The Role of Ultrasographic Elastography in the Differential Diagnosis of Breast Masses and Its Contribution to Classical Ultrasonographic Evaluation

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ABSTRACT

Objective: The aim of this study was to understand the role of ultrasonographic elastography method in the differentiation of breast masses and to assess its contribution to classic ultrasonographic evaluation.

Materials and Methods: In this retrospective study, 76 breast masses in 76 patients

were firstly evaluated by conventional ultrasonography (U.S.) and scored according to breast imaging report and data systems (BIRADS) and then evaluated with the Elastographic method during the same session between January and December 2013 in our hospital's Radiology Department. Findings were compared with pathological results. In statistical evaluation of the data, independent sample t tests were used for variables between groups.

Results: The mean strain ratio of benign masses was 2.48 ± 1.605 and strain score was 2.307 ± 1.327 . The mean strain ratio of malignant masses was 5.546 ± 1.434 and strain score was 4.458 ± 0.721 . The most frequent benign masses were fibroadenoma and fibrocystic lesions. The most common malignant lesion was invasive ductal carcinoma. When the cut-off value for strain ratio was accepted as 4.009 in receiver operating curve (ROC) analysis for the differential diagnosis of malignant breast masses, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated as 83.8%, 76.9%, 62.3%, and 90.7%, respectively. When the limit value of strain patterns was accepted as scores 4 and 5, the sensitivity, specificity, PPV, and NPV were calculated as 42.7%, 94.2%, 77.2%, and 78%, respectively. When conventional ultrasonography (U.S.) findings were considered together with the elastographic strain ratios the sensitivity, specificity, PPV and NPV were 87.5%, 71.1%, 58.3% and 92.5%, respectively.

Conclusion: Elastography is not a method that can replace conventional breast ultrasound for detecting breast cancer, however it may be an adjunct to conventional ultrasound by increasing its diagnostic power.

Key words: Elastography, strain ratio, strain score

Introduction

Early diagnosis and characterization of breast cancer are of critical importance. Although many modalities have been developed, the differential diagnosis of breast masses remains challenging. Ultrasonographic elastography is a method similar to palpation that is one of the main examination methods, it evaluates the hardness of a breast mass, and is currently being used as a new technique to help in the differentiation of malignant and benign breast masses (1).

The basic aim of this study was to evaluate ultrasonographic elastography by comparing its results to pathological results in benign and malignant breast lesions, and to determine its contribution to classical ultrasound (U.S.).

Materials and Methods

A total of 76 breast masses in 76 consecutive patients who applied to Uşak State Hospital Radiology Department between January 2013 and December were evaluated by B-mode ultrasonography (U.S.) and elastography, informed consent was obtained and the findings were compared retrospectively with fine needle aspiration biopsy (FNA), core biopsy and excisional biopsy results.

Sonographic assessment was performed by Toshiba Aplio 500 ultrasound system (Toshiba Medical System in İstanbul, Turkey) and a high-resolution linear 7-12 megahertz (MHz) probe was used for conventional ultrasound and elastography. The lesions were first assessed by classic ultrasonography (U.S.) and then by elastography during the same session. The results of both methods were evaluated both independently and in combination. The results of classic ultrasound were reported according to breast imaging report and data system (BIRADS). "Specific preset" settings were applied to the breast tissue during elastography method, and "Strain ratio" and "Strain pattern" were evaluated. Strain pattern

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Received: 04.01.2014
Accepted: 22.03.2014

scoring was performed according to the Tsukuba scoring method defined by Itoh et al (2) (Figure 1). According to this system, score 1 refers to completely green color-coded masses that have a soft and loose structure. Score 2 refers to masses coded in blue and green mosaic and emphasizes heterogeneously distributed soft -rigid internal structure. Score 3 masses are coded blue in the center and green in the periphery indicating that the mass is harder in its center and softer on the outside. Score 4 refers to completely blue masses and it shows that the whole structure is hard and tight. Finally, a score of 5 refers to blue encoding of an area that is larger than the size of the mass, covering the mass and its surrounding tissue. It indicates the hard structure of both the mass and the surrounding tissue due to desmoplastic reaction. In addition, cystic lesions show a specific "BGR" pattern of blue, green and red color coding (2) (Figure 1).

The strain ratio was obtained by dividing the fat tissue strain value to the strain value of the mass. In strain patterns, score 1, 2 and 3 emphasized benign features whereas masses with scores of 4 and 5 were considered as malignant. A cut-off value was set for the strain ratio, which is a quantitative method (2).

During statistical evaluation, "the Independent-Sample t" test was used for variables between independent groups. The sensitivity and specificity values calculated for Strain ratios, Strain patterns and B-mode

findings are shown by a receiver operating characteristic (ROC) curve. The parameters are summarized in tables. All analyzes were performed by using SPSS 20.0 for Windows, IBM SPSS Statistics New York/ USA statistical software package, with 95% confidence interval. $p < 0.05$ was considered as statistically significant.

Results

A total of 76 patients, including 1 male and 75 female were included in the study. The mean age of the patients was 41.79 ± 12.4 , the minimum age was 21, the maximum age was 73 years. The mean age of patients in the malignant group was 51.88 ± 9.61 , and the mean age of the patients in the benign group was found to be 37.13 ± 10.7 .

The study included a total of 76 breast masses in 76 patients. The mean size of the masses was 25.63 ± 1.2 mm, with a minimum of 10 and maximum of 54 mm. 52 were benign masses (68.4%) and 24 were malignant (31.6%). Benign lesions included 15 fibroadenoma (28.8%), 21 fibrocystic changes (40.4%), 3 intraductal papillomas (5.8%), 2 granulation tissue (3.8%), 3 fibroadenomatoid mastopathy (5.8%), 3 sclerosing adenosis (5.8%), 3 stromal fibrosis (5.8%), and 2 abscess (3.8%). Malignant lesions included 19 invasive ductal carcinoma (79.2%), 4 ductal carcinoma in situ (16.7%) and one invasive lobular carcinoma (4.2%) (Figure 3).

Figure 1. Score system of Strain patren

Figure 2. Elastographic evaluation of IVDC mass

Figure 3. Graphic of number of pathology results

Table 1. Pathology results according to BIRADS score criteria

		BIRADS score				
		BIRADS	BIRADS	BIRADS	BIRADS	Total
Pathology results	Benign	30	11	11	0	52
	Malignant	0	4	9	11	24
Total		30	15	20	11	76

BIRADS: Breast imaging, report and data systems

Figure 4. Relation between pathology results and strain ratio

Out of the 76 breast masses, 48 received fine-needle aspiration biopsy (FNA), 10 received core-biopsy and 18 were diagnosed with excisional biopsy.

The classical ultrasonographic evaluation involved mass shape, boundaries, location, echogenicity, presence of acoustic strengthening and calcification content (micro or macrocalcification). They were classified as benign, likely benign, suspicious malignancy, high probability of malignancy according to BIRADS score criteria (Table 1).

The mean strain ratio of 21 fibrocystic lesions was 0.913 ± 0.191 , with the lowest values within the group of patients with benign masses. The mean strain ratio of patients with fibroadenoma was 2.819 ± 1.135 . The mean strain ratio in the benign group was calculated as 2.48 ± 1.605 and the strain score as 2.307 ± 1.327 (Figure 4), (Table 2, 3). In this study although fibroadenomas were generally detected to have a similar and softer elasticity than the surrounding soft tissues, the strain ratios of two patients with fibroadenoma were higher than the cut off value. None of the fibrocystic lesions and intraductal papillomas showed a different elasticity from the surrounding soft tissue. Simple fibrocysts had a characteristic appearance with 3 layers: Blue-green-red (Figure 1). Blue was coded as the most superficial and red as the deepest color. All cystic lesions strain ratios were below 2. None of the granulation tissue, sclerosing adenosis and stromal fibrosis were below the chosen cut off value due to their hard consistency. Only one of the 3 fibroadenomatoid lesions was below our cut-off value (Table 4).

The mean strain ratio of 14 invasive ductal carcinoma (IVDC) was 5.967 ± 0.96 , with the highest values of patients in the malignant group (Figure 2). The mean strain ratio of malignant lesions was 5.546 ± 1.434 (Table 2). Their strain score was 4.458 ± 0.721 (Table 3). None of the our malignant lesions had a score of 1 or 2 by elastography. Only 3

Table 2. Pathology results and Strain ratio cross

		Mean	Number	Standard deviation
Benign	Fibrocystic change	.91333	21	.191677
	Fibroadenoma	2.81900	15	1.135700
	Intraductal papilloma	3.37633	3	.154907
	Inflammation (Granulation tissue)	4.59050	2	.545179
	Fibroadenomatoid mastopathy	4.24033	3	.351137
	Sclerosing adenosis	4.55567	3	.220874
	Stromal fibrosis	5.21033	3	.655006
	Abscess	3.10700	2	1.077631
	Total	2.48092	52	1.605497
Malignant	ISDC	3.55425	4	.634881
	IVDC	6.00789	19	1.191357
	Invasive Lobular Carcinoma	4.74100	1	.
	Total	5.54617	24	1.434468

ISDC: Intra ductal carcinoma; IVDC: Invasive ductal carcinoma

Table 3. Pathology results and elastography score cross

		Mean	Number	Standard deviation
Benign	Fibrocystic change	1.0000	21	.00000
	Fibroadenoma	2.6667	15	.89974
	Intraductal papilloma	3.0000	3	.00000
	Inflammation (Granulation tissue)	4.0000	2	.00000
	Fibroadenomatoid mastopathy	3.6667	3	.57735
	Sclerosing adenosis	4.0000	3	.00000
	Stromal fibrosis	4.6667	3	.57735
	Abscess	2.5000	2	.70711
	Total	2.3077	52	1.32159
Malignant	DCIS	3.5000	4	.57735
	IVDC	4.6842	19	.58239
	Invasive Lobular Carcinoma	4.0000	1	.
	Total	4.4583	24	.72106

ISDC: Intra ductal carcinoma; IVDC: Invasive ductal carcinoma

Table 4. Pathology results according to BIRADS score criteria

Pathology results		Cut-off value		
		>4.009	<4.009	Total
Benign	Fibrocystic change	0	21	21
	Fibroadenoma	2	13	15
	Intraductal papilloma	0	3	3
	Inflammation (Granulation tissue)	2	0	2
	Fibroadenomatoid mastopathy	2	1	3
	Sclerosing adenosis	3	0	3
	Stromal fibrosis	3	0	3
	Abscess	0	2	2
Total		12	40	52

Figure 5. Strain ratio of ROC curve

lesions had a score of 3, one ductal carcinoma in situ (DCIS), and 2 invasive ductal carcinoma (IDC).

The difference between the mean strain ratios of benign and malignant masses were statistically significant ($p < 0.05$). When the cut-off value for strain ratio was accepted as 4.009 in receiver operating curve (ROC) analysis (those above this value are accepted as malignant and those below as benign), the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the differential diagnosis of benign and malignant breast masses were calculated as 83.8%, 76.9%, 62.3%, and 90.7%, respectively (Area under the curve = 0.926 95%, confidence interval (CI) = 0.867-0.986, Figure 5). For the accepted cut-off value, 18 out of 19 masses diagnosed as IDC were above and 1 was below this value. All fibroadenomas and 13 out of 15 fibrocystic lesions were below this value (Table 4, 5). When the limit value of strain patterns was accepted as scores 4 and 5, the sensitivity, specificity, PPV, and NPV were calculated as 42.7%, 94.2%, 77.2%, and 78%, respectively. When BIRADS score 4 or above were combined with elastographic strain ratios with the cut off value identified as 4.009, the sensitivity, specificity, PPV and NPV were calculated as 87.5%, 71.1%, 58.3% and 92.5% respectively (Table 6).

Breast imaging report and data systems score of 4 or higher were considered as malignant masses and were evaluated as requiring biopsy. It was accepted that biopsy was unnecessary for BIRADS scores of 3 or less. In combined application, lesions with both BIRADS score of

Table 5. Cut of value of malign pathology results

Pathology results		Cut-off value		
		>4.009	<4.009	Total
Malignant	DCIS	1	3	4
	IDC	18	1	19
	Invasive Lobular Carcinoma	1	0	1
Total		20	4	24
DCIS: Ductal Carcinoma In Situ; IDC: Invasive Ductal Carcinoma				

Table 6. Analyzing of sensitivity, specificity, PPD and NPD

	Sensitivity	Specificity	PPD	NPD
Strain ratio	83.3%	76.9%	62.3%	90.7%
Strain score	42.7%	94.2%	77.2%	78%
Combined strain ratio and classical US	87.5%	71.1%	58.3%	92.5%
US: Ultrasonography; (compatible with BIRADS* score); PPD: Positive predictive value; NPD: Negative predictive value				
* Breast imaging-report and data systems				

4 or higher and elastography values higher than cut-off values were considered as candidates for biopsy. If the biopsy decision had been made according to only BIRADS findings, 22 of 52 benign masses would have received an unnecessary biopsy (Table 1). This number was reduced to 12 if the decision had been made according only to elastography findings. However, when BIRADS and elastography findings were combined, this number increased to 15. Although in combined application this number increased in comparison to elastographic evaluation alone, concomitant use of elastography and BIRADS scoring increased the number of biopsy planned for malignant lesions in a ratio of 21:20 as compared to only elastographic assessment. Although there was no difference between the number of malignant masses missed by BIRADS assessment alone or elastographic evaluation alone, the number of missed malignant masses dropped to 3 in the combined application. (Table 7, 8)

Discussion and Conclusions

Ultrasonographic elastography is a non-invasive medical imaging technique that discriminates masses based on their hardness (3). Malignant lesions tend to be significantly harder as compared to normal tissues (4). Although elastography method has been used since the 1990s, the Food and Drug Administration (FDA) has granted approval for clinical research use in 2006. Elastography uses gray scale or color scale maps to demonstrate tissue firmness (1, 2). We used the color scale mapping method to demonstrate the strain pattern in our study. Previous studies mainly used the "strain pattern", which is a qualitative method in distinguishing malignant from benign breast masses (2, 5). Garra et al (6) have used the "strain ratio", the quantitative measurement obtained by comparing the hardness of the target lesion and breast adipose tissue. In our study, we evaluated both of these elastographic findings. Two different elasticity scores are being used for characterization of breast masses. One of these is the "Tsukuba Score" developed by Itoh et al (2, 6), which was used in this study. There is also a second scoring system developed by the Italian working group Rizzatto G et al (8).

Table 7. Numeric distribution of the population according to Strain ratio and pathologic diagnosis

		Strain ratio ≥4.009	Strain ratio <4.009	Total
Pathology results	Benign	12	40	52
	Malignant	20	4	24
	Total	32	44	76

Table 8. Numeric distribution of the population according to combined Strain ratio and BIRADS score and pathologic diagnosis

		Combined Strain ratio and BIRADS (+)	Combined Strain ratio and BIRADS (-)	Total
Pathology results	Benign	15	37	52
	Malignant	21	3	24
	Total	36	40	76

BIRADS: Breast imaging, report and data systems

Ioanna A. et al. (9) stated that application of “strain ratio” was useful for quantitative comparison of the elasticity of soft tissues with the elasticity of the lesion. Several studies have identified the cut off value for strain ratio between 3 and 5 (9-11). The priority in our study was to retrospectively evaluate the diagnostic value of elastography method by comparing with pathological results. When the strain ratio cut off value was identified as 4.009, the sensitivity and specificity values in our study were calculated as lower than other studies (9, 12). Thomas et al (13) set their cut-off value to 2.45, Ioanna et al (9) to 3.0 and Zhi et al (11, 12) to 3.05. In our ROC analysis, if the cut off value was set as 3.0 the sensitivity of the test was calculated as 95.8% that was compatible with other studies, however, the specificity rate was calculated as 63.5% and the number of masses with false-positive diagnosis increased. In this study, the predominance of scirrhous masses like invasive ductal carcinoma within malignant lesions that have significantly higher strain ratios has increased the cut off value for high sensitivity and specificity. Similar to our study, Busko et al (14) have selected the cut-off value in ROC analysis as 4 due to high sensitivity. This situation is not explained in detail in their study, nevertheless the significantly higher number of malignant lesions similar to our study increased the strain ratio. Ioanna et al (9) reported five malignant lesions within score 1 and score 2 and they related this situation to the non-scirrhous properties of those masses. It was emphasized that non-scirrhous tumors’ containing more cells and less fibrotic tissue than scirrhous tumors might have an effect on this outcome (15). Some breast cancers like mucinous tumors may show benign properties. This issue could not be evaluated due to the lack of mucinous tumors within our malignant group. In this study, the strain scores of malignant lesions were generally score 4 and 5. The mean strain ratio of malignant lesions was above 4. In some studies it is indicated that the high strain rates in malignancies with scirrhous features like invasive ductal carcinoma are decreased in malignancies with non-scirrhous features (9). Invasive ductal carcinomas had the highest strain ratios, and although pathological subgroup analysis was not performed in the study, the strain rates of 3 out of 4 in situ ductal carcinoma lesions that were likely to have non-scirrhous features were below the cut off value.

Routine screening methods such as mammography and breast ultrasound are valuable methods for managing breast masses, nevertheless new methods such as elastography may be needed in identifying requirement of interventional procedures. Recent studies have showed that elastography markedly increased the specificity of ultrasound and the early diagnosis of breast cancer under one centimeter, and it decreased the number of unnecessary biopsies especially in BIRADS 3 and 4 lesions (16, 17). It is stated that elastography can be clinically used as an imaging method in patient follow-up or as a method for determining whether to perform an invasive procedure or not. It has been reported that distinguishing between score 2 and score 3 lesions by elastography might be difficult in some cases, but diagnosing score 1 lesions is very easy since a blue color is not present in these lesions (18). According to our study, it is unlikely to have trouble in the elastographic diagnosis of cystic lesions, however it is obvious that problems will arise due to the nature of some benign lesions mainly composed of fibrous tissue such as stromal fibrosis and sclerosing adenosis. In addition to this, we detected that when elastography was used in conjunction with BIRADS scoring a reduction in the number of unnecessary biopsies was achieved and the number of biopsies required for malignant lesions were affected positively.

The sensitivity of ultrasonographic elastography is less than classic ultrasonography in the evaluation of non-focal pathologic changes. It also fails to identify postoperative changes, diffuse lesions, and lesions larger than that of the probe. In addition, the role of elastography is limited in very dense fibrous parenchyma, in presence of hematoma and breast implants. Some studies have also showed its value in the differentiation of benign and malignant lymph nodes (18). It is reported that both the mechanical type of elastography method that we used in this study and the shearwave elastography method that is more software dependent provide similar results (19). In our study, we could not compare our data because we did not have the devices equipped with the appropriate software (20).

Breast elastography is a simple and fast method that increases the sensitivity of ultrasound especially in elastographic score 3 and 4 lesions. Combining classical ultrasound with elastography method, which causes an increase in the negative predictive value, may reduce the rate of unnecessary biopsies and may result in lower price/cost effectiveness. Although elastography is not a method that can replace conventional breast ultrasound for detecting breast cancer, it may be an adjunct to conventional ultrasound by increasing its diagnostic power.

Conflict of Interest: No conflict of interest was declared by the authors.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.Y.; Design - M.Y.; Supervision - M.Y.; Funding - Ç.Ö.; Materials - M.Y.; Data Collection and/or Processing - M.Y.; Analysis and/or Interpretation - M.Y.; Literature Review - E.T., Ç.Ö.; Writer - M.Y.; Critical Review - M.Y.; Other - M.Y.

Financial Disclosure: The authors declared that this study has received no financial support.

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