and there was no statistical significance. For its part, the detection rate in Group B had a negative linear correlation with the LN ($r_b = -0.436$, $P = 0.001$). In Group B, patients with $LN \geq 2$ and C cup and above had a decreased detection rate that was significantly lower than those in Group A and Group AI ($P < 0.05$) (Table 3 and 4). Moreover, detection rates throughout the three groups did not correlate with breast size ($P > 0.05$) (Table 3 and 4).

For benign lesions, missed diagnosis rates in Group A, Group AI, and Group B were 7%, 8%, and 20%, respectively. Group B had higher rates than Group A and Group AI (both $P < 0.05$) while there were no statistical differences between Group AI and Group A ($P = 0.629$). For malignant lesions, missed diagnosis rates in Group A, Group AI, and Group B were 4%, 8%, and 14%, respectively. There were no statistical differences between them ($P > 0.05$) (Table 5).

Table 2

Impact of LN, breast size, and pathological properties on the examination time in the three groups

Group	HHUS		AI-Breast	
	T _A (s)	T _B (s)	T _{AI scan} (s)	T _{AI interpretation} (s)
Lesion Number				
0	173.7±34.9	217.5±50.6	239.5±30.5	193.7±34.1
1≤LN≤5	223.5±75.9	275.8±77.4	259.8±35.4	223.9±38.8
≥5	340.6±190.9	342.6±106.1	286.3±55.7	251.1±56.1
P-value	<0.001	<0.001	<0.001	<0.001
1	183.5±61.7	254.4±63.7	265.9±37.5	228.1±37.9
2	210.9±67.7	254.0±69.3	254.6±35.0	220.3±37.0
3	258.8±71.9	296.4±80.6	262.1±35.4	225.1±44.2
4	248.1±84.2	295.0±81.1	250.0±27.4	215.8±34.7
5	282.2±59.9	338.9±91.8	263.0±42.0	230.6±41.0
P-value	<0.001	0.003	0.474	0.758
Breast cup size				
A	205.0±84.1	248.3±71.2	230.6±20.3	193.7±25.0
B	228.4±75.3	284.7±88.6	250.1±20.8	215.2±26.8
C	231.9±72.2	293.6±89.1	286.8±27.8	248.8±35.8
D and above	431.8±242.1	332.8±76.1	350.4±43.9	311.3±47.9
P-value	<0.001	0.007	<0.001	<0.001
Pathological properties				
Number of malignant lesions (n=44)	220.0±122.4	252.4±64.5	266.0±42.6	228.8±43.3
Number of benign lesions (n=113)	243.6±105.7	291.1±90.5	260.9±39.8	224.5±43.8
P-value	0.027	0.038	0.688	0.770

Table 3
Impact of LN and breast size on the detection rates in the three groups

	HHUS			Group AI	Comparison of P-value between AI and HHUS	
	Group A	Group B	P		Group A	Group B
Lesion Number						
0	100.0±0.0	100.0±0.0	1.0000	100.0±0.0	1.0000	1.0000
1	100.0±0.0	95.1±21.8	0.7038	95.1±21.8	0.7038	1.0000
2≤LN ≤3	92.5±79.8	79.8±26.2	0.0152	90.6±17.7	0.5816	0.0450
≥4	92.6±14.4	79.1±18.3	0.0001	91.5±13.8	0.5924	0.0002
P-value	0.054	<0.001	NA	0.385	NA	NA
Breast size						
A	93.5±14.0	86.1±20.7	0.1572	93.8±14.0	0.8806	0.1247
B	95.9±13.7	87.8±20.9	0.0216	94.3±15.4	0.4970	0.0812
C	93.8±14.5	82.8±24.5	0.0031	88.2±22.0	0.3260	0.0461
D and above	100.0±0.0	73.3±31.9	0.0153	98.5±5.2	0.7290	0.0262
P value	0.416	0.197	NA	0.193	NA	NA

Table 4
Correlation between LN, breast size, examination time, and detection rate in the three groups

	Lesion Number	Breast size
Examination time		
Scan time of Group AI	r =0.156 (P=0.042)	r = 0.745 (P< 0.001)
Interpretation time of Group AI	r =0.195 (P=0.011)	r = 0.665 (P< 0.001)
Group A	r = 0.512 (P< 0.001)	r =0.267 (P< 0.001)
Group B	r = 0.397 (P< 0.001)	r =0.268 (P< 0.001)
Detection rate		
Group AI	r =-0.248 (P=0.001)	r =-0.0756 (P=0.218)
Group A	r = -0.275 (P< 0.001)	r =-0.0943 (P=0.536)
Group B	r = -0.436 (P< 0.001)	r =-0.0473 (P=0.218)

Table 5
Influence of benign and malignant lesions on the examination time and missed detection rate in the three groups

	HHUS			Group AI	Comparison of P-value between AI and HHUS	
	Group A	Group B	P		Group A	Group B
Missed diagnosis rate (LN)						
Number of benign lesions (n=504)	35(7%)	102(20%)	< 0.001	40(8%)	0.6290	<0.001
Number of malignant lesions (n=51)	2(4%)	7(14%)	0.156	4(8%)	0.6646	0.515
Chi-square test P	0.186	0.398	NA	0.787	NA	NA

Discussion

Mammography is considered the main imaging method for the reduction of breast cancer mortality. However, the sensitivity of this method is lower in dense breasts. In China and other Asian countries, the proportion of women with dense breasts is higher than in western countries. Ultrasound systems overcome this issue with high screening efficiency in dense breasts [11, 12]. Because of this, the ultrasound is the main imaging method for breast cancer screening or diagnosis in China and the main supplementary method for screening in other countries. Nevertheless, the reliability of the conventional

HHUS is still controversial due to high false-positive rates and significant operator dependence [13–15]. In Filip Šroubek et al whole-breast ultrasound study, about 3% of the cases missed at least a portion of 1 cm² [16]. Another issue is that the central parts of the breast have better coverage compared to the periphery. Meanwhile, the poor repeatability of conventional HHUS reduces the accuracy of breast lesions follow-up [14, 17, 18]. In this present work, we focused on how to solve the ultrasound operator dependence and to reduce the risk of missed breast lesions. We also discuss some new technologies that have been developed and applied in the clinic.

A standardized breast scan is central to solve missed diagnoses of breast lesions. The current automated breast ultrasound applies wide-amplitude high-frequency probes to achieve a standardized scan. Previous studies have confirmed that the automated breast ultrasound does not depend on the operator's experience [6, 17] and increases the sensitivity and specificity of breast cancer screening when compared with mammography. The whole breast ultrasound (WBUS) system based on electromagnetic tracking has been reported as less dependent on the operator than HHUS [14, 19]. For its part, the AI-Breast ultrasound is similar to WBUS. Visualization during the whole scan process works through breast region localization and magnetic navigation, ensuring that the scan covers the whole breast and reduces blind areas. Moreover, the scan can be carried out according to a set standardized workflow, to solve the same HHUS problems. Meanwhile, the breast information is comprehensively recorded in video. The subject suffers no discomfort. Applying a standard examination can improve the accuracy and repeatability of breast screening [14]. Moreover, AI-Breast technicians are trained in a short time; then they can finish the whole breast scan independently and ensure the clearness of images for interpretation. With respect to radiologists, they do not need extra long-time training or accumulation of image interpretation experience to improve the efficiency of image interpretation.

This study compared the screening efficiency of both the method (AI-Breast ultrasound and HHUS) and the operator (radiologists with different years of experience) in breast lesions under a daily workflow mode. There have been many reports on the detection rate of breast cancer by HHUS. According to Lin X et al.'s study [6], the detection rate is up to 96%, but that of Niu L et al.'s [20] claims it is only 82%. A meta-analysis by Zhang X et al. [21] revealed that HHUS produces a 90% rate with a large deviation that is closely related to the operator's diagnostic experience. In this study, we found that the AI-breast ultrasound reported a higher breast lesions rate than that conducted by general radiologists. The results also showed that it was equivalent to breast image radiologists. The corresponding missed diagnosis rates of breast cancer in Group AI, Group A, and Group B were 8%, 4%, and 14%, respectively. Although there was no statistical significance, the AI-Breast ultrasound reported low missed diagnosis of malignant lesions and high detection rates, which are of great importance in the clinic. For breast cancer patients, early detection and diagnosis can improve the survival rate.

It has been reported that the lesion detection rate of HHUS may correlate with breast size, lesion size, and LN [22–26]. The smaller the breast lesion is, the lower the detection rate. When the breast size is large, the lesions tend to locate in the deep tissue, which increases the difficulty in the ultrasound analysis and reduces the detection rate. In this study, the detection rate of the AI-breast ultrasound was not affected by

breast size, LN, benign or malignant lesions, consistent with breast image radiologists. However, there was a negative linear correlation between the detection rate of general radiologists and LN. Additionally, their detection rate was significantly lower than that of AI-breast ultrasound in the cases with LN ≥ 2 and C cup or above. More than 1/3 (22/60) of the breast lesions missed by general radiologists were of less than 1 cm; the small size was probably the major reason for a low detection rate. On the other hand, lesions missed by the latter operators were found in the periphery of the breasts; thus, incomplete coverage could be an important factor leading to an unsuccessful diagnosis. The detection rate of the AI-Breast ultrasound is relatively higher compared with that periphery situation, indicating that this standardized scan is able to avoid insufficient coverage and reduce missed diagnosis.

In the efficiency assessment of breast cancer screening, the most important indicator is the detection rate of breast lesions, followed by scan time. In this study, the scan time was significantly influenced by breast size, and it increased with cup size in the three groups. The scan time of the AI-breast ultrasound had a positive linear correlation with breast size at a relatively constant time for different breast cups. In the HHUS group, the scan time of radiologists was also impacted by LN, with a positive linear correlation between them in both groups. AI-Breast ultrasound was the least affected by LN. Also, there was no correlation between scan time and LN (1-5). However, the AI-Breast ultrasound successively extended the scan time throughout the non-lesion group, the LN 1-5 group, and the LN ≥ 5 group, with statistical differences among the three. The reason for this could be the proportion of patients with large breasts (patients with C Cup and above): in the non-lesion group, they accounted for 27% of the patients (4/15); in the LN 1-5 group, 34% (44/130); and in the LN ≥ 5 group, 41% (11/27). When the proportion of patients with large breasts increased, the average scan time would prolong. In terms of scan time alone, the time spent by radiologists was the shortest, while that of AI-Breast was relatively shorter than general radiologists. Nevertheless, due to the different characteristics of scan and diagnosis in AI-Breast ultrasound, extra interpretation time was needed; therefore, the whole examination time was longer than those of the other two groups.

This study has some limitations as a single-center project with data from a hospital. The radiologists had relatively wide experience in breast diagnosis; thus the AI-Breast ultrasound had a high detection rate of breast lesions. Multicenter and large-sample databases are needed to assess the efficiency of the AI-Breast ultrasound in asymptomatic patients and primary hospital screening. Indeed, electromagnetic tracking devices have their limitations. An electromagnetic generator is usually placed near the head of the scan bed, and the magnetic sensor has a limited detection range. Thus, the patient needs to be close to the generator as much as possible. Simultaneously, patients need to remove metal and electronic objects from their bodies before the scan to prevent interference in the magnetic field.

Conclusion

Above all, AI-Breast ultrasound is similar to the conventional HHUS but achieves a separation between diagnosis and scan. Image scan is standardized, reproducible, and provides more objective location information in the daily clinical practice. This grants a research basis for the remote consultation and

breast cancer screening. The efficiency of the AI-Breast ultrasound screening is equivalent to the breast image radiologist. Its advantages, such as improving operator dependency, increasing the screening sensitivity, technician training with less time and cost, and focusing breast diagnosis to radiologists, have better social and economic benefits. AI-Breast ultrasound may be a potential approach for breast cancer screening in primary hospitals.

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board and Ethics Committee of Affiliated Hangzhou First People's Hospital, Zhejiang University School of Medicine. All patients provided signed informed consent before the examination. All methods were performed in accordance with the relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The authors confirm that the data supporting the findings of this study are available within the article.

Competing interests

The authors declare that there is no conflict of interest regarding the publication of this paper.

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Authors' contributions

LB designed and organized this study; CD, HY and LZ, XX summarized and analyzed the multicenter data and wrote the manuscript; YT, LY, JY and CJ, YS prepared and recorded the data. All authors reviewed the manuscript.

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Figures

Figure 1

AI-Breast and HHUS examination time quadrants. Red squares in the plot indicate that the value is larger than the upper quartile and is 3 times the quartile difference.