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Original Research Article

Determination of Anxiety Levels and Factors Affecting Anxiety in Patients Undergoing Transcatheter Aortic Valve Implantation

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Abstract

Background/aim: Transcatheter Aortic Valve Implantation (TAVI) is an alternative treatment for patients with severe aortic stenosis who are considered high-risk for surgery. Determine the anxiety levels of patients, who will undergo TAVI surgery, and factors affecting anxiety in the pre- and postoperative period. ***Materials and methods:*** This cross-sectional study was conducted in Sifa hospital in Izmir, Turkey between September 2014 and June 2015. Data were collected in the cardiology outpatient clinic for preoperative data, and in the coronary intensive care unit and cardiology outpatient clinic for postoperative data. The data were collected by interviewing patients who presented with aortic stenosis or aortic insufficiency and underwent TAVI surgery. Stress status of the patients before and after TAVI was measured with the State-Trait Anxiety Inventory (STAI). ***Results:*** The mean age of 34 patients participating in the study was 78.21(±6.67), and 61.8 % of the patients were women. The mean state anxiety scores of all patients were 45.5(±12.1) before the surgery, 36.4(±10.6) after the surgery. The anxiety experienced before the operation was moderate to high; and after the operation was lower. ***Conclusion:*** The patients were experiencing moderate to high and levels of anxiety. The factors affecting the state anxiety scores in the preoperative period were the age of the patient and the presence of chronic diseases. The factors affecting the stress of the patients in the pre- and post-TAVI period were subjective fear felt due to the stressful situation in the preoperative period were found to be age and the presence of chronic disease.

Keywords: TAVI, Aortic Stenosis, Anxiety Level, Risk Factors.

INTRODUCTION

Cardiovascular diseases are responsible for 3.9 million deaths in Europe and 1.8 million deaths in European Union countries each year [1,2]. At least 50% of these present with severe aortic stenosis in the symptomatic stage; requiring either surgical aortic valve replacement or TAVI [3,4]. The TAVI method is becoming more common since it is less invasive and less risky, and has a lower risk of post-procedure infection, provides rapid recovery, and is performed without open heart surgery [5,6]. Symptomatic heart diseases accelerates the onset of depressive symptoms and anxiety [7-10]. The literature on depression and anxiety in cardiac patients indicates high depression and anxiety scores [7,11,12].

Data on the prevalence of depression and anxiety in older patients with cardiovascular disease are limited, and few studies have focused on the effects of treatment [13]. Especially the latter study showed that the prevalence of depression in this patient cohort is <31.5% and was clearly associated with increased mortality rates. In contrast, when major depressive disorders were present in only 8.6% suggesting a high estimated number of unreported cases [14]. So far, only two studies have systematically evaluated depression and anxiety in patients with aortic stenosis (AS). A registrypublished in 2016 and a study investigating the association of depression and mortality in AS patients treated by either (surgical aortic valve replacement or TAVI was published in 2018 [14,15].

Between 60-80% of the patients are anxious in the preoperative period, and the rate of medical complications is higher in patients with high postoperative anxiety, and the level of postoperative anxiety is related to the level of preoperative anxiety [16].

Although psychological factors are very important in hospitalized and physically ill individuals in our country, this situation is neglected in practice. In order to emphasize the importance of this situation, we aimed to examine the preoperative and postoperative anxiety levels of patients diagnosed with aortic insufficiency. In a systematic review by Lichtman *et al*., (2014) despite the heterogeneity of published studies included in this report the preponderance of evidence supports the recommendation that depression should be elevate to the status of a risk factor for adverse medical outcomes in patients with acute coronary syndrome [16]. For this reason, it is thought that it is important to examine the anxiety levels of patients hospitalized for physical illness.

Many factors need to be taken into consideration in order to individualize the nursing care for patients having a TAVI procedure. Knowing the expectations, experiences and emotional states of the patients before and after TAVI will contribute favorably to their care and treatment.

RESEARCH OBJECTIVE

To estimate the frequency of preoperative SAS

MATERIALS AND METHODS

Design and Purpose

The study was performed in Sifa Hospital for Turkey between September 2014 and June 2015. Data were collected in the cardiology outpatient clinic for preoperative data, and in the coronary intensive care unit and cardiology outpatient clinic for postoperative data. The setting was the where patients were seen for symptoms of aortic stenosis or aortic insufficiency and needing TAVI surgery according to the EUROSKOR risk classification. The data were collected using an interview guided questionnaire and the State-Trait Anxiety Inventory (STAI) in the first 24 hours in the preoperative period. The STAI was repeated on the second or third postoperative day, since the patients were intubated on the first day after surgery.

Research objective 1. To estimate the frequency of preoperative anxiety state anxiety scores (SAS)
Research objective 2. To estimate the frequency of postoperative anxiety state anxiety scores (SAS).
Research objective 3. To test the difference between pre and post-operative SAS
Research objective 4. To estimate the frequency of preoperative TAS
Research objective 5. To estimate the frequency post-operative TAS
Research objective 6. To test the difference of between pre and post-operative anxiety scores
Research objective 7. To estimate if age, gender, marital status, occupation, presence of chronic disease, smoking status, previous hospital experience, status of getting information about the disease predict SAS and TAS.

Participants and setting

The sample size was 35. One patient died after inclusion to the study in the postoperative period, 34 patients remained [17]. *Inclusion criteria:* without dementia, without a diagnosis of depression and schizophrenia, no vision or hearing loss to interfere with communication. *Exclusion criteria:* Patients followed for less than 12 hours in the preoperative period, illiterate patients, and foreign nationals

Data collection

The personal characteristics form was prepared by the researcher in line with the literature [11,18,19] and consisted of 20 questions. The first seven questions were about the socio-demographic characteristics of the patients who were going to have TAVI; the remaining 13 questions were about the patient's medical history.

State-Trait Anxiety Inventory (STAI)

The most widely used measure for anxiety is the State-Trait Anxiety Inventory (STAI) scale developed by Spielberg et al. (1964). The Turkish adaptation and standardization were made by Öner and Le Compte in 1974-1977. The reliability of the inventory was between 0.83 and 0.92 for the state anxiety inventory and between 0.86 and 0.92 for the trait anxiety inventory. It consisted of two parts. First part; state anxiety scale is a description of how the individual feels at a certain moment and under certain conditions, the response options are 1 (Not at all), 2 (Slightly), 3 (Very much), 4 (Totally)" according to the severity of their feelings at that moment when reading the items of the scale.

The second part: Trait anxiety scale, that requires the individual to mark the frequency of their symptoms as 1 (Almost never), 2 (Sometimes), 3 (Most of the time), 4 (Almost always). There are 20 items in each scale and the scale consists of 40 items in total. The total value is 50 for the State Anxiety Score (SAS) and 35 for the Trait Anxiety Score (TAS). A high score indicates a high level of anxiety, and a low score indicates a low level of anxiety. The average score level determined in practices in Turkey varies between 36-41 [20,21].

Data Analysis

SPSS 22.0 package was used for data entry, management and analysis. The conformity of the variables to the normal distribution was examined using analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). The mean and standard deviations (sd) for normally distributed descriptive variables were obtained. The Mann-Whitney U test was used to compare the non-normally distributed variables (gender, occupation, marital status, disease information, chronic disease, and surgery status) in qualitative and/or independent groups, and the t-test was used to compare normally distributed variables in qualitative and/or independent groups. The reliability analysis of the state and trait questionnaires was evaluated with Cronbach's α value. Cases with a p-value below 0.05 were considered statistically significant. A regression analysis was done to estimate if any of the demographic and clinical variables would predict anxiety.

Ethical considerations

This study was approved by the Hospitals Medical Ethical Committee (Medical Research Ethics Committees United, reference L2019023), application number W20.081.

RESULTS

Patients participating in the study was 78.21 (±6.67) (n=34), and 61.8% of the patients were women, 52.9% were retired, 64.7% were married, 52.9% were primary school graduates, and 97.1% had social security (Table 1). Table 2. Shows that the mean SAS preoperatively was 45,5 (±12,1); and the mean SAS postoperative was 36,4 (±10,6). The differneces between the mean SAS preoperatively and postoperatively SAS was a 9.1% reduction. Table 2 also shows that the mean TAS preoperatively was 43,9 (±10,2) compared to the post-operative TAS was 41,9 (±9,6).

Table 1: Distribution of Demographics and Medical History (n=34)

		%	n
Gender	Women Men	61.8 38.2	21 13
Occupation	Housewife Retired	47.1 52.9	16 18
Education level	Illiterate Literate Primary school Secondary school High school	20.6 11.8 52.9 8.8 5.9	7 4 18 3 2
Marital Status	Married Single	64.7 35.3	22 12
Lives together at home	Wife/Husband Wife/Husband and children Children Alone Mother and Father	55.9 8.8 17.6 17.6 -	19 3 6 6 -
Smoking status	Yes No	2.9 97.1	1 33
Previous hospital experience	Yes No	97.1 2.9	33 1
Prior surgery status	Yes No	70.6 29.4	24 10
Chronic disease history	Yes No	82.4 17.6	28 6
Status of getting information about the disease	Yes No	52.9 47.1	18 16
Where did she get the information?	Doctor Internet	94.4 5.6	17 1
Assistance with care after discharge	Yes No	97.1 2.9	33 1

Table 2: Distribution of State Anxiety Scores (SAS) All PAtients (n=34)

	Pre-TAVI			**Post-TAVI**		
	Min	**Max**	**Mean±SD**	**Min**	**Max**	**Mean±SD**
SAS	29	69	45,5 (±12,1)	23	63	36,4 (±10,6)

Thus, the mean difference between the preoperatively and postoperatively TAS was 43,9 (±10,2) and 41,9 (±9,6) respectivly; a 2% reduction. Table 3. shows the factors that affected SAS and TAS; it was age and the presence of chronic disease that affected the SAS only in the preoperative period. The patients included in our study had higher SAS before TAVI, and lower state and trait anxiety scores in the postoperative period. A statistically significant difference was found between the TAVI preoperative SAS [45,5 (±12,1)] score and TAS score [3,9 (±10,2)] (Table 2). In our study, anxiety scores were higher in patients with chronic diseases. The difference between the preoperative SAS in patients with chronic disease and those without it was statistically significant (p=0.01). The pre-TAVI anxiety scores were higher in patients with chronic disease. A statistically significant difference was found between the pre-TAVI and SAS in patients with chronic diseases compared to those without chronic diseases (p<0.05) (Table 3).

Table 3: Multiple Regression Analysis Results on the Effect of Dependent Variables on Preoperative and Postoperative State Anxiety Scores (n=34) *

Dependent Variables	Predictors	Unstandardized Coefficients	Standardized Coefficients Beta	t	p-value	95,0% Confidence Interval for B	
						Lower Bound	Upper Bound
PRE-SAS	Age	,632	,349	2,153	**,04**	,03	1,23
POST-SAS		-,069	-,044	-,229	,82	-,69	,55
PRE-SAS	Gender	-5,453	-,222	-1,378	,18	-13,57	2,66
POST-SAS		-5,167	-,241	-1,263	,22	-13,56	3,23
PRE-SAS	Previous hospital experience	-4,629	-,066	-,378	,72	-29,77	20,52
POST-SAS		-8,207	-,133	-,648	,52	-34,21	17,79
PRE-SAS	Undergone surgery before	3,810	,146	,903	,35	-4,85	12,47
POST-SAS		-1,589	-,069	-,364	,72	-10,54	7,36
PRE-SAS	Chronic diseases	-13,063	-,418	-2,375	**,03**	-24,34	-1,77
POST-SAS		2,173	,079	,382	,71	-9,49	13,84
*: Multıple Regresyon was applied.							

Dependent variable: preoperative SAS Multiple R: , 619 Multiple R^2: ,247

Dependent variable: postoperative SAS Multiple R: , 375 Multiple R^2: ,051

Variables codes:

Age younger =1 older=2 Gender: Female= 1 Men=2

Previous hospital experience: Yes=1 No=2, Undergone surgery before:Yes=1 No=2

Chronic diseases: Yes= 1 No= 2, Pre SAS Yes=1 No=2, Post SAS Yes=1 No=2

In the model, in which variables such as age, gender, occupation, education level, marital status, smoking status, previous hospitalization experience, previous surgery experience, and presence of chronic disease were included, age and the presence of chronic disease were found to be factors affecting anxiety in the preoperative period, independent of other variables (Table 3).

According to the literature, if $0.80 \leq \alpha \leq 1$, State-Trait Anxiety Inventory is quite reliable. In our study, the Cronbach's alpha for state anxiety was 0.96, and the Cronbach's alpha value for TAS was 0.96; STAI was, therefore, found to be quite reliable (Table 4).

Table 4: Reliability Analysis of Anxiety Inventory (n=34)

	Cronbach's Alpha	n
Trait Anxiety	0,966	34
State Anxiety	0,967	34

Limitations of the Research

The cause of TAVI in 2010 was not very well known from the outset due to being less invasive. The STAI tool used in the study was found to be quite reliable in our study as a valid tool for situational-trait anxiety. In this context, our limitations; since it is not related to the subject, our research data has been tried to be compared with the data of valve surgeries performed with open surgery method. According to our research, our study is a first in this regard.

DISCUSSION

Data on quality of life and especially the presence of depression and anxiety in older patients with aortic stenosis who are eligible for TAVI are limited. In the literature, the number of studies that focus on anxiety levels of TAVI patients is negligible [13]. For this reason, we examined studies for anxiety levels in patients who had undergone a TAVI procedure.

Sidar *et al.*, [24] reported that the preoperative was 46.8, that the preoperative TAS was 56.3, that the postoperative SAS was 45.2, and that the postoperative TAS was 51.8. They also examined the relationship between anxiety and pain levels in 81 patients before and after open-heart surgery. They found that the preoperative SAS was 39.4 compared to the post-operative SAS, that was 37.9 that the preoperative and postoperative TAS were 45.4 and 46 respectively.

We found that the pre-TAVI SAS values were moderately high, and that their state and TAS were lower in the postoperative period. Our study findings were similar to other studies that reported high anxiety scores in patients having open-heart surgery and lower anxiety scores in TAVI patients [24]. One reason for this may be high preoperative anxiety scores in patients who will undergo open-heart surgery, and lower postoperative anxiety scores in patients who will undergo TAVI due to the expectation of a faster recovery in the postoperative period.

In this study, the relationship between the state and trait anxiety scores before and after TAVI was examined. A statistically moderately significant difference was found between the TAVI preoperative SAS and the TAS and the TAVI postoperative SAS. In the study performed on 109 patients, Budak [24] and Sidar [24] *et al.* who examined the preoperative anxiety of patients, who had open-heart surgery, and did not find a statistically significant difference between the preoperative and postoperative SAS of patients. When compared with the literature, the results of our studies were different from those of Budak and Sidar. At the same time, our research results could not be compared because studies on the anxiety of patients who underwent TAVI are still insufficient.

In their study, Koca, Kanan [22] and Nayir [9] evaluated the anxiety levels of patients, who had undergone open-heart surgery, and reported that the preoperative SAS was higher than the postoperative SAS in the experimental group and that the difference was statistically significantly higher. They also found that the preoperative TAS of the experimental group was higher than the postoperative TAS and that the difference was statistically significantly higher ($p<0.01$). The studies of Koca, Kanan [22] and Nayir [9] were similar to our study. When the results of our study and the studies showing similar results are evaluated, it is thought that individuals with high TAS may also have high state anxiety, and that high anxiety before surgery may also associated with high anxiety after surgery.

In this study, a significant positive correlation was found between age and preoperative SAS, and it was observed that preoperative SAS increased as age increased. This finding is inconsistent with the literature, where studies examining the relationship between age and anxiety. In some studies, age was not associated with anxiety level [26, 27]. Buyukasık [28] found SAS of patients ages 51-64 had significantly higher scores than those under 50 years of age. When they examined the effect of health education on the anxiety of patients who were to undergo coronary angiography. Our results are consistent with those by Buyukasık [28].

Since the average age of our patients is 78, the fact that the surgery to be performed affects the heart may trigger the fear of death in our patients in the preoperative period and cause an increase in the level of anxiety in older patients. In our study, 61.7% of the patients were women and 39.3% were men. In the studies conducted by Völler *et al.,* [18], Yücel *et al*. [29], and Dağdelen *et al*. [6] the majority of the sample were also women. The high rate of women in this study is similar to reports in the literature in terms of gender ratio. According to the 2019 data of the Turkish Statistical Institute, when the death rates in Turkey are analyzed on the basis of gender, deaths due to cardiovascular diseases in women are 49.8% [30]. This rate is quite high. In our study, the sample consisted of patients aged 65.

In our study, SAS and TAS of the women's scores were higher than that of the men. While this difference between men and women in terms of preoperative SAS was statistically significant, no significant difference were found between the preoperative and postoperative SAS and TAS. Reports in the literature show that the rate of anxiety are higher in women than men [31-34].

The fact that the level of anxiety is higher in women than in men is consistent with the literature. The reason for this is reported to be more intense anxiety in women due to separation from the family and women's ability to express their concerns more easily. Epidemiological data suggests that anxiety is more common in women was also observed in our results [26,35].

If patients have more information about their diseases it may reduce the level of anxiety in some patients, while it may have a negative effect in some patients and increase the level of anxiety. The lack of a relationship between educational level and anxiety level in our study can be explained within this context. In addition, patients' coping mechanisms with anxiety are individual and can therefore be easily affected by many internal and external factors.

In the pre-operative period, thoughts such as fear of death, body image change, and organ loss may cause anxiety, while thoughts such as inability to recover, pain and not returning to normal life in the post-operative period may trigger anxiety. Also, individuals who are living alone have less social support, cannot share the above-mentioned fears, and therefore have higher anxiety in the preoperative period.

Whereas patients living with their spouse and children focus on their family and they cannot control the environment, thus their anxiety levels may increase in the postoperative period. In our study, no statistically significant difference was found between the patients who had no previous surgery and the patients who had undergone surgery, in terms of pre-and postoperative SAS and TAS. This finding was consistent with other studies [23,26,36].

Anxiety is considered conditional learning. If the experiences of patients who have had previous surgery are good, their anxiety levels may be lower; if those experiences were bad, the anxiety levels may be increased. The fact that there was no significant relationship between previous surgery and anxiety level in the study may suggest that prior experiences are unrelated to present procedures.

In our study the anxiety scores were found to be higher in those with chronic diseases. The difference between the preoperative SAS in patients with chronic disease compared to those without it was found to be statistically significant. These results are similar to other studies [37,38].

It is thought that chronic diseases, which do not heal spontaneously, are generally not fully treated, affect the mental and social lives of patients in addition to physical symptoms that patients have to endure for a lifetime, cause the anxiety scores of patients to be higher [93,40]. In this study the SAS was found to be statistically significantly higher in those who did not have knowledge about the disease. Nayir and Bahar reported that there was no relationship between disease knowledge and anxiety score in their studies [9,37]. Demir *et al.*, in their study, reported that informing the patient before the operation reduces anxiety [27]. Demir *et al.*'s study supports the results of our research. There are studies in the literature emphasizing the importance of communicating with and informing the patient [27,41]. The lower level of anxiety in patients who had knowledge about the disease may be associated with this condition. The reliability of STAI was between 0.83 and 0.92 for the SAS and between 0.86 and 0.92 for the TAS (Öner and Le Compte). In our study, STAI was, therefore, found to be quite reliable. In the literature, STAI can be used in clinical settings to diagnose anxiety and to distinguish it from depressive syndromes (Table 4).

CONCLUSIONS

Age and presence of chronic diseases were found to be factors affecting anxiety scores in the preoperative period. What is remarkable in the study is that although TAVI is a heart surgery, the anxiety levels of the patients were low. In particular, the anxiety level of the patients was higher in the preoperative period and lower in the postoperative period. This reveals that TAVI surgery is a closed method and is less invasive; for that reason, patients generally feel more comfortable psychologically, and their anxiety levels were lower, especially in the postoperative period.

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