ShearWave™ Elastography BE1 Multinational Breast Study: Additional SWE™ Features Support Potential to Downgrade BI-RADS®-3 Lesions

Scherwellen-Elastografie: BE 1 internationale Multicenter Studie – Zusätzliche Scherwellen-Elastografie Kriterien unterstützen ein mögliches Downgrading von BI-RADS® 3 Läsionen

Authors   F. K. W. Schäfer[1], R. J. Hooley[2], R. Ohlinger[3], U. Hahne[3], H. Madjar[4], W. E. Svensson[5], C. Balu-Maestro[6], V. Juhan[7], A. Athanasiou[8], A. Mundinger[9], B. Order[1], M. Locatelli[10], D. Cosgrove[11], O. J. Wolf[12], J. P. Henry[13], M. Moutfi[14], J. M. Gay[15], C. Cohen-Bacrie[16]

Affiliations   Affiliation addresses are listed at the end of the article.

- breast
- ultrasound
- diagnostic radiology
- tumor

Correspondence
Joel M Gay
Education, SuperSonic Imagine
Les Jardins de la Duranne Bat F
510 rue René Descartes
13857 Aix-en-Provence Cedex
France
Tel.: ++33/48/679 03 13
Fax: ++33/48/307 56 33
joel.gay@supersonicimagine.fr

Zusammenfassung
!

Ziel: Evaluation der Scherwellen-Elastografie (SWE) zur näheren Charakterisierung von BI-RADS®-3 Läsionen in der Mamma.
Material und Methoden: Insgesamt wurden 303 BI-RADS®-3 Läsionen (Durchschnitt der Größe: 13,2 mm, Standardabweichung: 7,5 mm) aus dem Studienkollektiv der prospektiven BE1 Multicenter-Studie analysiert. 201/303 (66 %) Läsionen wurden minimalinvasiv zytologisch oder histologisch abgeklärt, bei 102/303 (33 %) lag ein Follow-up von mind. 1 Jahr vor. 8/303 (2,6 %) Läsionen waren maligne. Sieben verschiedene SWE-Kriterien wurden hinsichtlich ihres Einflusses auf eine korrekte Reklassifikation von BI-RADS®-3 Läsionen und eine mögliche Herabstufung auf eine neue Klassifikation BI-RADS®-3' untersucht.
Ergebnisse: Keine malignen Befunde ergaben sich für das Kriterium Elastografie-Farbe (E color) „schwarz bis dunkelblau", was ein Downgrading von 110/303 Läsionen erlaubte (p < 0,0001); nicht signifikanter Anstieg der Malignitätsrate in der neuen BI-RADS-3®' Klassifikation von 2,6 % auf 4,1 %. Mit dem Zusatzkriterium maximale Elastizität (E Max) ≤ 20 kPa (2,6 m/s) konnten 48/303 Läsionen reklassifiziert werden (p < 0,0001); geringerer nicht signifikanter Malignitätsanstieg von 2,6 % auf 3,1 %. Die übrigen SWE-Kriterien waren nicht geeignet für eine Reklassifikation der BI-RADS®-3 Läsionen.
Schlussfolgerungen: Die Anwendung einfacher Reklassifikationsregeln wie der maximalen Elastizität erlauben ein sicheres Downgrading von BI-RADS®-3 Läsionen in eine neue BI-RADS®-3' Untergruppe, ohne das es zu einem signifikanten Malignitätsanstieg kommt.

Purpose:
!

Purpose: To determine the benefit of Shear-Wave™ Elastography (SWE™) in the ultrasound characterization of BI-RADS® 3 breast lesions in a diagnostic population.
Materials and Methods: 303 BI-RADS® 3 lesions (mean size: 13.2 mm, SD: 7.5 mm) from the multicenter BE1 prospective study population were analyzed: 201 (66 %) had cytology or core biopsy, and the remaining 102 had a minimum follow-up of one year; 8 (2.6 %) were malignant. 7 SWE features were evaluated with regard to their ability to downgrade benign BI-RADS® 3 masses. The performance of each SWE feature was assessed by evaluating the number of lesions correctly reclassified and the impact on cancer rates within the new BI-RADS® 3' lesion group.
Results: No malignancies were found with an E-color "black to dark blue", which allowed the downgrading of 110/303 benign masses (p < 0.0001), with a non-significant increase in BI-RADS® 3' malignancy rate from 2.6 % to 4.1 %. E-max ≤ 20 kPa (2.6 m/s) was able to downgrade 48/303 (p < 0.0001) lesions with a lower increase in BI-RADS® 3' malignancy rate (3.1 %). No other SWE features were useful for reclassifying benign BI-RADS® 3 lesions.
Conclusion: Applying simple reclassification rules, SWE assessment of the maximum stiffness of lesions allowed the downgrading of a subgroup of benign BI-RADS® 3 lesions. This was accompanied by a non-significant increase in the malignancy rate in the new BI-RADS® 3 class.

ShearWave™ Elastography BE1 Multinational Breast Study: Additional SWE™ Features Support Potential to Downgrade BI-RADS®-3 Lesions

Thieme

Introduction
!

After mammography ultrasound (US) is the most used diagnostic tool in breast imaging. Since the initial work of Stavros et al. [1], US has been proven to properly identify liquid lesions and classify solid breast masses, thus being able to recommend initial short-term follow-up instead of biopsy. This has been further developed in the BI-RADS® – Ultrasound lexicon and scoring system to take the most appropriate clinical action on the basis of the US analysis of a breast lesion [2]. Recently, the emerging role of US elastography has raised expectations of improvements in breast US diagnosis through the combination of morphological information and the "virtual" palpation of breast lesions. Indeed, benign lesions tend to be stiffer than normal breast tissue, but usually softer than cancers, and this information is obtained by a physician on palpation during physical examination.

Relative tissue stiffness can be determined with strain elastography, in which tissue deformation is displayed as a color or black and white overlay of the region of interest [3, 4]. Measuring the tissue strain induced by compression may help differentiate breast cancer from benign breast lesions [5], although the challenge of generating consistent stress reduces the consistency of the information and ultimately, diagnostic performance.

Absolute tissue stiffness can be quantitatively measured and mapped in real time using ShearWave™ elastography (SWE) [6]. With this new technique, different features can be evaluated, such as color assessments or quantitative measurements of stiffness values or shear wave velocities, the ratio of stiffness between the lesion and the surrounding fatty tissue, the size measurements of the lesion on the SWE map, the ratio of the longest dimension in SWE to that in B-mode, and the homogeneity and shape of the elastogram of the lesion, as seen in SWE mode. These features have been evaluated in the "Breast Elastography 1" (BE1) multinational prospective study, which had 2 main objectives. First, it demonstrated that SWE features were reproducible by each operator and amongst observers [7]. Second, it reported that the addition of the maximum elasticity seen or measured with SWE was capable of improving the accuracy of the BI-RADS® 3 and 4a classification, with highly significant increases in the global specificity of the US diagnosis and in the positive predictive value for the BI-RADS® 4a class, without any decrease in sensitivity [8]. Therefore, SWE demonstrated its potential value in making a more accurate decision between initial short-term follow-up and biopsy for probably benign and low-suspicion breast masses. In addition, Berg et al. demonstrated that the SWE features could be graded in discrete categories to follow a stratification of the risk of malignancy in the population, similarly to the work performed on sonographic features by Stavros et al. [1]. Using the same stratification of the risk of malignancy, we wanted to investigate whether SWE features could potentially help in identifying the benign lesions within the probably benign masses, and increase the number of benign BI-RADS® 2' lesions. The acknowledged malignancy rate (≤ 2 %) in the BI-RADS® 3 class implies that a maximum of 98 % of the lesions that benefit from an initial short-term follow-up are actually benign. SWE may have a practical impact in helping to reclassify a BI-RADS® 3 lesion as benign.

Methods
!

Patients, investigators, equipment and techniques
We analyzed the subset of breast masses classified as BI-RADS® 3, taken from the total population of the first dataset reported by

Berg et al., in which 939 breast masses from 939 patients were recruited from 16 sites across 5 countries (France, Germany, Italy, United Kingdom, USA) [8]. The manufacturer (SuperSonic Imagine, Aix-en-Provence, France) of the prototype of the Aixplorer US system, called RUBI, funded the study.

Masses were classified as palpable or not palpable, and if palpable, mobile or not. Every patient first underwent a standard breast US diagnostic examination with each site's high-end system. Lesions were classified according to the Breast Imaging Recording and Data System (BI-RADS®) criteria for US [2]. A second targeted conventional US examination of the mass was performed on the RUBI system. However, as this system was not CE marked or FDA approved, the diagnostic BI-RADS® assessment was taken from the exam performed on each site's own system. Images of the lesions in SWE mode were also acquired on the RUBI system, ensuring a light touch technique to obtain images suitable for analysis while avoiding compression of the breast during examination. The default stiffness scale with a maximum value of 180 kPa (7.7 m/s) was recommended. The region of interest (ROI) in SWE mode included surrounding fatty tissue. A quantification tool, called the "Q-Box" was placed over the stiffest part of the lesion to measure its stiffness. A second Q-Box was placed in the adjacent fatty tissue, so as to calculate the ratio of elasticity between the mean values in the lesion and in fat.

Reference standard: Histopathological, cytological analysis and follow-up
As described by Berg et al. [8], a histopathological diagnosis was obtained for most lesions by core biopsy, surgical excision or cytopathological analysis after fine needle aspiration. If cytology proved malignant, atypical or suspicious, core biopsy or surgical excision was also performed. When histopathology revealed malignant, high-risk (lobular carcinoma in situ, atypical hyperplasia, radial scar, papillary lesion) or atypical findings, the lesion was excised. For BI-RADS® 3 lesions, a minimum follow-up of one year was required, possibly including preceding follow-up information, or even histopathological or cytological correlation. A BI-RADS® 2 assessment was accepted as benign in the absence of any interventional procedure. Finally, all lesions were classified as benign or malignant.

Reclassification and statistics
The analyzed SWE features were qualitative (elastography shape: E-shape; elastography homogeneity: E-homogeneity; color of maximum stiffness: E-color; quantitative maximum stiffness in kPa (or m/s): E-max; average stiffness in kPa (or m/s): E-mean; lesion/fat stiffness ratio: E-ratio; SWE-to-B-mode diameter ratio: E-dia ratio). We considered that a BI-RADS® 3 mass showing benign SWE features could be downgraded to a benign mass (new BI-RADS® 2' class). The priority was given to classes of SWE features in which the malignancy rate was 0 %, as identified by Berg et al. [8].

The Fisher exact test was used to compare proportions between independent groups and assess changes in malignancy rates. The Mann-Whitney U test was used to compare the medians between independent groups of continuous variables. The impact of SWE features on the reclassification of lesions was estimated calculating the increase in benign lesions in BI-RADS® 2' and the decrease in malignant lesions in BI-RADS® 3'; p-values to assess these changes were calculated with the McNemar test for paired comparison of proportions. Malignancy rates in the new BI-RADS® 2' and 3' categories were also calculated.

ShearWave™ Elastography BE1 Multinational Breast Study: Additional SWE™ Features Support Potential to Downgrade BI-RADS®-3 Lesions

Scherwellen-Elastografie: BE 1 internationale Multicenter Studie – Zusätzliche Scherwellen-Elastografie Kriterien unterstützen ein mögliches Downgrading von BI-RADS® 3 Läsionen

Authors   F. K. W. Schäfer[1], R. J. Hooley[2], R. Ohlinger[3], U. Hahne[3], H. Madjar[4], W. E. Svensson[5], C. Balu-Maestro[6], V. Juhan[7], A. Athanasiou[8], A. Mundinger[9], B. Order[1], M. Locatelli[10], D. Cosgrove[11], O. J. Wolf[12], J. P. Henry[13], M. Moutfi[14], J. M. Gay[15], C. Cohen-Bacrie[16]

Affiliations   Affiliation addresses are listed at the end of the article.

- breast
- ultrasound
- diagnostic radiology
- tumor

Correspondence
Joel M Gay
Education, SuperSonic Imagine
Les Jardins de la Duranne Bat F
510 rue René Descartes
13857 Aix-en-Provence Cedex
France
Tel.: ++33/48/679 03 13
Fax: ++33/48/307 56 33
joel.gay@supersonicimagine.fr

Zusammenfassung
▼

Ziel: Evaluation der Scherwellen-Elastografie (SWE) zur näheren Charakterisierung von BI-RADS®-3 Läsionen in der Mamma.
Material und Methoden: Insgesamt wurden 303 BI-RADS®-3 Läsionen (Durchschnitt der Größe: 13,2 mm, Standardabweichung: 7,5 mm) aus dem Studienkollektiv der prospektiven BE1 Multicenter-Studie analysiert. 201/303 (66 %) Läsionen wurden minimalinvasiv zytologisch oder histologisch abgeklärt, bei 102/303 (33 %) lag ein Follow-up von mind. 1 Jahr vor. 8/303 (2,6 %) Läsionen waren maligne. Sieben verschiedene SWE-Kriterien wurden hinsichtlich ihres Einflusses auf eine korrekte Reklassifikation von BI-RADS®-3 Läsionen und eine mögliche Herabstufung auf eine neue Klassifikation BI-RADS®-3' untersucht.
Ergebnisse: Keine malignen Befunde ergaben sich für das Kriterium Elastografie-Farbe (E color) „schwarz bis dunkelblau", was ein Downgrading von 110/303 Läsionen erlaubte (p < 0,0001); nicht signifikanter Anstieg der Malignitätsrate in der neuen BI-RADS-3®' Klassifikation von 2,6 % auf 4,1 %. Mit dem Zusatzkriterium maximale Elastizität (E Max) ≤ 20 kPa (2,6 m/s) konnten 48/303 Läsionen reklassifiziert werden (p < 0,0001); geringerer nicht signifikanter Malignitätsanstieg von 2,6 % auf 3,1 %. Die übrigen SWE-Kriterien waren nicht geeignet für eine Reklassifikation der BI-RADS®-3 Läsionen.
Schlussfolgerungen: Die Anwendung einfacher Reklassifikationsregeln wie der maximalen Elastizität erlauben ein sicheres Downgrading von BI-RADS®-3 Läsionen in eine neue BI-RADS®-3' Untergruppe, ohne das es zu einem signifikanten Malignitätsanstieg kommt.

▼

Purpose: To determine the benefit of Shear-Wave™ Elastography (SWE™) in the ultrasound characterization of BI-RADS® 3 breast lesions in a diagnostic population.
Materials and Methods: 303 BI-RADS® 3 lesions (mean size: 13.2 mm, SD: 7.5 mm) from the multicenter BE1 prospective study population were analyzed: 201 (66 %) had cytology or core biopsy, and the remaining 102 had a minimum follow-up of one year; 8 (2.6 %) were malignant. 7 SWE features were evaluated with regard to their ability to downgrade benign BI-RADS® 3 masses. The performance of each SWE feature was assessed by evaluating the number of lesions correctly reclassified and the impact on cancer rates within the new BI-RADS® 3' lesion group.
Results: No malignancies were found with an E-color "black to dark blue", which allowed the downgrading of 110/303 benign masses (p < 0.0001), with a non-significant increase in BI-RADS® 3' malignancy rate from 2.6 % to 4.1 %. E-max ≤ 20 kPa (2.6 m/s) was able to downgrade 48/303 (p < 0.0001) lesions with a lower increase in BI-RADS® 3' malignancy rate (3.1 %). No other SWE features were useful for reclassifying benign BI-RADS® 3 lesions.
Conclusion: Applying simple reclassification rules, SWE assessment of the maximum stiffness of lesions allowed the downgrading of a subgroup of benign BI-RADS® 3 lesions. This was accompanied by a non-significant increase in the malignancy rate in the new BI-RADS® 3 class.

以上内容仅为本文档的试下载部分，为可阅读页数的一半内容。如要下载或阅读全文，请访问：https://d.book118.com/797143010145006030