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Automated Breast Ultrasound: Lesion Detection and BI-RADS™ Classification – a Pilot Study

Automatisierte Sonografie der Brust: Detektion von Läsionen und ihre BI-RADS™-Klassifizierung – eine Pilotstudie

Autoren E. Wenkel, M. Heckmann, M. Heinrich, S. A. Schwab, M. Uder, R. Schulz-Wendtland, W. A. Bautz, R. Janka

Institut Radiologisches Institut, Universitätsklinikum Erlangen

Key words
- breast
- ultrasound
- automated
- ABUS
- lesion detection
- breast cancer

Zusammenfassung

Ziel: Die Wertigkeit eines automatisierten Brustultraschallsystems (ABUS) wurde bezüglich Detektion und Einteilung von Brustläsionen nach BI-RADS überprüft.

Material und Methoden: In die Studie wurden selektiv Frauen eingeschlossen, bei denen sich auswärts im Rahmen einer Brustdiagnostik (Palpation, Sonografie oder Mammografie) ein unklarer Befund ergeben hatte und die zur weiteren Abklärung zugewiesen wurden. Bei allen Patientinnen wurde eine handgeführte Brustsonografie (HHUS) mit einem 13-MHz-Schallkopf, eine klinische Untersuchung und eine Mammografie von beiden Brüsten durchgeführt. Die abklärungsbedürftige Brust erhielt zusätzlich eine Sonografie mit ABUS (SomoVu™, U-Systems, Inc., San Jose, CA, USA; EC Representative: Siemens, Erlangen, Germany) mit einem 8-MHz-Schallkopf. Fünf Radiologen werteten unabhängig voneinander die ABUS-Bilder bezüglich des Vorhandenseins von Läsionen aus. Alle entdeckten Läsionen wurden gemäß BI-RADS eingeteilt. Die Auswerter kannten weder den klinischen Tastbefund noch das Ergebnis der Mammografie oder des HHUS. Die Ergebnisse der Auswerter wurden mit denen des HHUS verglichen.

Ergebnisse: 35 Frauen wurden in die Studie eingeschlossen. 25 BI-RADS-4- und -5-Befunde wurden histologisch (n = 23) oder zytologisch (n = 2) abgeklärt und ergaben 13 maligne und 12 benigne Befunde. Die Größe aller Läsionen lag bei 6 bis 32 mm (Median 14 mm). Mit dem ABUS detektierten die Auswerter 29 bis 30 Läsionen. Mit dem HHUS wurden 30 Läsionen diagnostiziert. Ein mit dem HHUS diagnostiziertes suspektes Areal, das histologisch ein Mastopathieareal ergab, war mit dem ABUS von keinem Auswerter erkannt worden. Keine gutartige Läsion wurde mit dem ABUS oder HHUS als BI-RADS 5 eingestuft. Alle Mammakarzinome wurden mit dem

Abstract

Purpose: Evaluation of an automated breast ultrasound system (ABUS) regarding the detection and classification of breast lesions according to BI-RADS.

Materials and Methods: Women were selected for the study who had unclear findings in breast diagnosis performed elsewhere (palpation, sonography or mammography) and who were referred for further work-up. All patients received a hand-held ultrasonography (HHUS) with a 13 MHz transducer, clinical examination and mammography of both breasts. Additionally, the affected breast received the ABUS (SomoVuTM, U-Systems, Inc., San Jose, CA, USA; EC Representative: Siemens, Erlangen, Germany) which was performed with an 8 MHz transducer. Five radiologists independently evaluated the ABUS images regarding lesion detectability. All detected lesions were classified according to BI-RADS assessment. The examiners had no knowledge of the patients' clinical examination or of the result of the mammography or the HHUS. Results of the ABUS were compared to HHUS.

Results: 35 women were included in the study. 25 BI-RADS 4 or 5 lesions had further histological (n = 23) or cytological (n = 2) work-up which revealed 13 malignant and 12 benign findings. The size of all lesions ranged from 6 to 32 mm (median 14 mm). With the ABUS all examiners detected 29 to 30 lesions while HHUS revealed 30 lesions. One suspicious area in HHUS was not reported by any of the five examiners with the ABUS. Histology of this area revealed mastopathic disease. No benign lesion was classified as BI-RADS 5 with the ABUS or HHUS. All breast cancers were found with the ABUS by all examiners and correctly classified as BI-RADS 4 or 5. There was good agreement regarding BI-RADS classification of HHUS and ABUS for the five different examiners with Kappa values between 0.83 and 0.87.

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Korrespondenzadresse
Dr. Evelyn Wenkel
Radiologisches Institut,
Universitätsklinikum Erlangen
Maximiliansplatz 1
91052 Erlangen
Tel.: + 49/91 31/3 60 65
Fax: + 49/91 31/3 20 81
evelyn.wenkel@uk-erlangen.de

ABUS von allen Auswertern entdeckt und korrekt als BI-RADS 4 oder 5 klassifiziert. Die Kappa-Werte für die Übereinstimmung der BI-RADS-Klassifizierung mit HHUS und ABUS für die fünf Auswerter lagen zwischen 0,83 and 0,87.

Schlussfolgerung: Mit der automatisierten Brustsonografie können solide und zystische Mammaläsionen mit einer großen Treffsicherheit in einem selektierten Patientengut diagnostiziert and nach BI-RADS eingeteilt werden.

Conclusion: These preliminary results show that the ABUS allows detection of solid and cystic lesions and their BI-RADS classification with a high reliability in a selected patient group.

Introduction

Ultrasound is an accepted tool in the imaging of breast cancer. The use of breast ultrasound is well established preoperatively [1] and in interventional procedures [2].

In addition to mammography, sonography increases sensitivity for breast cancer detection especially in dense breasts [3–5]. Ultrasound is not yet a routine part of screening programs but is accepted in intensified programs for breast cancer detection in high risk women [6]. In contrast to mammography, sonography is an examiner-dependent method and the examiner has to be present at the time of image acquisition. As a consequence, breast sonography is difficult to realize in a screening setting or in regions with low population density. In these cases an automated ultrasound system where the images are acquired by a technician and sent to specialists for evaluation could be helpful. In our study we wanted to evaluate whether breast lesions could be detected and classified by independent radiologists with an automated breast ultrasound system (ABUS; SomoVu U-Systems, Inc., San Jose, CA, USA; EC Representative: Siemens AG, Medical Solutions, Erlangen, Germany) in comparison to handheld ultrasonography (HHUS).

Materials and Methods

Between June 11 and July 11, 2007, patients were selected for the study who were admitted for further work-up of unclear findings in breast diagnosis: palpable mass (n = 6), suspicious ultrasound (n = 6) and mammographical mass or density in the course of opportunistic screening performed elsewhere (n = 23). Patients who were sent for further work-up of suspicious microcalcifications were excluded. All patients gave oral consent to the application of the ABUS.

A radiographer (RA) was trained how to perform the ABUS in five random patients who were not included in the study. She had no knowledge of the study patients' clinical history and mammography but was told by the radiologist which breast to scan. Depending on her subjective impression of the whole breast volume, the RA performed two or three views of the affected breast. ABUS images were acquired with the patient in supine position. The breasts were scanned with an 8 MHz high-frequency linear transducer with an aperture of 14.5 cm that is built in a rigid frame. The axial resolution for the 8 MHz transducer is 0.4 mm and the lateral resolution is 0.8 mm. To minimize contact artifacts, the scanner frame is covered by a compressive polyester film sheet. Ultrasound gel is homogeneously distributed between the polyester film sheet and the patient's skin. Handheld ultrasonography (HHUS) was performed with a 13 MHz scanner (Antares Siemens, Erlangen, Germany) by one breast radiologist who had knowledge of each patient's clinical history and mammography at the time of the examination.

Lesions detected with the ABUS or HHUS were classified according to the Breast Imaging Reporting and Data System (BI-RADS) [7]. Lesions that were assessed as BI-RADS 4 or 5 lesions with the HHUS received histological or cytological work-up.

Five radiologists evaluated the ABUS independently without knowing the clinical findings and the results of the other imaging modalities. Their experience in breast sonography totaled 60, 24, 18, 6 and 6 months.

The images were analyzed on a separate viewing station with the cine function in three different planes (axial scanning plane, coronal and sagittal reconstructions).

The radiologists independently evaluated the ABUS according to the following criterion: Is a lesion detectable? If yes, the lesion was classified according to BI-RADS. The results were compared to the ones of HHUS and to histology. The concordance of BI-RADS classification with HHUS and the ABUS evaluation of each examiner was calculated with the Cohan's Kappa test.

Results

A total of 35 women with a median age of 55 years (range 30 to 79 years) were enrolled in the study. With the ABUS all examiners detected 29 to 30 lesions while HHUS revealed 30 lesions. One lesion was only detected with HHUS. Histology of that lesion showed a benign mastopathic area. With the ABUS, no additional lesion was found and all breast cancers were found by all examiners. Kappa values regarding BI-RADS classification for HHUS and the ABUS results of the five examiners were between 0.83 and 0.87. The results of the different examiners are summarized in **Table 1**.

Core biopsy was performed in 22 patients with 22 solid lesions and revealed seven fibroadenoma, three fibrocystic mastopathies and 12 invasive carcinoma (11 intraductal, 1 lobular cancer). In 8 patients, sonography revealed cystic findings which were multiple cystic lesions in five patients and solitary cysts in three patients. Two of the solitary cysts were not completely anechoic. Puncture revealed benign cytology. The third solitary cyst showed suspicious intracystic solid parts and was completely removed by surgery (**Fig. 1**). Histology revealed intraductal papillary carcinoma. Ten patients had no suspicious finding with the HHUS and therefore no histological work-up was necessary.

The median size of all lesions was 14 mm (range 6 to 32 mm), for benign lesions (n = 17) 13 mm (range 6 to 25 mm) and for malignant lesions (n = 13) 17 mm (range 9 to 32 mm).

No benign lesion was classified as BI-RADS 5 with the ABUS or HHUS. 5/13 malignant lesions were classified as BI-RADS 5 in HHUS and ABUS by all five examiners and 5/13 as BI-RADS 4. Two breast cancers that were classified as BI-RADS 5 in HHUS were also classified as BI-RADS 5 by three examiners and as BI-RADS 4 by two examiners. One breast cancer that was classified

Table 1 BI-RADS lesion classification of examiners 1 – 5 of the ABUS (automated breast ultrasound system) compared to HHUS (handheld ultrasonography). Agreement of HHUS and ABUS with 5 different examiners was calculated with Cohen's Kappa test

Tab. 1 BI-RADS™ Befund-Klassifikation der Untersucher 1 – 5 des ABUS (automated breast ultrasound system), verglichen mit HHUS (handheld ultrasonography). Die Übereinstimmung von HHUS und ABUS bei 5 verschiedenen Untersuchern wurde mit Cohen's Kappa Test berechnet.

	HHUS	ABUS examiner 1				ABUS examiner 2				ABUS examiner 3				ABUS examiner 4				ABUS examiner 5			
BI-RADS		**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**
1	5	4		1		4		1		4			1	5				5			
2	5		5				5				5				4	1			5		
4	18	2		16		1		16	1	1		16	1	1		17		1	1	15	1
5	7				7			1	6			1	6			1	6			1	6
Σ n		6	5	17	7	5	5	18	7	5	5	17	8	6	4	19	6	6	6	16	7
kappa value		0.87				0.83				0.83				0.87				0.83			

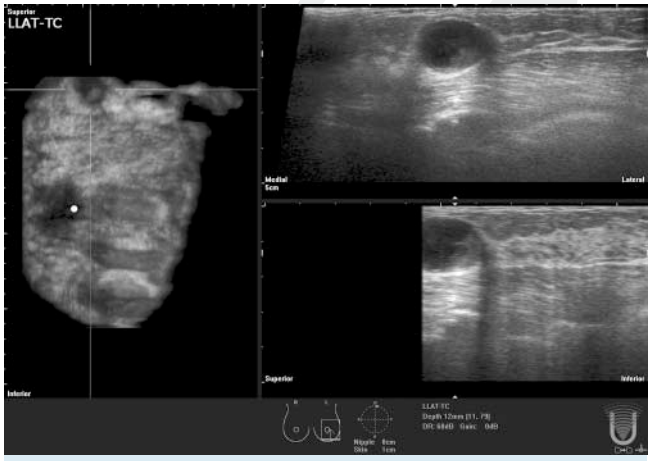

Fig. 1 Viewing station sight with the breast in three different planes: Coronal reconstruction (left image), axial original plane (upper right image) and sagittal reconstruction (lower right image). The white point marker is set at the nipple (coronal reconstruction). The crosshair is positioned at the lesion center to facilitate its detection in the other planes. Orientation is possible with the marker positions on the breast and clock pictogram. The position of the crosshair center is indicated on the screen by the distance to the nipple and to the skin. 50-year-old woman with a cystic lesion in the left breast: Hypoechoic, circumscribed, oval-shaped lesion with increased posterior echoes. There is an intracystic isoechoic, solid-appearing area on the lateral, inferior parts of the lesion. The lateral shadowing of the lesion is typical of cystic lesions. The lesion was surgically removed and histology revealed papillary carcinoma.

Abb. 1 Darstellung der Untersuchungssituation der Brust in drei verschiedenen Ebenen: coronare Rekonstruktion (linkes Bild), axiale Ausgangsebene (oberes rechtes Bild) und sagittale Rekonstruktion (unteres rechtes Bild). Die weiße Markierung liegt auf der Brustwarze (coronare Rekonstruktion). Das Fadenkreuz liegt im Zentrum der Läsion, um ihre Erkennung in den anderen Ebenen zu erleichtern. Die Orientierung wird ermöglicht durch die Lage der Markierungen auf der Brust und das Uhren-Piktogramm. Die Lage des Zentrums des Fadenkreuzes wird auf dem Bildschirm durch die Entfernung zur Brustwarze und zur Haut angegeben. 50-jährige Frau mit einer zystischen Veränderung der linken Brust: Echoarme, umschriebenen, ovaläre Veränderung mit dorsaler Schallverstärkung. Auf den linken unteren Anteilen der Läsion sieht man eine isoechogene, solide erscheinende Struktur innerhalb der Zyste. Die laterale Schallauslöschung ist typisch für zystische Veränderungen. Der Befund wurde operativ entfernt, und die Histologie ergab ein papilläres Karzinom.

as BI-RADS 4 in HHUS was also classified as BI-RADS 4 by two examiners and as BI-RADS 5 by three examiners (**Table 2**). One cyst in a patient with multiple cysts was classified as BI-RADS 4 by one examiner. Three examiners classified the same perimamillary artifact as a suspicious BI-RADS 4 lesion (**Fig. 2**). HHUS and 4/5 examiners judged an inhomogeneous area of 12 mm as suspicious which revealed fibrocystic changes in histology. One examiner did not detect a 15 mm fibroadenoma that was isoechoic to the surrounding breast tissue (**Table 2**).

Discussion

BI-RADS categories are used to characterize and classify breast lesions in mammography. Its usefulness has also been proved for sonography [8, 9].

In our study we were able to show that correct BI-RADS assessment is possible with the ABUS compared to HHUS without additional information from clinical examination or mammography. Similar results were presented at the RSNA 2006 [10] with 165 patients who achieved the same BI-RADS classifications in more than 90% of cases using ABUS plus mammography and HHUS plus mammography. In another scientific presentation [11], a sensitivity of 98% and specificity of 85% were reported for 182 breast lesions studied with ABUS in a retrospective analysis by two radiologists unaware of the clinical, mammographical and histological results. In our evaluation the examiner of the HHUS was aware of the clinical result and mammography while the five ABUS investigators did not have this information.

Detection of early stage breast cancer with mammography is possible in screening situations [12] with limited sensitivity in dense breast tissue [13]. The additional use of sonography in screening situations is discussed controversially [14, 15]. Several studies suggested that ultrasound may increase the detection of breast cancer in asymptomatic women [3 – 5] especially in mammographically dense breasts. In our study all malignant lesions were detected by all examiners using ABUS. This result leads to a calculated sensitivity for the detection of breast cancer of 100%. All examiners had the subjective impression that tumor margins especially of spiculated lesions were best demonstrated in coronal views (**Fig. 3**). This is consistent with the findings in a study that compared 92 lesions with 2D and 3D ultrasound. Two independent examiners found especially the coronal view of the 3D measurements helpful for differentiating between benign and malignant lesions [16]. In terms of benign lesions, the detection rate was also high since all but one was detected with ABUS. The one benign lesion that was not detected with ABUS was histologically proven to be mastopathic disease. In this case one could assume that HHUS might have shown inhomogeneous breast tissue that mimicked a circumscribed lesion. The possibility of ultrasound in three planes

Table 2 BI-RADS lesion classification of examiners 1 – 5 of the ABUS (automated breast ultrasound system) compared to HHUS (handheld ultrasonography)

Tab. 2 BI-RADS Befund-Klassifikation der Untersucher 1 – 5 des ABUS (automated breast ultrasound system) im Vergleich mit HHUS (handheld ultrasonography)

	HHUS				examiner 1				examiner 2				examiner 3				examiner 4				examiner 5			
BI-RADS	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**	**1**	**2**	**4**	**5**
no lesion, n = 5	5				4		1		4		1		4			1	5				5			
multiple cysts, n = 5		5				5				5				5				4	1			5		
solitary cysts w benign histology, n = 2			2				2				2				2				2				2	
solitary cysts w malignant histology, n = 1			1				1				1				1				1				1	
benign mass, n = 10			10		2		8		1		9		1		9		1		9		1	1	8	
malignant mass, n = 12			5	7			5	7			5	7			5	7			6	6			5	7

Fig. 2 60-year-old woman with a hypoechoic area at 6.00, 3 cm from the nipple marker, directly under the skin (white arrow). 3/5 examiners classified this area as suspicious while 2 examiners recognized the area correctly as an artifact due to the lack of ultrasound gel.

Abb. 2 60-jährige Frau mit einem echoarmen Befund bei 6 Uhr, 3 cm von der Brustwarzenmarkierung entfernt, direkt unter der Haut (weißer Pfeil). 3/5 der Untersucher stuften diesen Befund als verdächtig ein, während 2 Untersucher diesen Bezirk korrekt als Artefakt einstuften, der durch zu wenig Ultraschallgel hervorgerufen wurde.

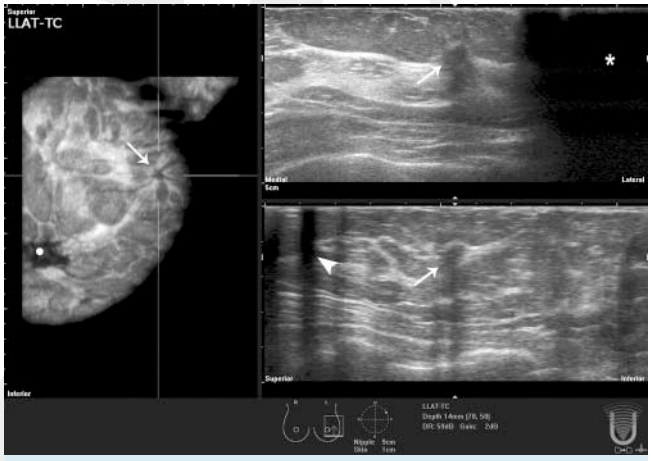

Fig. 3 51-year-old woman with a spiculated lesion (arrows) in the left breast at 2.00, 9 cm from the nipple and 1 cm to the skin. Histology revealed a 7 mm invasive ductal carcinoma. Malignant features are best delineated in the coronal view. Contact artifacts due to air between the polyester sheet, scanner and patient (arrowhead). Missing patient contact on the lateral part of the scanner (asterisk).

Abb. 3 51-jährige Frau mit einer zipfeligen Veränderung (Pfeile) in der linken Brust bei 2 Uhr, 9 cm von der Brustwarze und 1 cm von der Haut entfernt. Die Histologie ergab ein 7 mm großes duktales Karzinom. Maligne Veränderungen werden am besten in der koronaren Schnittebene dargestellt. Kontakt-Artefakte aufgrund von Luft zwischen Polyesterplatte, Scanner und Patientin (Pfeilspitze). Fehlender Patientenkontakt auf der lateralen Seite des Schallkopfes (Stern).

may help to distinguish between real lesions and inhomogeneous areas due to mastopathic breast tissue.

The handling of ultrasound equipment and the evaluation of breast ultrasound images demand a certain expertise by the examiner. Lesion detection and classification with ABUS was not dependent on the examiner's experience with performing breast ultrasound since all five examiners detected and classified all breast cancers correctly as BI-RADS 4 or 5. This might be caused by the mean lesion size of 14 mm. In a prospective study with HHUS by Berg, 11 experienced breast radiologists examined 20 breasts with 88 breast lesions with a mean size of 6.7 mm which resulted in 968 potential detections [17]. Berg found lesion detection to be most consistent in lesions larger than 11 mm (64 of 66 lesions detected). Lesion detection decreased with size: 67.8% for lesions at 7.1 – 9 mm, 52.7% at 5.1 – 7 mm and 18% at 3 mm or smaller. Reproducibility of ultrasound images has always been an issue. In the study by Berg [17] the findings of the different examiners were highly consistent since they performed the exams and evaluation following a standardized protocol. The consistent reporting of lesions might be easier with a breast scanning system. The ABUS viewing station provides proper orientation and documentation of the lesion location. Follow-up studies might be facilitated especially if different examiners perform ultrasound. In this case breast ultrasound might become a more objective method.

If the acquisition of ultrasound images was as standardized as mammography, one might assume that image analysis might be able to be performed by trained radiologists at a different time and location than the actual acquisition. Additionally, the volumetric data sets might provide potential information for computer-aided detection of pathologies.

Coverage of the whole breast volume in HHUS and ABUS depends greatly on the examiner's performance. Analogous to mammography, continuous training of the persons performing ultrasound should help to ensure coverage of the whole breast tissue. However, coverage of the whole breast volume with the ABUS was not addressed by this study. A drawback of ABUS may be contact artifacts mimicking suspicious lesions (**Fig. 3**). Such contact artifacts could also be avoided by training the person performing the ABUS.

One limitation of the study was the selected patient group with a high number of lesions that does not reflect a screening population. Furthermore, some histological subgroups such as DCIS or medullary carcinoma were not present in our study cohort. Therefore we cannot know whether these entities are detectable by ABUS. A potential bias of the study is that only the affected breast was scanned and analyzed. This may have resulted in a higher alertness level by both the RA and the analyzing radiologist. We did not report the duration of the examination time nor the time of the evaluation. This could be important if ABUS were to be used in daily routine.

Conclusion

ABUS allows detecting and classifying of solid and cystic breast lesions with a high sensitivity in a selected patient group. The results are too preliminary to recommend the ABUS in daily routine. Methods have to be established to ensure the quality and reproducibility of ABUS.

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