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BREAST DIAGNOSIS: CONCORDANCE ANALYSIS BETWEEN THE BI-RADS CLASSIFICATION AND TSUKUBA SONOELASTOGRAPHY SCORE

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Abstract

Aims. *To establish the correlations between the ultrasound (US) BI-RADS classification and Tsukuba elastography score when assessing breast lesions. To determine which type of breast lesion (BI-RADS category) would benefit most from an elastographic assessment.*

Patients and methods. *The investigated sample of imaging comprised a number of 129 images belonging to 92 subjects examined with a Hitachi 8500 US device. Each lesion was assessed according to the BI-RADS and Tsukuba elastography score. Histopathology was obtained by means of percutaneous biopsy or post-surgery. Fibroadenoma-like lesions unchanged over a period of 3 years were considered benign.*

Results. *The 1, 2 and BGR Tsukuba scores mostly correlated with BI-RADS II and III lesions such as cysts, hamartomas, lipomas, hematomas, non-palpable fibroadenomas. Palpable fibroadenomas initially included in BI-RADS IVa/b category, usually received benign elasticity scores (1 or 2), the exception being represented by a minority of cases of old, fibrotic or calcified lesions (elastic score 3 or 4). Non-specific BI-RADS IVa/b lesions, such as mastopathic nodules demonstrated rather soft, elastic properties on elastogram (score 1 or 2). The 4 and 5 Ueno-Itoh scores were predominantly correlated with BI-RADS IVc and V categories represented by high risk lesions (radial scar, papillomas, atypical epithelial ductal hyperplasia) and in situ or invasive carcinomas.*

Conclusions. *Generally the BI-RADS classification correlates well with the Tsukuba elasticity score, the main exception being represented by fibrotic, calcified lesions which falsely appear more suspicious post-elastography. BI-RADS III and IV lesions would benefit most from an elastographic assessment, a low Tsukuba score allowing a less invasive approach, while a high score imposes histopathological evaluation.*

Keywords: breast, ultrasound, elastography, BI-RADS, Tsukuba

Background and aims

Breast lesions are assessed nowadays using the well known BI-RADS categories and the more recently instated Tsukuba ultrasound elasticity score [1,2]. The **BI-RADS**

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acronym stands for **Breast Imaging-Reporting and Data System** which is a widely accepted risk assessment and quality assurance tool in mammography, ultrasound (US) and MRI [1]. Modern ultrasound devices allow combined elasticity and 2D real time assessment of breast lesions, using the same probe as for conventional ultrasound imaging [3].

Strain sonoelastography (USE) may show how *stiff* is a focal lesion by comparison to neighboring tissue. Most of the breast cancers are more rigid than surrounding breast parenchyma [3,4,5,6,7]. According to the ultrasound equipment type, various colors or gray shades are super imposed on 2D images. For the US Hitachi systems, stiff areas are coded in blue tints, while softer, elastic tissues appear in green and/or red [3,4,5,6,7].

At present the Tsukuba elasticity score is one of the most known and used scoring systems in elastography [2].

The aim of the present study was to evaluate the relation (agreement or concordance) between overall BI-RADS classification and Tsukuba elastography score when assessing breast lesions. Furthermore, we investigated what type of lesion was more susceptible to false positive or false negative diagnostic aspect on elastography and which BI-RADS category would benefit most from an elastographic assessment.

Patients and methods

A prospective cohort study was conducted to fulfill the aim of the research. The target population was represented by asymptomatic and symptomatic patients referred to the Breast Unit Department of ER County Hospital of Cluj-Napoca between May 2007 and September 2010. Although conventional ultrasound and elasticity images of breast focal lesions were acquired by the same Consultant Radiologist, overall BI-RADS category and Tsukuba elasticity score per lesion were independently and twice given by the same two breast radiologists in order to determine the inter- and intra-observer variability. Final BI-RADS categories and elastography scores were established in consensus whenever differences were noted.

The following criteria were applied for inclusion of breast lesions in the cohort:

- sonoelastography assessment for each US detected focal lesion;

- a pathology report obtained either post biopsy or post surgery for BI-RADS 4 and 5 lesions;

- a minimum 3 years, unchanged follow-up report for BI-RADS 3 lesions (e.g. non-palpable fibroadenoma , non-palpable mastopathic nodule or cyst with impure content). Note: Some BI-RADS 3 lesions were biopsied at the patient's request;

- US and USE images acquired by the same Consultant Radiologist for each included case;

- final BI-RADS category and elastography score established in consensus by the same two radiologists, both experienced in breast imaging and sonoelastography. There was no case for which consensus agreement was not achieved.

Non-focal breast abnormalities such as diffuse infiltrating processes or inflammation were not included in the cohort. US and USE images acquired by other radiologists in the department were also not considered for the analysis. And last but not the least, USE acquisitions which did not meet quality criteria stated in the examination protocol were excluded from the cohort.

The examination protocol of included cases is further described.

The standard radio-imaging examinations (mammography, conventional ultrasound, MRI) were performed according to the ACR (*American College of Radiology*) recommendations, considering the age of patient and case peculiarities. Each detected lesion was classified into a BI-RADS category from II to V taking into account all conventional imaging aspects available at that time. To be mentioned that lesions such as calcified fibroadenomas or cytosteatonecrosis with typical benign mammographic appearance were classified as BI-RADS 2 regardless of their conventional ultrasound aspect.

The elastographic assessment was obtained using a Hitachi 8500 EUB machine with linear 13 MHz probe and elastography option. The elastography acquisition parameters were kept identical for all included lesions: *color gain* was set at 26%, *density* 2, *frame rate* high. Minimum 6 acquisitions per lesions were obtained in perpendicular planes.

The elastography examination was performed according to Hitachi guidelines for obtaining correct USE images [6] and here we should mention the probe position on the skin surface: perfectly perpendicular, applying a minimal compression and avoiding lateral translation or

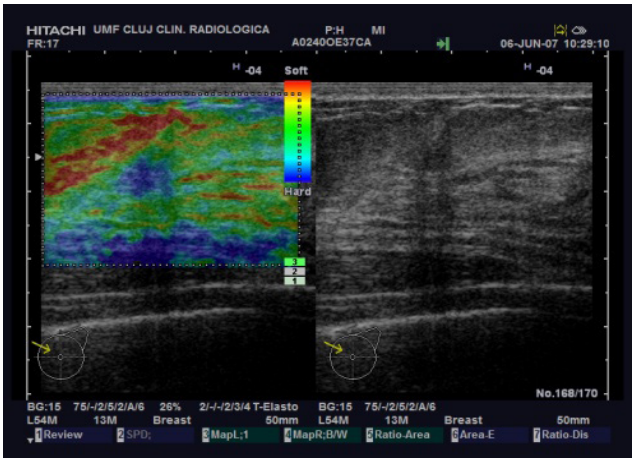

Figure 1. Example of correct USE image of a focal breast lesion: note the large elastography box, the soft predominantly red and green aspect of subcutaneous fat (white star) and a more rigid appearance (predominantly blue and green) of the pectoralis muscle (white arrow).

angulation. The quality criteria for images included within the final analysis are summarized as follows (Fig. 1):

- centered lesion within a large elastography box with anterior border fixed immediately under the skin surface and caudal border fixed on the posterior margin of the pectoralis muscle;

- subcutaneous fat depicted in predominantly red and green hues versus the pectoralis muscle depicted predominantly in blue and green tints;

- frequency of compression maintained between 3 to 4 as indicated by the vibration scale visible on the US screen.

The current analysis considered lesions included within BI-RADS categories II, III, IVA as most likely benign and those classified as BI-RADS IVB, C and V as most likely malignant. For the elasticity assessment, Tsukuba scores 1, 2 and BGR were considered benign, while scores 3, 4 and 5 most likely malignant.

The statistical analysis was performed using commercially available software (MedCalc for Windows, version 9.5.0.0., MedCalc Software, Mariakerke, Belgium). Continuous variables were presented as mean values and standard deviation or median values and confidence interval (CI) and categorical variables as percentages. In cases where the variables were not normally distributed, a logarithmic transformation was performed. The diagnostic accuracy was evaluated by calculating sensitivity (Se%), specificity (Sp%), positive and negative predictive values (PPV, NPV) and ROC curves ("Receiver-Operating Characteristic curve"). Optimal cut-off values were chosen to maximize the sum of Se% and Sp%. A p value of 0.05 or less was considered to indicate a significant difference regarding anthropometric and elastography parameters, the multiple regression test and ROC curve analysis.

Interobserver reliability was measured by using the intraclass correlation coefficient (ICC). ICCs range from 1 (100% reliability, with all the variability caused by patient characteristics) to −1 (100% disagreement, with all the variability being caused by the rater's performance). Reliability was classified as poor (ICC, 0.20–0.40), fair to good (ICC, 0.41–0.75), or excellent (ICC, 0.76–1.00). The interobserver agreement was assessed by using the Cohen κ coefficient. A κ value of 0 indicated poor agreement, a value of 0.01–0.20 indicated slight agreement, a value of 0.21–0.40 indicated fair agreement, a value of 0.41–0.60 indicated moderate agreement, a value of 0.61–0.80 indicated substantial agreement, and a value of 0.81–1.00 indicated an almost perfect agreement.

All the clinical studies performed during the study were carried out in full accordance with the Declaration of Human Rights (Helsinki, 1975) and with its further revisions. Being a clinical research and involving human subjects, a complete, comprehensive and clear informed consent was obtained for each case. In addition, the Ethics Committee of the University revised the study protocol and gave its approval.

Results

The investigated imaging sample comprised a number of 129 images belonging to 92 subjects. The maximum number of images belonging to one patient was 6. The patients' age ranged between 17 and 77 years, with a mean and a standard deviation of 43.38±14.99 years.

Out of 129 breast lesions, the majority proved benign: 61.24% (95%CI [51.94–69.76]) benign vs. 38.76% (95%CI [30.24–48.06]) malignant. The mean age of patients with malignant breast lesions proved significantly higher compared to the mean age of patients with benign breast lesions (malignant: 53.67±14.19 years old; benign: 37.58±10.12 years old; t-statistics = -6.4322, p-value = $5.73 \cdot 10^{-9}$).

The pathology subtypes of the breast lesions in the investigated sample are presented in Table I.

Figure 2 depicts the BI-RADS categories versus pathology findings over the 3 years follow-up of breast lesions

Figure 3 shows the elasticity score versus pathology findings over the 3 years follow up of breast lesions.

The maximum diameter of the investigated breast

Table I. Breast focal lesions: pathology subtypes.

Subtype	No of cases	% [95%CI]
carcinoma	50	38.76 [30.24–48.06]
fibroadenoma	45	34.88 [26.36–43.40]
cyst	15	10.85 [6.21–18.60]
mastopathic nodule	6	4.65 [1.56–10.07]
papilloma	3	2.33 [0.78–6.97]
adenoma	2	1.55 [0.01–5.42]
cytosteatonecrosis	2	1.55 [0.01–5.42]
hamartoma	2	1.55 [0.01–5.42]
radial scar	2	1.55 [0.01–5.42]
hematoma	1	0.78 [0.01–3.87]
lipoma	1	0.78 [0.01–3.87]

Table II. Performances of the BI-RADS classification as a diagnostic test.

	Golden = mgn	Golden = bgn	Total
BI-RADS = mgn	44	10	54
BI-RADS = bgn	6	69	75
Total	50	79	129

Se (sensitivity) = 88.00% [76.04−95.96]
Sp (specificity) = 87.34% [78.50−93.65]
PPV(positive predictive value) = 81.48% [68.55−90.71]
NPV (negative predictive value) = 92.00% [84.02−97.32]

Table III. Performances of elastography classification as a diagnostic test.

	Golden = mgn	Golden = bgn	Total
BI-RADS = mgn	39	14	53
BI-RADS = bgn	11	65	76
Total	50	79	129

Se (sensitivity) = 78.00% [60.04−87.96]
Sp (specificity) = 82.29% [72.17−89.86]
PPV (positive predictive value) = 73.58% [60.41−84.87]
VPN (negative predictive value) = 85.53% [75.02−92.09]

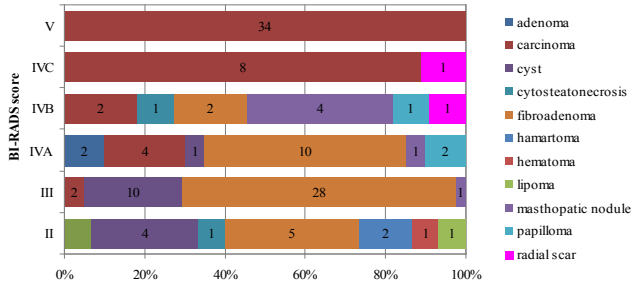

Figure 2. BI-RADS categories versus pathology report or 3 years follow-up of breast lesions.

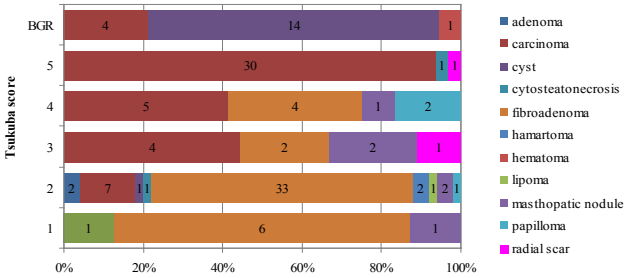

Figure 3. Elasticity score versus pathology findings over the 3 years follow up of breast lesions.

lesions varied from 3 mm to 50 mm with significantly higher diameter of benign lesions compared to malignant lesions (Mann-Whitney test, Z-statistics = -2.17, p-value = 0.0302) .

The measure of inter-observer agreement on the BI-RADS score was of 0.791 ($p = 4.44 \cdot 10^{-73}$).

In 113 cases (87.60% [80.63−93.02]) the BI-RADS correctly classified the breast lesions as benign and malignant respectively (Table II).

The measure of inter-observer agreement on Tsukuba score was of 0.729 ($p = 2.40 \cdot 10^{-61}$), while intra-observer agreement was of 0.856 ($3.96 \cdot 10^{-79}$) for one radiologist and 0.910 ($p = 1.46 \cdot 10^{-93}$) for the second radiologist.

In 104 cases (80.62% [72.87−86.82]) the elastography correctly classified the breast lesions as benign and malignant respectively (Table III).

No significant difference has been identified in the performance of correct classification of breast lesion between the BI-RADS method and elastography – score based method (Z-statistics = 1.5334, p = 0.1252). One diagnostic parameter out of four proved significantly higher for BI-RADS compared to elastography (Fig. 4).

The concordance between BI-RADS and elastography scores in the classification of lesions as malignant and benign was of 81% [72.87–86.82] (p-value (McNemar test) = 0.9999) when all classes of BI-RADS were investigated, and it become 78% [66.68–86.40] (p-value (McNemar test) = 0.8145) when lesions with BI-RADS II and V were withdrawn from the analysis.

The following graphic representation (Fig. 5) correlates the number of breast lesions displaying a specific Tsukuba score with the BI-RADS category and the

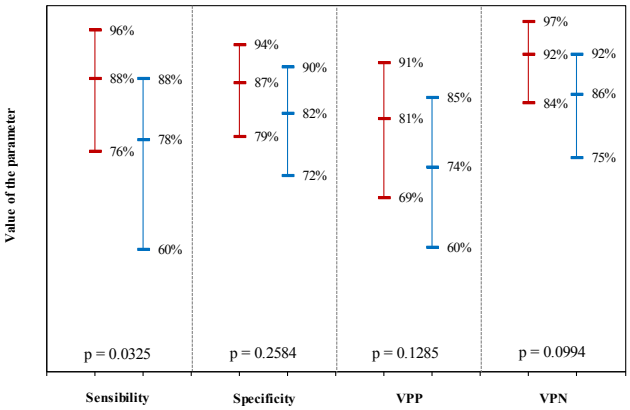

Figure 4. Comparison between BI-RADS (red) and elastography score (blue) as diagnostic tools.

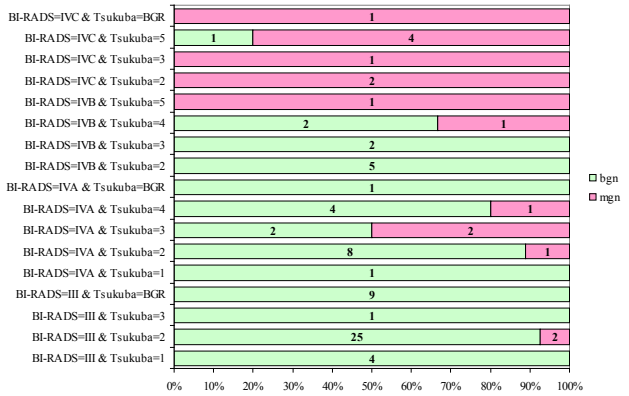

Figure 5. Benign and malignant breast lesion count according to Tsukuba and BI-RADS category.

pathology result: benign versus malignant.

The following images were selected to show those cases where the US and/or USE assessments proved to be either falsely suspicious or falsely reassuring.

To resume: the benign lesions which demonstrated a *stiff* appearance on elastography (score 3, 4 or 5) were in order of frequency: old/calcified fibroadenomas, mastopathic nodules (adenosis, focal fibrosis), papillomas (Fig. 11), cytosteatonecrosis (Fig. 7) and radial scar (Fig. 10b); 11 out of 50 breast cancers displayed falsely benign elastography appearances: 7 with score 2 and 4 BGRs. The score 2 - *soft* looking cancers were either in situ neoplasias (4 DCIS) or hypercellular IDCs (3) not otherwise specified (Ki67 staining more than 50%, more than 10 mitoses per field – data not shown). The stratified BGR pattern was found in 4 large carcinomas (25 up to 50 mm in diameter) due to necrotic/cystic degeneration (Fig. 8c).

Discussion

Concordance analysis

The current study showed sensitivity (Se) and specificity (Sp) values similar with those already published in literature for both BI-RADS classification and Tsukuba elasticity score [9,10,11,12] (Table II, III) and tolerable

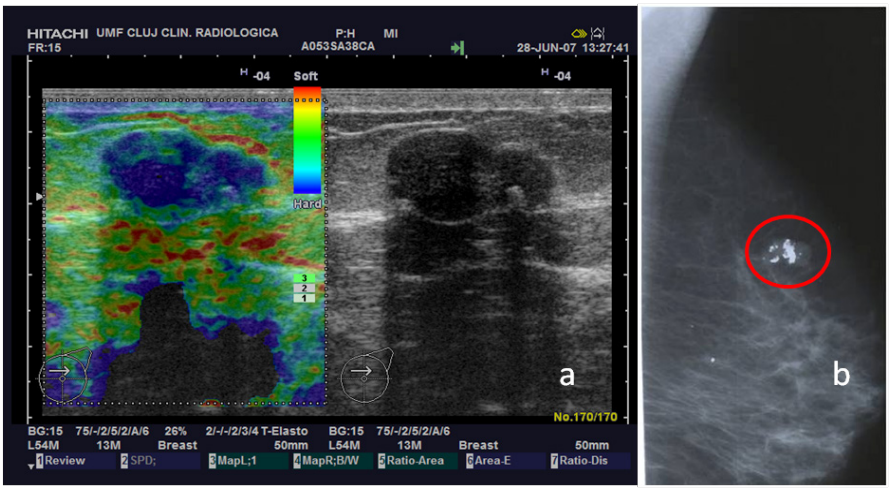

Figure 6. Partially calcified fibroadenoma with typical benign, BI-RADS II mammography appearance **(b)**, displaying a suspicious score 4 on USE **(a)**.

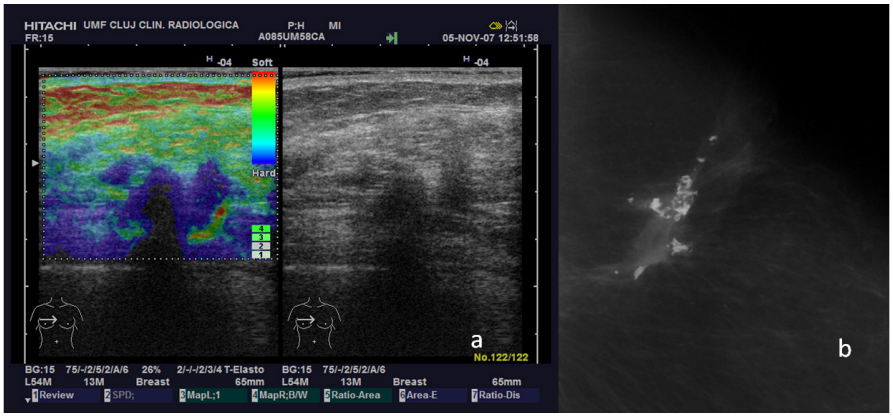

Figure 7. a - Post-traumatic CSN displaying a highly suspicious US (distortion with posterior shadowing) and USE appearance (Tsukuba score 5). **b** - Same case on mammography: asymmetrical density with macrocalcifications depicting a typical, non-suspicious BI-RADS II aspect for a post-traumatic CSN.

inter- and intra-observer variability coefficients. The values for Se, Sp, PPV (positive predictive value) and NPV (negative predictive value) between BI-RADS classification and Tsukuba score were relatively close (slightly lower for the elasticity assessment); the more obvious or significant difference was noticed for the negative predictive value in favor of BI-RADS classification (Fig. 4). This can be explained by a particular series of lesions such as: calcified fibroadenomas or cytosteatonecrosis with typical BI-RADS 2 (benign) mammographic aspect, but suspicious *stiffness* displayed on USE images [9,10,11,12].

Also to be noted are the large typically malignant cancers (BI-RADS 5 category) with an important necrotic component which conferred a falsely benign but expected BGR/stratfied pattern on elastography (Fig. 8c), plus a series of *in situ* or hypercellular carcinomas with a *softer* (score 2) aspect on USE (Fig. 9 a, b), which led to the slightly lower negative predictive value for elastography (Fig. 4) .

When typically benign (BI-RADS 2) or malignant (BI-RADS 5) looking lesions were eliminated from the analysis, there was no statistically significant difference between the two classification systems.

Falsely benign or malignant Tsukuba scores versus true ones

If we take a close look to our correlative analysis (Fig. 2, 3, 5) it may be noted that the **1, 2 and BGR elasticity scores** are mostly assigned to BI-RADS II and III benign lesions such as cysts, hamartomas, lipomas, hematomas, non-palpable fibroadenomas or mastopathic nodules – a result concordant with literature data [13,14,15,16]. In the enumeration above the cystic lesions classified as BI-RADS III (Fig 8a) or IV (1 palpable inflammatory cyst –Fig. 8b) are to be mentioned, due to their viscous content which led to a pseudo-solid aspect on gray scale ultrasound. Either monitored or percutaneously evacuated through FNA (fine needle aspiration), all these lesions displayed benign elastography appearances: mostly the BGR pattern or score 2 [13].

Tsukuba score 3 assigned mostly to BI-RADS

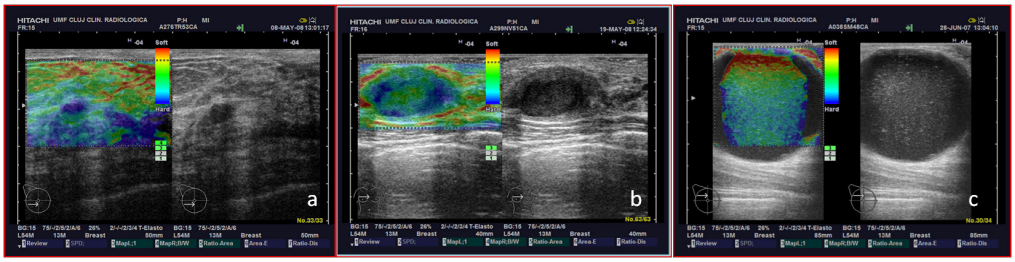

Figure 8. a - Small cyst with viscous content (documented by FNA) displaying a non-specific BI-RADS IV aspect on gray scale US and a reassuringly stratified pattern on USE indicating its fluid nature. **b** - Complex cyst (BI-RADS IVB) on gray scale ultrasound displaying a stratified pattern on USE (FNA revealed an inflammatory cyst). **c** - Complex cyst in an elderly patient with hemorrhagic nipple discharge (BI-RADS V) displaying a non-suspicious stratified pattern on USE (excision biopsy revealed a necrotic squamous carcinoma).

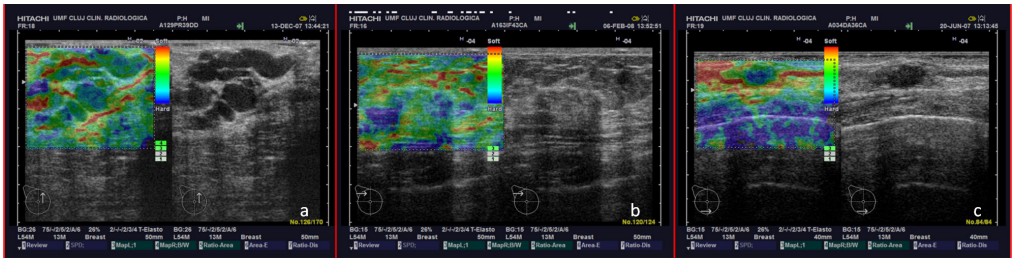

Figure 9. a - Focal duct ectasias with hypoechoic content (BI-RADS 3) displaying a score 2 on USE. Due to a suspicious nipple discharge an excision biopsy was performed revealing a ductal carcinoma *in situ* (DCIS). **b** - Isoechoic, oval, slightly lobulated lesion (BI-RADS IV) with a Tsukuba score 2 on USE. Percutaneous biopsy showed also a DCIS. **c** - Small mastopathic-like nodule (BI-RADS 3) demonstrating a Tsukuba score 3 on USE. Percutaneous biopsy showed a hypercellular invasive ductal carcinoma (IDC).

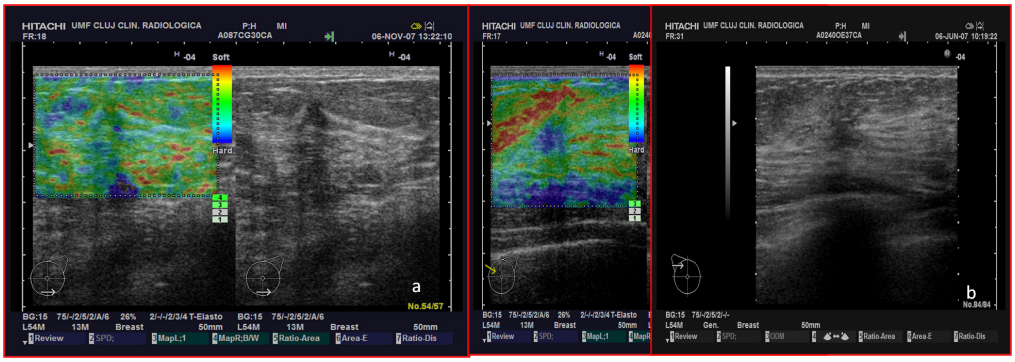

Figure 10. a - Non-specific small nodule with slightly posterior shadowing (BI-RADS IVA) presenting a soft-score 2 aspect on USE. Percutaneous biopsy revealed a mastopathic nodule. **b -** Small architectural distortion (BI-RADS IVC) presenting a score 3 on USE. Excision biopsy revealed a radial scar.

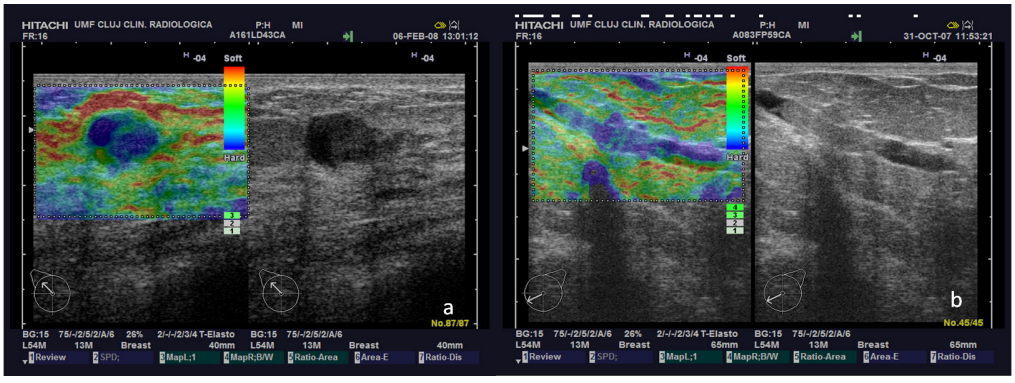

Figure 11. a - Complex cyst with intracystic hypoechoic mass (BI-RADS IV) displaying a stiff-score 4 appearance on USE. Excision biopsy evidenced a small intracystic papilloma. **b -** Intraductal mass (BI-RADS IVB) with stiff –score 4 appearance on USE. Excision biopsy revealed an intraductal papilloma.

IV lesions (7 out of 9) was associated with malignancy in 44% of the cases: 4 out of 9 lesions with score 3 were malignant (3 small 9 to 13 mm IDCs - Fig. 9c- and a 4 mm DCIS), while the rest were represented by fibroadenomas [2], mastopathic nodules [2] and a radial scar [1] - Figure 10b - a result similar to other studies, which indicates a rather high probability of risk lesions or malignancies associated with score 3 and thus the necessity of biopsy in such circumstances [17].

Tsukuba score 4 also given to predominantly BI-RADS IV and V lesions (11 out of 12) was associated with malignancy in 41% of the cases, although the expectance would have been for a higher figure. This rather similar percentage with score 3 may be explained by a series of benign lesions such as old hyalinized or calcified fibroadenomas [4], one mastopathic nodule (focal adenosis) and papillomas [2] (Fig. 11), which displayed a stiff appearance on elastography. Although calcified fibroadenomas are not usually biopsied due to their non-suspicious mammography appearance, the rest of the above mentioned lesions usually appear as non-specific (BI-RADS IV) or even suspicious (BI-RADS V) on conventional imaging and should undergo pathologic verification through biopsy or excision, thus indicating that a higher Tsukuba score should promote a more invasive diagnostic attitude.

When it comes to **Tsukuba score 5** it is obvious that it correlates best with BI-RADS V category and malignant pathology results [18]. In only one circumstance a score 5 was given to a BI-RADS II lesion which corresponded to a typical post-traumatic CSN (cytosteatonecrosis) aspect on mammography (Fig. 7).

BI-RADS categories which benefit the most from the elastographic assessment

Ten out of the 15 cysts included in our analysis showed a pseudo-solid- hypoechoic aspect classified as BI-RADS III on ultrasound (Fig. 8a). One palpable complex cystic lesion was classified as BI-RADS IVB (Fig. 8b). On elastography all these lesions displayed either a stratified BGR pattern (9 cases including the palpable one) or a score 2 certifying their fluid/benign nature. In these cases elastography reinforced the benign standard imaging interpretation and multiple short follow-ups or even aspirations could have been avoided in favor of annual screening, with better financial outcome and less anxiety for the patient [19,20].

Forty-three of the 53 benign solid nodular lesions classified as BI-RADS III or IV displayed benign scores (1 or 2) on elastography. In such cases a *soft* USE aspect may down grade the original BI-RADS category and thus reduce the frequency of follow-ups or unnecessary biopsies (e.g. for a BI-RADS IVA/B nodule displaying a score 2 on USE a regular follow-up attitude may be more suitable than a biopsy) (Fig. 10a).

On the other hand, BI-RADS III or IV lesions displaying *stiff* (score 3 to 5) aspects on elastography with negative or non-specific mammography findings should be biopsied or excised due to their risk potential. In our study 4 of such lesions proved to be fibroadenomas, 3 mastopathic nodules (2 adenosis, 1 focal fibrosis), 1 adenoma, 2 papillomas, 1 radial scar and 6 carcinomas (4 DCIS and 2 IDCs).

Limitations

One of the study's main limitation derives from its reproducibility. The major question when it comes to elastography and ultrasound is the ability to obtain images with similar characteristics even when they are acquired at different times or by different operators. Although we obtained good inter-observer variability coefficients when interpreting images, it is to be mentioned that this double reading of data was performed using a set of images acquired by one and the same breast radiologist and not by two distinct US machine operators.

However, it is our opinion that the results would not have differed significantly if the images would have been acquired by two distinct operators, based on the fact that a previous study conducted in our unit on an elastography phantom showed good inter-observer variability coefficients for the two readers in this study [21].

Conclusions

Generally speaking, the BI-RADS classification correlates well (is concordant or in agreement) with the Tsukuba elasticity score, the main exception being represented by calcified or fibrotic lesions and papillomas that falsely appear more suspicious post-elastography and also some in situ, hypercellular or necrotic invasive carcinomas that may look falsely benign on sonoelastography.

BI-RADS III and IV lesions would benefit the most from an elastographic assessment, a low elasticity score (BGR, 1 or 2) allowing a lesser invasive approach, while a high score (3, 4 or 5) imposes a pathological evaluation after correlating with history and mammography appearances (excluding calcified fibroadenomas or typical CSN).

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