The Effects of Interactive Briefing Methods for Breast Biopsy on Patients' Anxiety Level

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Abstract

Objective: To assess the effects of different patient briefing methods on patients' anxiety levels and the efficiency of demonstration of the breast biopsy procedure using video animations and experienced patient interviews and to evaluate their potential applicability in clinical practice.

Methods: In total, 156 patients were randomized into 4 groups based on the type of patient briefing method used: group 1(n = 37), patients with standard informed consent form; group 2(n = 42), patients with a standard informed consent form and a video depicting breast biopsy procedure; group 3(n = 32), patients with a standard informed consent form and video depicting breast biopsy procedure and interview; and group 4(n = 45), patients with standard informed consent form and interview. Patients in all 4 groups filled the State-Trait Anxiety Inventory forms both pre and post-preatively. State-Trait Anxiety Inventory scores both pre and post-interventionally have been compared between these groups.

Results: In each group and for all patient populations, the anxiety level significantly decreased in post-procedural state compared to pre-procedural state. (P < .001). There was no significant different in anxiety levels between groups in pre-procedural state (P = .551), post-procedural state (P = .47), and general state (P = .869). When the change in anxiety level in pre and post-procedural state are assessed, no difference among groups was found (P = .384)

Conclusion: Despite finding no difference in anxiety reduction level between different briefing methods like written informed consent, video, and interviews, we have received positive feedback from patients. We have shown the clinical utility of video briefing and interview, which are relatively new methods that increased patient cooperation.

Keywords: Anxiety, breast biopsy, interview, video

Biopsy and other interventional procedures, whether performed in inpatient or outpatient clinics, are an important cause of fear and anxiety for patients, which affect disease management. Fear of histopathological diagnosis of cancer risk or the procedure itself can be the source of anxiety. In daily clinical practice, this fear and anxiety might be overlooked by the caring physician. Beyond the mandatory informed consent procedure, reducing patient anxiety would ameliorate the potential psychological trauma, prevent drawbacks, and lessen the procedure difficulty for both the patient and physician. It has been shown previously that patient education on the procedure helps to decrease or alleviate patient anxiety. Discussing the indications for the procedure and how the procedure will be performed resolves the uncertainty for the patient and helps the patient mentally to cope with the procedure. Additional discussion of post-procedural course and recommendation is also helpful to alleviate

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patient anxiety. Studies had shown that pre-operative patient education is helpful to decrease post-procedural pain level also.²

Informed consent is an important and mandatory component of current clinical practice. Different patient education/briefing methods are available. The most commonly used form is traditional briefing method, which includes discussion of the procedure, indication, complication risks, benefits of alternative methods with the patient, and obtaining a written informed consent form signed by the patient.³ However, the efficiency of this method is questionable due to the content of the discussion and patient's comprehension capability.⁴⁻⁶ Therefore, written informed consents have been started to be used in 1970's, and additional use of videos and computers for patient briefing has been started in 1980's and 1990's, respectively.⁷

In this study, we aimed to assess the effects of different patient briefing methods on patients' anxiety levels. Additionally, we assessed the efficiency of the demonstration procedure by using video animations and experienced patient interviews and aimed to evaluate their potential applicability in daily clinical practice. We hypothesized that the video briefing and interview, which are relatively new methods, could reduce patients' anxiety levels during the procedure of the breast biopsy.

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Methods

Study design and participants

This prospective study is performed in the department of radiology, Deparment of Radiology, Cerrahpasa Faculty of Medicine, Istanbul University, after the approval of institutional review board (Date: March 18, 2015. Code: 83045809/604.01/02). In total, 196 patients were referred for a suspected malignant breast mass, and 190 patients of them were decided to have biopsy for Breast Imaging Reporting and Data Systems (BIRADS) IV and V lesions. Two patients refused to participate in the study. They preferred a different center for the biopsy. Other 8 patients who failed or refused to cooperate patients with a medical history of psychiatric diseases, patients with limited Turkish lingual skills, and patients with limited visual or hearing capacities were excluded from the study. In this study, 180 patients agreed to participate. Initially, all participants were distributed with 45 patients in each group. However, 24 patients were excluded from the study due to incompletely filled forms. Hereby, 156 patients were randomized into 4 groups (n = 37, n = 42, n = 32, and n = 45, respectively). Core biopsy was applied to all patients as a biopsy method. After the breast biopsy, 1 patient from group 1 and 2 patients from group 2 did not want to fill out the form about post-procedural anxiety level.

Procedure and measures

The State-Trait Anxiety Inventory (STAI) is a psychological inventory, which was developed by Spielberger, based on a 4-point Likert scale and consists of 40 questions on a self-report basis.8 It clearly differentiates between the temporary condition of "state anxiety" (S-anxiety) and the more general and long-standing quality of "trait anxiety" (T-anxiety). Each type of anxiety has its own scale of 20 different questions that are scored.9 Scores range from 20 to 80, with higher scores correlating with greater anxiety. Each measure has a different rating scale. The 4-point scale for S-anxiety is as follows: (1) not at all, (2) somewhat, (3) moderately so, and (4) very much so. The 4-point scale for T-anxiety is as follows: (1) almost never, (2) sometimes, (3) often, and (4) almost always.¹⁰ The internal consistency alpha coefficients of the state portion range from 0.86 to 0.92. It is simple to use, generally taking <5 minutes to complete, and easy to score. 11,12 The STAI was adapted to the Turkish population by LeCompte et al in 1976 and confirmed for reliability and validity by Oner in 1977.13

On the day of biopsy, prior to the procedure, the State-Trait Anxiety Inventory (STAI) 1 and 2 was used to assess the pre-procedural basal anxiety level and general anxiety level, respectively. Patients' concerns about the procedure were discussed. In the post-procedural state approximately 30 minutes after biopsy procedure,

STAI 1 was used to assess anxiety level. Patients who participated in the study were selected by using the sealed envelope randomization method. Patients were randomized into 4 groups based on the type of patient briefing method used: group 1, patients with standard informed consent form; group 2, patients with a standard informed consent form and a video depicting breast biopsy procedure; group 3, patients with standard informed consent form and video depicting breast biopsy procedure and interview; and group 4, patients with a standard informed consent form and interview. The video that we used in our study was a schematic video depicting breast biopsy. In the interview method, we performed a question-and-answer conversation (including how the biopsy procedure was, whether they have done research on the procedure before and whether it was as difficult as they were worried) with 2 patients who underwent breast biopsy in our clinic. The schematic video and interview were shown to group 2, group 3, and group 4 while they were waiting before the biopsy procedure in the waiting room. Patients in all 4 groups filled the STAI forms both pre and postoperatively. Patients' anxiety about the biopsy has been assessed. The need for sedation or analgesia was recorded. Subsequently, STAI scores both pre and post-interventionally have been compared between these 4 groups.

Statiscal analysis

Statistical Package for the Social Sciences version 22.0 (IBM SPSS Corp.; Armonk, NY, USA) was used for statistical analysis. Normal distribution of data was assessed with Kolmogorov–Smirnov and Shapiro–Wilk tests. Data were presented as mean, standard deviation, median, frequency, and ratio. Analysis of variance test was used for the comparison of continuous variables and paired sample t-test was used for related groups. Pearson chi-square and Fisher's exact test were used for categorical variables. Correlation between variables was assessed with Pearson correlation test. P < .05 was considered as statistically significant.

Results

Mean age of all patients was 42.7 ± 13.3 . Mean age of patients were 46.3 ± 12.6 , 42.3 ± 12.7 , 43 ± 13.2 , and 39.3 ± 14.2 for groups 1, 2, 3, and 4, respectively (Table 1). Median age of all patients was 44. There was no statistically significant different between mean ages among groups (P = .119, P > .05). Occupation of patients included housewife (n = 78 (50.0%)), retirement (n = 21 (13.4%)), clerkship (15 (9.6%)), freelancer (15 (9.6%)), student (14 (9.0%)), and laborer (13 (8.3%)) (Table 2).

In each group and for all patient population, the anxiety level significantly decreased in post-procedural state compared to pre-procedural state (P < .001) (Table 3). There was no significant difference

Table 1. Demographic Data								
		Age						
	N	Mean	95% CI	Minimum	Maximum	P		
Group 1	37	46.3 ± 12.6	(42-50)	22.00	71.00	.119ª		
Group 2	42	42.3 ± 12.7	(38-46)	19.00	66.00			
Group 3	32	43 ± 13.2	(39-48)	18.00	70.00			
Group 4	45	39.3 ± 14.2	(35-43)	18.00	89.00			
Total	156	42.7 ± 13.3	(40-44)	18.00	89.00			
^a Paired samples	test.							

	Group 1 (%)	Group 2 (%)	Group 3 (%)	Group 4 (%)	Total (%)	P
Job						
Housewife	18 (48.7)	21 (50.0)	15 (46.9)	24 (53.3)	78 (50.0)	N/A
Officer	8 (21.6)	3 (7.1)	1 (3.1)	3 (6.7)	15 (9.6)	
Employee	3 (8.1)	5 (11.9)	2 (6.2)	3 (6.7)	13 (8.3)	
Student	2 (5.4)	3 (7.1)	3 (9.4)	6 (13.3)	14 (9.0)	
Retired	5 (13.5)	5 (11.9)	9 (28.1)	2 (4.4)	21 (13.4)	
Self-employment	1 (2.7)	5 (11.9)	2 (6.2)	7 (15.6)	15 (9.6)	
Total	37 (100.0)	42 (100.0)	32 (100.0)	45 (100.0)	156 (100.0)	

in anxiety levels between groups in pre-procedural state (P = .551), post-procedural state (P = .47), and general state (P = .869). When the change in anxiety level in pre and post-procedural state are assessed, no difference among groups was found (P = .384).

There was a significantly positive correlation of pre-procedural anxiety level to post-procedural anxiety level (r = 0.41) and general anxiety level (r = 0.29). No significant correlation between age and post-procedural anxiety level was found (P > .05). Detailed information on pre-procedural, post-procedural, and general anxiety levels are presented in Table 4.

Discussion

Anxiety prior to a medical or surgical procedure can lead to a potential negative outcome. It has been shown that preoperative anxiety affects patient satisfaction level and may prolong the post-operative inpatient stay.¹⁴ Additionally, anxiety is used as a quality indicator.¹⁵ For these reasons, more research has been started to be performed on patient anxiety alleviation.

Breast cancer is the most common malignancy in women worldwide, and it impacts psychological and physical health.¹⁶ Breast cancer diagnosis creates psychological distress,¹⁷ with anxiety and depression being common demonstrations.¹⁸ Anxiety related to breast biopsy has been thought as potential damage of screening mammography in the literature.¹⁹ It may be associated with uncertainty about the biopsy procedure and potential adverse consequences of the biopsy.^{20,21} Biopsy procedures cause intense anxiety in patients due to both the fear of cancer diagnosis and procedure-related pain.^{20,21} Hereby, interventions that could decrease anxiety before

 Table 3. Pre and Post-Procedural Anxiety Levels

		Pre-Procedural Anxiety Level	Post-Procedural Anxiety Level	
	n	Mean ± SD	Mean ± SD	P
Group 1	35	47.5 ± 9.8	40.3 ± 9.3	.000ª
Group 2	38	43.5 ± 10.9	38.9 ± 10.3	.033ª
Group 3	32	44.4 ± 8	38.3 ± 8.3	.000a
Group 4	45	45.1 ± 10.4	41.2 ± 8.9	.011ª
Total	150	45.1 ± 10	39.8 ± 9.2	$.000^{a}$

^aPaired samples test.

SD, standard deviation.

and during the breast biopsy procedure have become very significant. Moreover, in the literature, there are several studies that aim to evaluate the effects of music on alleviating the anxiety of the patients caused by breast biopsy.^{19,22-24} Especially, the study of Akin²⁴ showed that music intervention was easy to apply for low and middle-income countries and can be proposed as an efficient method for reducing patient anxiety before and during a breast biopsy procedure.

Patient briefing is the fundamental component to minimize patient anxiety prior to a medical or surgical procedure. Irrespective of the briefing method used, the most important component is conveying

Table 4. Detailed Information on Pre-procedural, Post-procedural, and General Anxiety Levels

	n	Mean ± SD	95% CI	Min-Max		
Pre-procedural anxiety levels						
Group 1	37	46.8 ± 10	43.5-50	28-72		
Group 2	42	43.6 ± 11	40.1-47	20-66		
Group 3	32	44.4 ± 8	41.6-47.3	24-58		
Group 4	45	45.1 ± 10.4	42-48.3	27-66		
Total	156	45 ± 10	43.4-46.6	20-72		
Post-procedural anxiety levels						
Group 1	35	40.3 ± 9.3	37.1-43.5	24-68		
Group 2	39	38.8 ± 10.3	35.4-42.1	20-61		
Group 3	32	38.3 ± 8.3	35.3-41.3	24-53		
Group 4	45	41.2 ± 8.9	38.6-43.9	21-58		
Total	151	39.8 ± 9.2	38.3-41.2	20-68		
General anxiety levels						
Group 1	37	44.3 ± 8.4	41.6-47.2	28-72		
Group 2	42	43.9 ± 7.3	41.6-46.1	24-61		
Group 3	32	45.4 ± 7.8	42.6-48.2	32-62		
Group 4	45	44.8 ± 8.2	42.3-47.2	24-61		
Total	156	44.6 ± 7.9	43.3-45.8	24-72		
SD, standard deviation.						

the information at an appropriate level to the patient's perception in a time-efficient fashion without increasing patient anxiety.²⁵ There are studies reporting the discussion of potential risks and complications that may lead to increased patient anxiety.²⁶ However, there are other studies refuting this notion. Wallace et al²⁷ reported that patients with more knowledge about surgery have fewer apprehensions and they recover faster. Elsass et al²⁸ showed that patients who were given detailed information about their sedation procedure were less anxious. High situational stress has also been shown to decrease working memory capability, thereby intertwining knowledge and anxiety further.²⁹

Knowledge and anxiety levels differ among societies and among different locations. Additionally, personal factors like education level, sex, and age can lead to variability. Majority of studies have shown higher anxiety levels in females compared to males.³⁰⁻³² Badner et al¹⁴ attributed this difference to family separation anxiety, whereas Shevde and Panagopoulos²⁴ and Domar et al³² linked this difference to easier expression of anxiety for females compared to males. Some studies reported increased anxiety level with higher education levels, whereas other studies showed no correlation between education degree and anxiety level.^{32,33}

In comparison to the conventional oral briefing, studies on informed consent and video informed consent are limited. Studies on written informed consent have variable results stating that this method can be either used as the optimal or alternative method. Italian et al showed that patient briefing by video decreased patient anxiety levels. Limited number of studies had compared these 3 methods in terms of patient's comprehension, anxiety, and satisfaction. In this study, we have used the video interview method in addition to these 3 methods.

Mason et al³⁷ previously indicated that video informed consent in addition to traditional oral consent did not significantly decrease patient anxiety levels compared with solely an oral format. The same way, Agre et al³⁸ compared video consent alone, video plus oral discussion, and discussion alone in patients before colonoscopy and represented no significant differences in patient anxiety. Herrmann et al³⁹ contrarily demonstrated a reduction in anxiety with the use of video. But, their study compared a written plus oral format against a written plus oral plus video format. Astley et al³⁶ compared anxiety levels after informed consent by written, oral, or video methods. They used a 5-point Likert scale and they found no differences in anxiety levels among the 3 methods. Goldberger et al³ indicated the dominance of data demonstrates that oral, written, and video informed consent formats show no significant differences in respect to patient anxiety levels.³

In our study, each group showed a significant reduction in anxiety level in the post-procedural state. However, no significant difference was detected between groups in pre-procedural, post-procedural, and general anxiety levels. This may be due to the traditional and demographic differences of the Turkish population. Patients may also be anxious about whether they will develop cancer, which may have affected our results. In each group, the possibility of cancer is a situation that causes more anxiety rather than the intervention and the excitement of the procedure. That is why we could not detect the difference between the groups. Also, we demonstrated that oral, written, and video, and interviewing informed consent formats show no significant differences with respect to patient anxiety levels and, therefore, be considered equivalent in this regard. In addition, it can be thought that learning by experience is more important than visual or auditory methods. There was a positive correlation between post-procedural anxiety level and pre-procedural anxiety level and general anxiety level.

There are several limitations in our study. This study includes small number of patients. The education level and comprehension of patients were not evaluated in detail. Hence, it was not questioned whether the patients had researched about the biopsy procedure before and whether they had knowledge or not.

Patient anxiety has important effects in daily clinical practice on diagnostic and therapeutic stages. For this reason, studies investigating how to minimize patient anxiety gained pace. In this study, despite finding no difference in anxiety reduction level between different briefing methods like written informed consent, video, and interviews, we have received positive feedback from patients. Additionally, we have shown the clinical utility of video briefing and interview, which are relatively new methods that increased patient cooperation.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of İstanbul University-Cerrahpaşa (Date: March 18, 2015, No: 83045809/604.01/02).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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