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Evaluation of The Effect of Pre-Operative Informed Consent Form On Pre-Operative Anxiety

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ABSTRACT

Objective: This study aimed to evaluate the effect of a detailed pre-operative informed consent form on pre-operative anxiety.

Methods: The research was designed as a quasi-experimental study. The participants were 66 patients, aged 18-70, who were randomly selected based on their order of registration from those admitted to the General Surgery Service of Atatürk University Faculty of Medicine between March and June 2013. The same method was applied to patients staying in the same room: odd-numbered room numbers were assigned to Group 1, and even-numbered room numbers to Group 2. The standard informed consent form was read to Group 1 using a face-to-face interview technique, while the Beck Anxiety Scale was applied to Group 2 after they received a detailed informed consent form that included photographs of the surgical technique, procedures, and potential complications. Statistical significance was determined with Student's t-test, Mann-Whitney U test, and Pearson's chi-square test.

Results: The mean age of participants was 45.5±14.66 years, with 31 (47%) female and 35 (53%) male participants. It was found that 31.8% of the participants did not experience anxiety (n=24), 36.4% had mild anxiety (n=13), 19.7% had moderate anxiety (n=8), and 12.1% had severe anxiety. In Group 1, 15.2% (n=5) did not have anxiety, 36.4% (n=12) had mild anxiety, 36.4% (n=12) had moderate anxiety, and 12.1% (n=4) had severe anxiety. In Group 2, 48.5% (n=16) did not have anxiety, 36.4% (n=12) had mild anxiety, 3% (n=1) had moderate anxiety, and 12.1% (n=4) had severe anxiety. The difference between the two groups regarding the presence of anxiety was statistically significant (*P* = .04). Group 2 showed a lower anxiety level compared to Group 1. Furthermore, a positive correlation was found between lower education levels, presence of chronic disease, smoking, and higher anxiety levels.

Conclusion: The study results emphasize that providing a detailed informed consent form, which includes images of the surgical procedure, significantly reduced pre-operative anxiety levels in patients. Moreover, factors such as male gender, marital status, smoking, and the presence of chronic diseases were associated with higher anxiety levels prior to surgery.

Keywords: Anxiety, informed consent, surgery

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INTRODUCTION

Informed consent is a collaboration process between physicians and patients to reach a mutual treatment decision. By obtaining this consent, not only does the physician protect himself from situations that could be considered fault before the law, but it also increases the success of the treatment while improving patient compliance. Informed consent is one of the leading requirements of good medical practice. Within the context of good medical practices, it is important and necessary for the physician to involve the patient in decisions about treatment and to mobilize for the implementation of individual health-related decisions. The information to be provided for this purpose must be clear and understandable.[1]

The consent of individuals is obtained through informed consent after they are informed. Informed consent has broader meaning than information does and means that the patient authorizes the physician to intervene in his/her own body.[2]

While the patient's consent is obtained, before any medical intervention, verbal information is given to the patient in accordance with the patient's culture and education level on issues such as possible causes, complications, course and treatment stages of the current disease, and whether the information is understandable is checked.[3]

In China, the content and implementation methods of informed consent are regulated by national legislation and international agreements. Patient rights, which are guaranteed by the declarations of Lisbon and Amsterdam, the Council of Europe Convention on Human Rights and Biomedicine and the European Convention on Patient Rights, are also protected by national legislation.[4]

Through informed consent, the patient is given the right to know in detail any intervention that will be performed on his or her body and to delegate the necessary authority to the physician to intervene in his or her body. It is a legal obligation to obtain informed consent from patients before medical intervention. In addition, the Turkish Medical Association also has decisions regarding the necessity of obtaining informed consent. In accordance with the Turkish Medical Association Disciplinary Regulation and Turkish Medical Association Medical Professional Ethics Rules, informed consent must be obtained before any medical intervention can be performed on the patient's body.[5]

Completing the informed consent form not only strengthens patient–physician communication in the joint decision-making process but also reduces fears and anxiety by informing the patient. In addition, it is highly important for physicians, and in this way, the physician can protect himself against situations that may occur during and after the medical intervention he provides to the patient should inform the patient accordingly. Therefore, what is required in an ideal informed consent form will include the correct description of the procedure or treatment to be applied to the patient, the risks that may occur and the benefits to the patient after the procedure, the probability of the benefit he or she will receive, its benefits, possible positive or negative consequences that may occur if the procedure or treatment is not performed, alternative methods to the current procedure and the risks of these methods.

This study was planned because there are not enough studies in the national and international literature on the effects of informed consent, including visual information on patient anxiety. This study aimed to evaluate the effect of a preoperative informed consent form on preoperative anxiety levels.

METHODS

The Atatürk University nonpharmaceutical clinical research ethics committee received approval from the decision number B.30.2.ATA.0.01.00/64, and the study was conducted in accordance with the principles of the Declaration of Helsinki. Informed consent was obtained from the participants.

This study was planned as quasiexperimental research. The participants were 66 people between the ages of 18 and 70 years who were randomly selected according to the order of registration among the patients who were admitted to the General Surgery Service of Atatürk University Faculty of Medicine between March and June 2013. The same method was applied to patients staying in the same room; odd-numbered room numbers were considered group 1, and even-numbered room numbers were considered group 2.

The Atatürk University nonpharmaceutical clinical research ethics committee received approval from the decision number B.30.2.ATA.0.01.00/64, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

The informed consent form was read to group 1 via face–to–face interviews. Before the informed consent form was read, group 2 consisted of photographs showing the surgical technique, its application and possible complications, and the Beck Anxiety Scale was subsequently applied to both groups.

When the Beck Anxiety Scale was evaluated, 0–8 points indicated no anxiety, 8–15 points indicated mild anxiety, 16–25 points indicated moderate anxiety, and 26–63 points indicated severe anxiety. The population of the study consisted of 66 volunteer patients who were hospitalized for surgery at the General Surgery Service for four months.

The criteria for inclusion in the study were to be hospitalized for surgery at the General Surgery Service of Atatürk University Faculty of Medicine, to be between the ages of 18–70, and to be a volunteer. The exclusion criteria were the presence of coronary artery disease (CAD); the presence of respiratory disease, such as asthma and *chronic obstructive pulmonary disease (*COPD*)*; the

presence of acute cerebrovascular accident (CVA); the presence of nervous system diseases that affect mental status; the presence of a disease caused by exposure to hypoxia; the presence of a psychiatric disease; the presence of hemiplegia and hemiparesis in the upper extremities; the presence of aphasia; the presence of vision and hearing problems during the postoperative period; and the use of sedative, anticholinergic, sedative-acting anticonvulsant, tricyclic antidepressant, antipsychotic, or narcotic analgesic medication.

Independent variables examined in the evaluation of groups obtained via systematic sampling. While the Beck Anxiety Scale score was the main outcome measure, anxiety levels were determined according to the sociodemographic characteristics of the participants in the 1st and 2nd groups.

The data obtained were analyzed with SPSS Statistics 26 (IBM SPSS Corp., Armonk, NY, USA). The number and percentage were used as descriptive statistics; the arithmetic mean and standard deviation were used. Student's t test, the Mann–Whitney U test, the Pearson chi-square test, and the Fisher–Freeman–Halton exact test were performed to determine the level of statistical significance, and the significance value was accepted as P <.05.

RESULTS

In our study, while our mean age was 45.5 ± 14.66 years, 31 (47%) female participants and 35 (53%) male participants were included. A total of 13.6% (n=9) of the participants were single, 86.4% (n=57) were married, 16.7% (n=11) had no children, and 83.3% (n=55) had children. A total of 66.7% (n=44) of the participants smoked, 33.3% (n=22) did not smoke, 7.6% (n=5) used alcohol, and 92.4% (n=61) did not use alcohol. While (n=24) 36.4% of the participants had a chronic disease, (n=42) 63.6% did not have a chronic disease. A total of 28.8% (n=19) of the participants used medication regularly, and 71.2% (n=47) did not use medication regularly.

The mean age of group 1 was 44.5±15.3 years, and for group 1, 42.4% (n= 14) of the participants were women, 57.6% (n=19) were men, 15.2% (n=5) were single, 84.8% (n=28) were married, 78.8% (n=21) smoked, 3% (n=19) drank alcohol, 39.4% (n=13) had a chronic disease, and 33.3% (n=11) used medication regularly. A total of 54.5% (n=18) of the participants in group 1 were primary school graduates. Three percent master's degrees were detected. Comparisons of the group features are presented in Table 2. There was no significant difference in the health history or sociodemographic characteristics of the participants in either group, and the distribution within the groups was homogeneous. (Table 1 and Table 2)

Table 1. Characteristics of the participants

		Group 1 n (%)	Group 2 n(%)	*P*
Alcohol	Yes	1 (3)	4 (12.1)	
	No	32 (97)	29 (87.9)	>.05
Smoking	Yes	21 (63.6)	23 (69.7)	
	No	12 (36.4)	10 (30.3)	>.05
Chronic disease	Yes	13 (39.4)	11 (33.3)	
	No	20 (60.6)	22 (66.7)	>.05
Drug use	Yes	11 (33.3)	8 (24.2)	
	No	22 (66.7)	25 (75.8)	>.05

The data are presented as frequencies (%). Pearson chi-square test, Fisher-Freeman-Halton exact test (P<.05)

Table 2. Sociodemographic characteristics of the participants

Marital status	Group 1 n (%)	Group 2 n (%)	*P*
Married	28 (84.8)	29 (87.9)	>.05
Single	5 (15.2.)	4 (12.1)	>.05
Children			>.05
Presence	26 (78.8)	29 (87.9)	>.05
Absence	7 (21.2)	4 (12.1)	>.05
Education level			>.05
Illiterate	1 (3)	5 (15.2)	>.05
Primary school	18 (54.5)	14 (42.4)	>.05
High school	10 (30.3)	7 (21.2)	>.05
University	3 (9.1)	7 (21.2)	>.05
Master's degree	1 (3)		>.05

The data are presented as frequencies (%). Pearson chi-square test, Fisher-Freeman-Halton exact test (P<0.05)

The number of participants who did not have anxiety in group 1 was n=5 (15.2%), and the number of participants who did not have anxiety level in group 2 was n=16 (48.5%) (Table 3). The difference observed between the groups in terms of the presence of anxiety was significant (P = .04).

Table 3. Anxiety levels of the groups

Anxiety levels	group 1 n (%)	group 2 n (%)	*P*
Absent	5 (15.2)	16 (48.5).	*.04*
Mild	12 (36.4)	12 (36.4)	>.05
Moderate	12 (36.4)	1 (3)	>.05
Severe	4 (12.1)	4 (12.1)	>.05
Total	33 (100)	33 (100)	

The data are presented as frequencies (%). Pearson chi-square test, Fisher-Freeman-Halton exact test (P<.05)

When the factors affecting anxiety level were evaluated, there was a significant difference in the anxiety level of the participants with chronic diseases according to education level in Group 1 (P = .02, Table 4).

Table 4. Anxiety Levels of Participants with Chronic Diseases According to Education Level

		Group1	Group 2	*P*
Primary school	Absent	1 (7.7)	2 (18.2)	
	Mild	4 (30.8)	3 (27.3)	*.02*
	Moderate	4 (30.8)	00	
	Severe	2 (15.4)	00	
High school	Absent	1 (7.7)	1 (9.1)	
	Mild	00	00	
	Moderate	00	00	>.05
	Severe	00	2 (18.2)	
University	Absent	00	1 (9.1)	
	Mild	00	1 (9.1)	
	Moderate	00	00	>.05
	Severe	00	1 (9.1)	
Master's degree	Absent	00	00	
	Mild	00	00	>.05
	Moderate	1 (7.7)	00	
	Severe	00	00	
Total		13 (100)	11 (100)	

The data are presented as frequencies (%). Pearson chi-square test, Fisher-Freeman-Halton exact test (p<0.05)

All of the participants with chronic disease and severe anxiety levels in group 1 and 80% of the participants with moderate anxiety levels were primary school graduates (Table 4).

In group 1, the difference in anxiety level according to sex was not significant (*P*>0.05). However, while the proportion of male participants with moderate anxiety among all male participants was 42.1%, the proportion of female participants with moderate anxiety in the same group was 28.6% among all female participants. In group 1, the percentage of male participants without anxiety was 21.1%, and the percentage of female participants was 7.1%. In the same group, the percentage of male participants with severe anxiety was 5.3%, and the percentage of female participants was 21.4%. In Group 1, the differences in the presence of chronic disease, marital status and anxiety level were significant (*P* = .04, Table 5).

Table 5. Anxiety Levels of Participants with Chronic Diseases According to Marital Status

		Group 1	Group 2	*P*
		n (%)	n (%)	
Married	Absent	2 (15.4)	3 (27.3)	
	Mild	4 (30.8)	3 (27.3)	*0.04*
	Moderate	5 (38.5)	0	
	Severe	2 (15.4)	1 (9.1.)	
Single	Absent	00	1 (9.1)	
	Mild	00	1 (9.1)	0.05
	Moderate	00	00	
	Severe	00	2 (18.2)	
Total		13 (100)	11 (100)	

The data are presented as frequencies (%). Pearson chi-square test, Fisher-Freeman-Halton exact test (P<0.05)

All of those with chronic diseases and moderate to severe anxiety were married, and 85.7% of those who were married were men.

When the factors affecting anxiety level were evaluated in the second group, there was no significant difference between the sexes, but the rate of moderate and severe anxiety in men was 60%, whereas this rate was 40% in women.

When the relationship between smoking and anxiety was evaluated, there were no participants with moderate or severe anxiety among nonsmokers. In the second group, the difference between the presence and levels of anxiety and education levels was not significant, but when all education levels were evaluated, the rate of severe anxiety in high school graduates was 50%. When those with severe anxiety were evaluated in the second group, the percentage of those with chronic diseases was 75%, whereas 60% of the participants with severe anxiety in the same group were married.

DISCUSSION

In our study, the percentage of participants who did not have anxiety or minimal anxiety among the participants who signed a detailed informed consent form was higher than the percentage who did not have anxiety among the participants who signed a standard informed consent form. The rates of moderate and severe anxiety in group 2 were lower than those in group 1. In contrast, Erten et al. reported that excessive information could cause stress and increase the level of anxiety. Additionally, in Kiriş S.'s study, detailed informed consent forms increased the anxiety levels of patients.[6] Similar to our study, in a study conducted by Demir et al., anxiety levels decreased with increasing preoperative information. In Beder's study, when adequate and clear information was given with informed consent, the patients' anxiety scores decreased significantly.

In the study conducted by Şavk et al., a positive relationship was found between the perception of the disease and the level of preoperative anxiety, and as the perception of the disease increased, the level of anxiety also increased. In line with the literature, it was determined that preoperative information reduces the level of anxiety.[7]

According to the literature, providing clear answers to patients' questions and providing clear, reliable, necessary and sufficient information to patients who are given by taking enough time without being bogged down in detail has positive effects on preoperative patients, and even displaying this information and presenting it to patients in concrete form leads to a decrease in anxiety levels.

When the difference between anxiety levels in our study was examined, it was determined that the anxiety level of the participants who signed a standard informed consent increased with the presence of a chronic disease and that the patients with high anxiety levels had low education levels and were also married. When the majority of the participants in this group were male, the percentage of male participants was higher than the percentage of female participants. There was no significant difference between the anxiety level and gender of the participants who signed a detailed informed consent form, but the rates of moderate and severe anxiety were higher in men than in women. In this group, there were no smokers among the participants who did not have severe anxiety. In this group, 75% of those with severe anxiety had a chronic disease, and 60% of these participants were married. Similar to our study, Altınbaş et al. reported that the rate of preoperative anxiety was high in married participants. In studies conducted by Dursun A. and Arslan et al., male participants had greater preoperative anxiety. In a study conducted by Gok et al., the presence of a chronic disease caused an increase in anxiety levels.[8]

In our study, no significant relationship was found between marital status and preoperative anxiety, but anxiety scores in single and female patients were lower than those in married and male patients. Women may have low anxiety scores because they have had experiences such as birth and cesarean section, and married people have high anxiety scores because of their responsibilities for their spouses and children.

In the present study, the relationship between education level and the presence of anxiety was not significant. In a study conducted by Demir et al., high levels of anxiety were found in patients with low education levels.[9]

Considering the anxiety-inducing effect of a lack of information and uncertainty in patients, it seems that high anxiety in patients with low education levels is a natural result. To prevent this barrier, educating and informing the patient before the surgery, with realistic information about the procedure and after the procedure, can strengthen the patient's ability to cope with anxiety and can be an important step for postoperative success. The limitation of this study is that incomplete information on chronic disease type was provided by patients, and the type of chronic disease information could not be determined.

CONCLUSION

In this study, it was determined that obtaining informed consent from preoperative patients with a consent form containing images of the procedure to be performed reduces the anxiety level of surgical patients in general. The creation of visual and auditory consent forms may be planned on the basis of the results of studies with larger patient groups.

Ethics Committee Approval: The Atatürk University nonpharmaceutical clinical research ethics committee received approval from the decision number B.30.2.ATA.0.01.00/64, and the study was conducted in accordance with the principles of the Declaration of Helsinki.
Informed Consent: Informed consent was obtained from the participants.
Peer-review: Externally peer-reviewed.
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