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Research Article

Does intra-procedural enlightenment change the level of anxiety and pain in scheduled breast ultrasonography?

Randevulu meme ultrasonları esnasında bilgilendirme yapılmasının hasta kaygısı ve meme ağrısı üzerine etkisi var mıdır?

Funda Ulu Ozturk[1]*, Sehnaz Tezcan[2]

[1]Department of Radiology, Memorial Ankara Hospital, Ankara, Turkey
[2]Department of Radiology, Koru Hospital, Ankara, Turkey

Abstract

Aim: Scheduled breast ultrasounds are stressful procedures for women. We aimed to study the effect of informing patients during breast ultrasound and investigate associated anxiety and pain alterations.

Material and Methods: After approval of the state hospital ethics committee and informed consent, women scheduled for breast ultrasound between November 2022 and March 2023 were prospectively enrolled in this randomized controlled study. Patients were either informed during the ultrasound about the procedure itself or not. The participants completed State-Trait Anxiety Inventory for measuring anxiety and visual analog scale for pain scores, immediately before and after the examination. Demographic data, anxiety and pain scores were statistically evaluated by using chi-square test, independent samples t-test and Mann-Whitney U test. The alteration of anxiety and pain scores considering enlightenment were compared with paired samples t-test and Wilcoxon test.

Results: Among 143 patients, preprocedural anxiety was lower in oncological follow-ups and higher in positive clinical breast examination, breast self-examination and mammography subgroups. Trait and preprocedural state anxiety scores were similar between the two groups regarding enlightenment. Anxiety and pain reduction was observed after ultrasound and both were statistically significant in the informed group ($p<0.001$ and $p=0.03$, respectively).

Conclusion: Informing the patients during breast ultrasound reduces anxiety levels and pain perception.

Keywords: Anxiety; stress; breast ultrasound; pain; enlightenment.

Corresponding Author*: Funda Ulu Ozturk, Department of Radiology, Memorial Ankara Hospital, Ankara, Turkey
E-mail: nepandes@hotmail.com
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Öz

Amaç: Randevulu meme ultrasonları kadınlar için oldukça stresli işlemlerdir. Bu çalışma ile ultrason esnasında hastaları bilgilendirmenin, işlem ilişkili kaygı ve meme ağrısı üzerindeki etkilerini araştırmayı hedefledik.

Gereç ve Yöntemler: Şehir hastanesi etik kurulu onayı ve hasta onamı alınmasını takiben Kasım 2022 ve Mart 2023 tarihleri arasında randevulandırılmış meme ultrasonu olan hastalar prospektif olarak değerlendirildi. Hastalar bilgilendirme yapılıp yapılmamasına göre randomize-kontrollü olarak iki gruba ayrıldı. Çalışmaya katılan hastalar kaygı ölçümü için "Durumluk-Sürekli Kaygı Ölçeği" formunu, ağrı skorları için de "Görsel Analog Ölçeği" formunu hem ultrasondan önce hem de ultrason bitiminde doldurdu. Demografik veriler, kaygı ve ağrı skorları istatistiksel olarak Ki-kare testi, bağımsız örneklem t-testi ve Mann-Whitney U testi ile analiz edildi. Hasta bilgilendirmesine göre yapılan kaygı ve ağrı skorları değişimi, eşleştirilmiş örneklem t-testi ve Wilcoxon testi ile değerlendirildi.

Bulgular: 143 hastada işlem öncesi kaygı, onkolojik takip hastalarında daha düşük olup fizik muayene bulgusu olan, öz muayene yapan ve aynı gün mamografi çekimi bulunan hastalarda ise anlamlı olarak daha yüksek saptandı. Sürekli ve işlem öncesi durumluk kaygı skorları hasta bilgilendirmeye göre iki grup arasında benzer bulundu. Ultrason sonrası genel kaygı ve ağrı skorlarında azalma dikkati çekmiş olup hastaların bilgilendirildiği grupta bu düşüş anlamlı bulundu (sırasıyla $p<0.001$ ve $p=0.03$).

Sonuç: Meme ultrasonu çekimi esnasında hastaları bilgilendirme, kaygı seviyeleri ve meme ağrısını azaltmaktadır.

Anahtar kelimeler: Kaygı; stres; meme ultrasonu; ağrı; bilgilendirme.

Introduction

There has been an increasing need for radiological imaging in recent decades. Screening programmes, diagnostic purposes and follow-up patients, either oncological or non-oncological, compose the pool of radiological examinations (1). Breast imaging is one of the main topics that attracts attention, especially of women.

Anxiety is a common problem for people having or waiting for a scheduled radiological examination. It is generally related to the possible results of health impairment (2). According to National Cancer Institute, approximately one in every eight women will be diagnosed with breast cancer in her lifetime and the death rate is 19.6 per 100.000 women every year (3). Therefore, patients that undergo breast ultrasonography (US) cannot avoid the thought of cancer possibility and experience a personal variable degree of anxiety regarding this high emotional status from the time the examination was scheduled (4). The burden of stress reflects during the ultrasound procedure, where the patient is uncomfortable and asks questions about the imaging as the radiologist performs.

Pain is one of the breast symptoms that precipitate anxiety. According to previous studies, about 10-30% of women present with breast pain in their lifetime (5). Even though breast cancer related breast pain comprises very few amount of the cases and researchers show that other symptoms, such as breast mass, nipple discharge etc, are mainly involved in malignancy diagnosis, breast pain is still one of the primary reasons for hospital referrals (6, 7).

We aimed with this study to investigate if informing the patients for breast US about the procedure itself and patient related imaging results, either during or at the end of the examination, would influence the level of anxiety and breast pain.

Material and Methods

From November 2022 to March 2023 patients (age>18 years) waiting to undergo breast US in the radiology department of one institution were invited to participate in this prospective study, after obtaining the approval of the state hospital ethics committee (decision number: 2022-10/2127). The study was conducted according to the Declaration of Helsinki. All patients were informed for the implementation of the psychological test that they will be submitted and written consent was provided. Exclusion criteria were the use of anxiolytic medication on the same day prior to the US procedure, illiteracy and reading disorders.

In the waiting hall of the radiology department, the participants were welcomed with an US technician first. They were informed about the study individually and then randomized into two groups. Group 1 was labelled for enlightenment, where patients were provided with the information of the US procedure itself and the results of a kind that the patient would understand. Before the procedure, the ultrasound technician gave the participant an enlightenment form where it is explained what breast US is, why to do this imaging, that the technique does not involve ionized radiation, what can go wrong during the session, how long will it take and when the

results can be achieved. After this interaction, the participants were asked to fill in the "trait" part of Spielberger State-Trait Anxiety Inventory (STAI) form, a sheet of demographic data and a visual analog scale (VAS) form to score pain, if the patient has breast pain. Finally, the patient was introduced to the radiologist for breast examination. She was told that the results of the US could be discussed at the end of the session. If the patient had findings of BI-RADS 3 or less, she was explained in detail by the radiologist what the findings meant and that she should not worry about the results since it would not need any further investigation. Also if called for a follow up, she was explained why and what future possibilities are likely to happen. If the participant had results of BI-RADS 4 or 5, she was explained that a suspicious finding was detected which would need histopathological confirmation before discussing anything about cancer and that benign possibilities are still in consideration. The enlightenment was provided by the same doctor and US technician for each patient. The total procedure of both enlightenment and breast US ranged from 20 minutes to 35 minutes. Group 2 was referred as the control group, where no specific information about the US procedure was provided. If the case did not need biopsy evaluation (BI-RADS 3 or less), the patient was told to see her clinician for the results. But if the BI-RADS score was 4 or higher, the patient was told that there is a problem that needs to be discussed with her doctor and was referred for an urgent appointment with the clinician. The participants were asked to fill in the STAI and VAS forms before the US, similarly as in Group 1. Immediately after the procedure, patients were asked to complete the "state" anxiety part of the STAI, together with a second VAS form for evaluating breast pain again.

STAI is a validated, 40-item questionnaire on a self-report basis that is used to evaluate anxiety in two subscales, consisting of 20 items each (8). Trait anxiety refers to individual's behavioral attitude and how they feel for anxiety in general. State anxiety is a temporary emotional condition under particular circumstance of a perceived event. Each question is scored on a scale from 1 to 4. Final evaluation of each inventory range from 20 to 80, where higher scores correlate with elevated levels of anxiety. VAS is a self-reported Likert-type scale where responses are scored from 0 (no pain) to 10 (unbearable pain). We evaluated breast pain using this scale at the beginning of the breast ultrasound and right after the procedure ended.

Data analysis was performed through the statistical software (SPSS, v. 20.0, IBM Company, Chicago, IL). The Kolmogorov-Smirnov test was used to check for data normality. Categorical variables were expressed as number (n) and percentage (%), while continuous variables were reported as mean, standard deviation (SD), or median values depending on the distribution. When testing continuous variables, the Independent Samples t-test was used if the test's parametric assumptions were fulfilled. Otherwise, the Mann-Whitney U test was used. Demographic differences were calculated by using chi-square test. The alteration of anxiety scores and VAS scores regarding enlightenment were compared with paired samples t-test and Wilcoxon test. Statistical significance was defined for p less than 0.05.

Results

Of 235 patients eligible for research, a total number of 176 women were enrolled in the study. The rest 59 patients refused to participate except for 33 cases who did not fulfill the requirements of a scorable test. A total of 143 patients were randomized into two groups where 57 were informed (group 1) an 86 were not informed (group 2) of the US results. The demographic data of the patients are shown in Table 1.

Regarding the medical records, 44 % (n=63) of patients were submitted to radiology department for an oncologic follow-up. Among non-oncological patients, 26 % (n=38) were suspected of breast cancer in clinical breast examination (CBE), and 29 % (n=42) applied for a due breast screening programme. 52 % (n=75) of patients had scheduled mammography workup on the same day with the US, and this group showed higher levels of state anxiety before US (p=0.036). The state anxiety score before US was higher in the group with abnormal CBE and those who make breast self-examination. Oncological patients, including breast cancer, had significantly lower state anxiety scores (Table 2).

Enlightenment related anxiety alteration during US was evaluated by STAI scores (Table 3). The baseline level of anxiety was referred as the trait STAI score, which was obtained before the US examination. The trait anxiety was similar between the two groups (38.91 ± 4.97 in group 1 and 38.69 ± 5.21 in group 2) The state anxiety score before US was also similar among the groups (44.81 ± 5.13 in group 1 and 44.91 ± 5.27 in group 2). The state anxiety after US decreased significantly in group 1($p<0.001$).

About 46 % (n=66) of the patients were presented with breast pain. Patients who had mammography the same day and those in menstrual period had significantly higher pain scores before the US procedure (Table 4). The mean intensity of breast pain on VAS scale was 6.02 ± 1.90 before US and 5.62 ± 2.00 after US. Enlightenment related pain reduction after US procedure was statistically significant (p=0.03).

Table 1. Demographic data of study population.

	Group 1 (enlightenment) (n=57)	Group 2 (no enlightenment) (n=86)	p value
Age (years), mean±SD	49.07±13.08	49.91 ± 12.44	0.409*
Marital status			
Married	32	36	0.094Δ
Single	25	50	
Education			0.555Δ
High school or less	23	39	
University or higher	34	47	
Employment	27	36	0.516Δ
Offspring	25	30	0.280Δ
Breastfeeding	24	35	0.867Δ
Personal history of cancer	28	35	0.320Δ
Personal history of breast cancer	18	27	0.982Δ
Breast self-examination	26	35	0.561Δ
Abnormal CBE	19	25	0.589Δ
BI-RADS category			0.548Δ
BI-RADS 3 or less	36	50	
BI-RADS 4 or more	21	36	
Mammography	30	45	0.971Δ
Pain	32	34	0.051Δ
Present menstrual period	19	17	0.067Δ
Use of COCs	19	17	0.067Δ

SD, Standard deviation; CBE, clinical breast examination; BI-RADS, breast imaging and reporting and data system; COCs, combined oral contraceptives.
*Mann-Whitney U test
ΔChi-square test

Table 2. State STAI anxiety scores before breast ultrasound in different subgroups

	Mean state STAI score before US SD (n)		P value
Feature	Yes	No	
University graduate or more	43.98±4.99 (81)	46.03±5.28 (62)	0.020¶
Employment	43.49±4.78 (63)	45.95±5.29 (80)	0.004¶
Offspring	45.75±5.24 (55)	44.32±5.13 (88)	0.113¶
Breastfeeding	44.53±5.05 (59)	45.11±5.32 (84)	0.512¶
Personal history of cancer	43.24±4.95(63)	46.15±5.06 (80)	0.001¶
Personal history of breast cancer	42.87±4.39 (45)	45.79±5.30 (98)	0.002¶
Breast self-examination	45.97±4.70 (61)	44.05±5.43 (82)	0.029¶
Abnormal CBE	46.55±5.07 (44)	44.12±5.11 (99)	0.010¶
Mammography	45.73±5.07 (75)	43.91±5.22 (68)	0.036¶

STAI, state trait anxiety inventory; US, ultrasound; SD, Standard deviation; CBE, clinical breast examination.
¶Independent samples t-test

Table 3. Patient self-reported outcomes.

Outcome	Group 1 (enlightenment) (n=57)	Group 2 (no enlightenment) (n=86)	p value	p value (before and after US)	
				Group 1	Group 2
Anxiety scores (mean±SD)					
Trait STAI	38.91 ± 4.97	38.69 ± 5.21	0.804*		
State STAI (before US)	44.81 ± 5.13	44.91 ± 5.27	0.910¶		
State STAI (after US)	40.33 ± 5.95	45.83 ± 7.97	<0.001*	<0.001$^{\Delta}$	0.162$^{\Delta}$
Reduction in stateSTAI	4.51 ± 4.89	-1.44 ± 4.57	<0.001*		
Pain scores					
VAS (before US)	5.84 ± 2.25	6.18 ± 1.52	0.499*		
VAS (after US)	5.12 ± 2.12	5.09 ± 1.79	0.046*	0.030$^{\Sigma}$	0.669$^{\Sigma}$
Reduction in VAS	0.72 ± 1.57	0.09 ± 1.13	0.075*		

STAI, state trait anxiety inventory; US, ultrasound; SD, Standard deviation.
*Mann-Whitney U test
¶Independent samples t-test
ΔPaired samples t-test
∑Wilcoxon test

Table 4. Pain VAS scores in 66 patients before breast ultrasound in different subgroups

	Mean VAS scores before US SD (n)		P value
Feature	Yes	No	
Breastfeeding	6.00 ± 1.94 (21)	6.02 ± 1.91 (45)	0.939*
Personal history of cancer	6.06 ± 1.95 (32)	5.97 ± 1.89 (34)	0.922*
Personal history of breast cancer	5.73 ± 2.16 (22)	6.16 ± 1.77 (44)	0.424*
Present menstruation	6.53 ± 1.86 (32)	5.53 ± 1.84 (34)	0.041*
Abnormal CBE	5.56 ± 1.94 (18)	6.19 ± 1.88 (48)	0.336*
Mammography	6.35 ± 1.85 (51)	4.87 ± 1.68 (15)	0.009*
Use of COCs	6.13 ± 2.32 (23)	5.95 ± 1.67 (43)	0.791*

VAS, visual analog scale; US, ultrasound; SD, Standard deviation; CBE, clinical breast examination; COCs, combine combined oral contraceptives.
*Mann-Whitney U test

Discussion

Due to longer life expectancy and new diagnostic approaches, breast imaging workups and screening programmes are lately in demand amongst women. On the other hand, fear of breast cancer brings out the increment of anxiety related to the radiological procedure itself and its consequences (9). Our study emphasizes that women having breast US, especially those who were referred for an abnormal physical examination finding, are stressed out more than follow-up patients, either oncological group or patients due to a screening programme. Also, our results encourage the consideration of enlightenment during the US procedure, which reduces anxiety and pain.

It is previously reported that radiological diagnostic procedures induce emotional reactions which may eventually lead to disrupted patient cooperation (10, 11). Also, the quality of imaging is found to be inversely proportional to the degree of anxiety the patient experiences (12). In such a status where the procedure itself is the stressor, the anxiety level would proceed through the sonography session increasingly. Therefore, we hypothesized that the enlightenment of the patient during sonography at a certain necessity level would reduce the imaging related anxiety.

In a study of anxiety investigation among scheduled different radiological examinations, US revealed the highest level of anxiety scores. This finding was related to the quick delivery of the US reports rather than the other imaging modalities, or the fear of necessity for having another advanced type of imaging examination after US (9). In this context, anxiety seen in women awaiting breast US cannot be undervalued and should be supported by health professionals where necessary.

The possibility of having breast cancer eventually is the main stressor factor in women undergoing screening, which means to face big changes in one's life. The reason of anxiety in this population is related to the fear of both having a cancer

diagnosis and being exposed to its consequences considering the treatment. On the other hand, women who already have cancer diagnosis and visit radiology department for an oncological follow-up are reported to show lower anxiety (9). Similarly, our study revealed that women referred to radiology for breast US from clinics with abnormal CBE have higher state anxiety levels and oncological follow-up patients show lower stress levels. We think this is because the clinician's concrete physical finding is a stronger fact than the unknown results of a routine screening for breast cancer or a follow-up. Patients who had mammography before breast US on the same day showed higher levels of state anxiety. We thought that the reason of this induced anxiety was in parallel with the elevated number of examinations taken in a restricted time period, where the imaging workup related stressor factor multiplies. The state anxiety scores were also higher in patients who make breast self-examination. This is probably because the abnormality that the patient realizes on her own leads her to associate this fact with potential breast cancer. The presence of employment and high education level were features with the advantage of lower state anxiety scores. Lo Re et al. reported similar results and suggested that the more knowledge the patient has, the better understanding of the disease and treatment she will have, which would reduce anxiety. We think the employment has a similar effect where the patient would have the comfort of upcoming financial burden related to a possible cancer.

Several studies revealed that the more anxiety the patient has before surgery, the worse prognosis is followed after, including postoperative pain and treatment (9). Therefore, we think that other than the organic etiologies, breast pain could be associated with high levels of anxiety related to the scheduled breast imaging appointment. Health professionals working in radiology departments are not trained for managing screening related patient anxiety. Only MRI procedures, if needed, could be implemented with the scheduled collaboration of anesthesia department in many centers of our country. But most women undergoing breast US experience the stress of taking a diagnostical examination.

There is a variety of relaxation methods used to reduce patient's anxiety throughout a medical intervention. These methods include meditation, hypnosis, music and medication (13-16). The most practical, cheapest and noninvasive method among these supporting implementations is music. We tried to develop an alternative feasible method to music with this study. Unlike cross-sectional imaging modalities and X-rays, breast ultrasound is a workup of a kind, where the radiologist is present at the time of the procedure and is able to evaluate the severity of the case. Speaking for breast imaging, it is important to evaluate the patient as a whole, where other modalities, if necessary, should also be analyzed and concluded to the final decision. But in many patients that take a breast US, it is possible to speak of discrimination between BI-RADS 3 and BI-RADS 4, viva voce. We realized that informing the patient under this context brings out a relief, and we tried to support our hypothesis by measuring the anxiety levels before and after breast US in informed and control groups.

The development of breast cancer in patients with mastodynia is reported as a very small possibility (17). Several studies confirmed this finding with an estimated rate of 1.2-6.7%. Zarei et al. reported in their study that patients revealed less breast pain after even only implementing breast sonography. However, the population of this study was restricted to the cases who had only breast pain as a symptom, but also had normal CBE. They also commented that their study population included both menstrual cyclic and noncyclic pain (18). Our study comprises a larger range of population and we analyzed the impact of informing the patients during the sonography procedure, for both pain and anxiety related to the imaging. We think that the significantly reduced pain levels would not be the result of enlightenment effect only, but also could originate from the diversity of our study group. Some of our patients scheduled for breast US had a mammography session just before the US procedure. Therefore, mammography related mastodynia was not ruled out in this inhomogeneious study group, and this might have affected the overall pain experienced. Similarly, cyclic and noncyclic pain was not studied separately. The pain reduction could be the consequence of both the relief related to US implementation itself or enlightenment.

We had several limitations in this study. First, there was an inhomogeneious group of patients evaluated for breast pain. Patients both with various breast symptoms and normal CBE findings were included. Also, some patients were referred to mammography before the US procedure. These facts could be optimized with a larger study group, working on each subgroup seperately. Second, in our country the US procedures are all performed by the radiologists in person. However, in different countries, the sonographers are responsible for this task and it is impossible for such centers to inform the patient throughout a breast US procedure.

Conclusion

In conclusion, informing the patient throughout a breast US examination reduces the anxiety levels and pain. This

enlightenment makes a probable relief concerning the imaging workup related anxiety itself which also has an effect on pain perception.

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