Available online at **www.ijmrhs.com**

ISSN No: 2319-5886

International Journal of Medical Research & Health Sciences, 2017, 6(10): 21-32

Validity and Reliability of the Florida Patient Acceptance Survey and Florida Shock Anxiety Scale in Turkish Patients with Implantable Cardioverter Defibrillation

Oz Alkan H* and Enç N

Medical Nursing Department, Istanbul University, Turkey

**Corresponding e-mail: havvaoz@hotmail.com*

ABSTRACT

Despite its established effectiveness, living with an implantable cardioverter defibrillator (ICD) is associated with ongoing psychosocial distress. Patient device acceptance and shock-related anxiety might be essential in identifying patients at risk for adverse patient-reported outcomes following implantation of an ICD. The purpose of study was to examine the validity and reliability of the Florida Patient Acceptance Survey (FPAS) and the Florida Shock Anxiety Scale (FSAS) of ICD patients. ***Methods:*** *The sample included 180 participants (146 male, mean age=60.56 ± 13.88). Patients completed the FPAS, the FSAS, the Beck Anxiety Inventory (BAI), the State Anxiety Inventory (STAI-TX1) and Trait Anxiety Inventory (STAI-TX2).* ***Results:*** *Confirmatory factor analysis (for FPAS) revealed that a four-factor structure: Return to Function, Device-Related Distress, Positive Appraisal and Body Image Concerns (χ^2_{84} =157.75, p=0.00, comparative fit index (CFI)=0.91, root mean-square error of approximation (RMSEA)=0.07). Confirmatory factor analysis (for FSAS) revealed that a two-factor structure with items loading such that Factor 1 could be conceptualized as a Consequence Factor and Factor 2 as a Trigger Factor χ^2_{34} =81.48, p=0.00, comparative fit index (CFI)=0.93, root mean-square error of approximation (RMSEA)=0.09). The FPAS was negatively correlated with FSAS, BAI, STAI-TX1 and STAI-TX2 (p<0.01). The FSAS was positively correlated with BAI, STAI-TX1 and STAI-TX2 (p<0.01). We found satisfactory evidence of internal consistency (Cronbach's α was 0.81 for FPAS and Cronbach's α was 0.87 for FSAS).* ***Conclusion:*** *FPAS and FSAS are valid and reliable instruments to assess device acceptance and shock-related anxiety in Turkish patients with ICD.*

Keywords: Implantable cardioverter-defibrillators, Patient acceptance, Anxiety

INTRODUCTION

Patients undergoing Implantable Cardioverter Defibrillation (ICD) implantation may encounter some difficulties while adapting to the device [1]. Having an artificial device for a lifetime in the body, the need of regular controls, having the fear that the ICD function can be disrupted and their hearts may stop working without the ICD, the feeling that the ICD will shock at any time lead to psychosocial problems in the ICD patients such as fear, weakness, worry, stress, anxiety, and depression [1-3]. The safety measures such as restriction of driving, against the possibility of harming either the patient himself/herself or around, taken in case of mental fog that can be developed due to dysrhythmias, cause psychosocial problems in the patients [4]. These psychosocial problems encountered, affect the level of device acceptance of the patient [5].

The patients fear that shock can be developed due to activity and exercise. About 55% of the patients refrain from people, activities and being in different environments to avoid shocks [6]. In the study by van Ittersum, et al. [7], the fear of doing exercise felt by the individuals affected their quality of life adversely. In the studies [2,3,8-18], it has been reported that in the patients undergone ICD implantation, the psychosocial problems of those who have previously experienced the ICD were high when compared to ones who have not experienced the shock.

The appropriate psychosocial attempts to be made to the patient reduce the ratio of psychosocial problems in patients [3,19-23]. The integrated approach in the diagnosis and management of psychosocial problems, which is highly seen in ICD patients, is important to increase the strength of patient's coping and quality of life. Treatment and care should be continued within the team mentality.

Scales have been developed to evaluate the psychosocial factors in patients with ICD. Florida shock anxiety scale (FSAS) [24] has been developed in order to determine the level of shock anxiety, also studies of validity and reliability of Florida patient acceptance scale (FPAS) for the ICD patients, have been performed [1]. FSAS's [25,26] and FPAS's [5] validity and reliability studies have been made in different countries. The use of this scales is recommended in the evaluation of ICD patients.

This study has been carried out to conduct the studies of validity and reliability of FPAS and FSAS in order to adapt these scales into Turkish language and culture.

MATERIAL AND METHODS

This study has a cross-sectional design for psychometric testing and validating of FPAS and FSAS.

Participants

The research has been performed in Istanbul University, Medical Faculty, Department of Cardiology, Arrhythmia Intensive Care Unit, between the years 2008-2011, with 180 patients who have undergone the ICD implantation (N=297), still continued their outpatient controls, whose ICD implementation periods were >3 months, who did not have any communication problem and agreed to participate in the research. For the adaptation of a scale to another culture, it has to reach to a sample number, which is 5-10 times of the number of items of the scale [27]. In the calculation of the size of the sample, the 18-item FPAS, whose item number is more than the scales of which the reliability and validity studies are to be conducted, has been taken into consideration. According to the alpha level of 0.05, beta level of 0.80 (20% margin of error) criteria, 153 patients should be taken into the samples. By reaching to 10 times of FPAS, the research has been completed with 180 patients. The purpose of the study was explained to the patients who conform to the selection criteria and all those who accept were included in the study.

Instruments

Florida Patient Acceptance Scale (FPAS)

The FPAS, it has been developed by Burns, et al. [1] in order to evaluate the status of the device acceptance of the patients, who had undergone the ICD and the permanent pacemaker implantation in the United States. The FPAS is an 18-item measure used to assess patient acceptance of a cardiac implantable device. All items are scored using a 5-point Likert scale from 1 to 5, with higher total scores indicating more acceptance of the cardiac device. The scale is composed of 4 factors: Return to Function, Device-Related Distress, Positive Appraisal and Body Image Concerns. In the 4 subscales of the instrument, a high score on Return to Function and Positive Appraisal means more acceptances, whereas a high score on Device-Related Distress and Body Image Concerns represents fewer acceptances. In addition, there are 3 single items that are not included in the subscales or total scale scoring, related to knowledge of the device and continuing normal sexual activities. The FPAS demonstrated good internal consistency, with Cronbach's α=0.83, and the internal consistency for each subscale ranging from 0.74 to 0.89 [1].

Florida Shock Anxiety Scale (FSAS)

The FSAS is a 10-item measure used to assess ICD shock-related anxiety. It consists of two subscales, the consequence factor that assesses anxiety related to the consequences of device, and the trigger factor that is related to anxiety about triggering device shock. All items are scored using a 5-point Likert scale from 1 to 5. High scores on the FSAS seem to reflect a patient's unique anxiety about his or her own ability to cope with the impact of shock. The reliability analyses revealed strong support for the factor structure; the Cronbach's α of the overall items was 0.91, split half was 0.92, and the test-retest score was 0.79, $p<0.01$. The reliability of the consequence subscale was high with Cronbach's α=0.88 and the Cronbach's α of the trigger subscale=0.74 [24].

State-trait anxiety

It has been developed by Spielberger, et al. [28] in 1983. It is a Likert-type scale that measures the levels of state and trait anxiety separately with 20 questions. The answers given varies between "none" to "completely". The total score value obtained from the two scales range between 20-80. The great score indicates high anxiety level, while the smaller score indicates low anxiety level.

Beck anxiety inventory

It is a 21-item scale that is used in order to determine the anxiety level of persons. The persons answering the scale, by taking into consideration their situations within the last one week, are requested to indicate to what extent the symptoms of each item have bothered themselves. It has been developed by Beck, et al. [29] in 1988. For each symptom, the score of zero [none] with three points [severe anxiety level] is considered so.

Procedures

A three-stage route was followed to adapt FPAS and FSAS to Turkish language and Turkish culture and to test its validity and reliability in the study. At the first stage, language and content validity of FPAS and FSAS, at the second stage, its construct validity and at the third stage, internal consistency was measured.

Validity of language and content

The scales were translated into Turkish by native English-speaking linguists and psychologists. The best expressions were selected by comparing the translations. Turkish expressions were translated into English by people who lived in both cultures with the back-translation method. Original expressions were compared with English expressions obtained by back translation method [30].

The scales were presented to the expert for validity of the content. At this stage, it was judged as to what extent the items within each dimension measure what they are intended to measure. The recommendations of 12 experts in their fields who are familiar with scale preparation techniques and methods were obtained for this purpose. Conformity of each item was assessed by the experts through grading between 1 and 4 (1: not suitable, 2: suitable a little/the phrase should be revised, 3: well suitable but minor changes should be made, and 4: very suitable). Content Validity Index (CVI) is the percentage calculated based on the total items rated by the experts as either 3 or 4. A CVI score of 80% or higher is considered to have good content validity [27].

The experts' opinions and recommendations were evaluated and language and content validity were approved after a pilot practice was performed with 30 patients conforming to the case selection criteria to test the intelligibility of the scale that language and scope validity were ensured. At the end of the pilot study, the necessary changes were made to expressions that were not well understood.

Construct validity

The data obtained from the Turkish form of the scales was examined by using the confirmatory factor analysis to what extent the theoretical constructures, which the original form of the scales based on, could explain. At the same time, the convergent-divergent validity were also evaluated by using the inventories of Beck Anxiety and State-Trait anxiety and by examining the Pearson correlation coefficients between them.

Reliability

The reliability of the scales was examined by calculating the internal consistency coefficients Cronbach's alpha reliability coefficient normally ranges between 0 and 1. However, there is actually no lower limit to the coefficient. The closer Cronbach's alpha coefficient is to 1.0 the greater the internal consistency of the items in the scale ($\alpha \geq 0.9$ Excellent, $0.9 > \alpha \geq 0.8$ Good, $0.8 > \alpha \geq 0.7$ Acceptable) [27].

Data analysis

CVI was used in evaluating the expert opinions for the content validity. Construct validity was tested with confirmatory factor analysis. Confirmatory factor analysis (CFA) on tetrachoric correlation among observed variables was used to test the structure of the FPAS and FSAS. The fit of the model for the data was based on goodness of fit index (GFI), adjusted goodness of fit index (AGFI), comparative fit index (CFI), root mean square error of approximation (RMSEA), standardized mean square residual (SRMR). By means of convergent-divergent validity, we used Pearson's correlations between measurement. Pearson's correlation coefficient with 95% CI was used to correlate the scores with each other. Internal consistency was assessed by Cronbach's alpha reliability coefficient. Data were analyzed using SPSS 21.0 for Windows. The CFA was calculated using LISREL 8.

Ethical considerations

Permission for the use of scales was obtained from the writers. We conducted the study according to the Helsinki Declaration and got approval by the Local Ethical Committee of the Istanbul University.

RESULTS

Sample characteristics

The distribution of socio-demographic characteristics of the patients and of variables related to the disease is given in Table 1. The majority of patients with a mean age of 60.56 were male (81.1%), married (86.7%), primary school graduates (50.6%) and retired (69.4%). The ICD insertion period of 27.8% of the patients is between 1-2 years. The ICD of 50.6% of the patients have shocked, and the shocking time of the ICDs of 28.3% is between 1 month and 1 year. The ICDs of 69.4% of the patients were inserted for primary prevention.

Table 1 The distribution of socio-demographic characteristics of the patients and the variables related to the disease

Variables		N	%
Gender	Male	146	81.1
	Female	34	18.9
Marital Status	Single	11	6.1
	Married	156	86.7
	Widower	13	7.2
Age, Year (Avg ± SS)	60.56 ± 13.88 (Range=21-84)	-	-
Educational Status	Uneducated	22	12.2
	Primary Education	91	50.5
	Secondary Education	48	26.7
	Higher Education	19	10.6
Occupation	Public Servant	5	2.8
	Worker	6	3.3
	Self-Employed	15	8.3
	Retired	125	69.4
ICD insertion period	Less than 1 year	29	16.1
	1 year	50	27.8
	2 years	29	16.1
	3 years	40	22.2
	4 years	32	17.8
Shocking status of ICD	Yes	89	49.4
	No	91	50.6
Shocking time of ICD	Less than 1 month	14	7.8
	Between 1 month – 1 year	51	28.3
	Between 2 - 4 years	24	13.3
Exposing to ICD shock	More than 3 in 1 year	23	12.8
Frequency	Less than 3 in 1 year	66	36.7
According to the insertion of ICD	Primary prevention	125	69.4
	Secondary prevention	55	30.6
ICD: Implantable Cardioverter Defibrillation, EF: Ejection Fraction VF: Ventricular Fibrillation, VT: Ventricular Tachycardia			

Validity of language and content

The translation-back translation method of FPAS and FSAS were adapted into Turkish. The content validity index of FPAS was found as 0.94 and validity index of FSAS was found 0.97.

Construct validity

Construct validity of Florida Patient Acceptance Scale (FPAS)

The construct validity of the measurements obtained from the Turkish form of FPAS were examined by confirmatory factor analysis, the results are given in Figure 1.

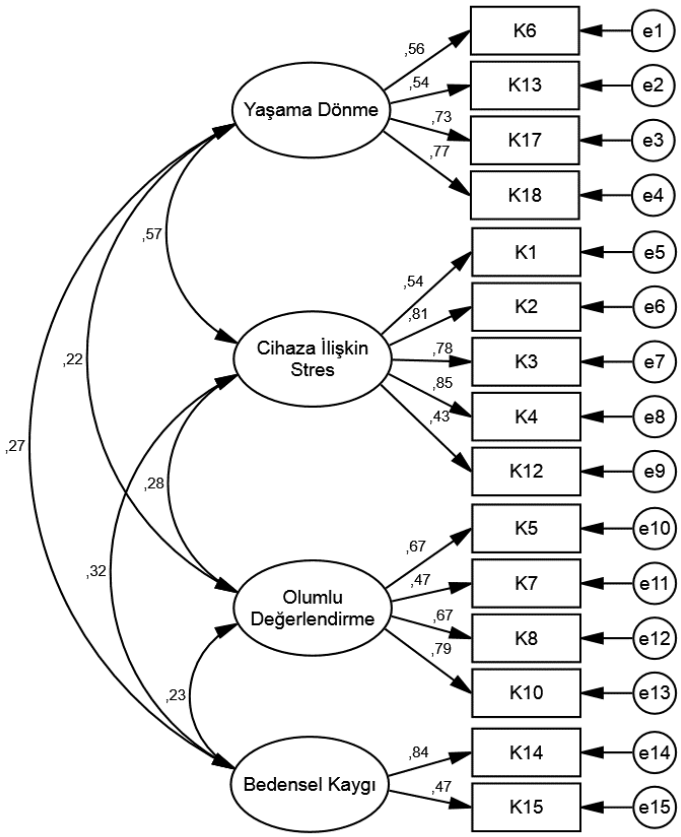

Figure 1 Measurement model of Florida Patient Acceptance Scale

As seen in Figure 1, the standardized regression coefficients (factor load) is between 0.43-0.85. The average variance (AVE) explained by each sub-scale, for return to function it is 0.44; device related to stress, it is 0.49; for positive appraisal, it is 0.43; and for body image concerns, it is 0.46. The construct reliability coefficients for sub-scales respectively are 0.75, 0.75, 0.82 and 0.61. The squares of largest common constructural covariances (MSV) and common constructural covariance mean squares (ASV) are lower than the AVEs.

$$\frac{\sum_{i=1}^{n} \lambda_i^2}{n} \quad (1)$$

The general adjustment (overall compliance) coefficients related to the model measurement are χ^2_{90}=157.75; p=0.00; normed χ^2=1.88; CFI=0.91; RMSEA=0.07 (GA: 0.05-0.09); SRMR=0.07. When it is examined that to what extent the variance and covariance between the items existing in the FPAS was explained by a one-dimensional construction (given the scale is unidimensional) it has been observed that the standardized regression weights, ranged between 0.17 and 0.81; and its ensemble coefficients were χ^2_{90}=407.45; p=0.00; normed=4.53; CFI=0.60; RMSEA=0.14 (GA: 0.12-0.15); SRMR=0.13 ($\Delta\chi^2_6$ =247.7; p=0.00). The correlations between the sub-factors are between 0.22-0.57 and only the two of 6 correlation coefficients are greater than 0.30 (Equation 1).

Construct validity of Florida Shock Anxiety Scale (FSAS)

Within the scope of construct validity, in the first instance, by considering the theoretical model, the data obtained from of the Turkish form of the scale was examined by confirmatory factor analysis; the results are presented in Figure 2. As shown in Figure 2, the standardized regression coefficients (factor load), for the result size is between 0.43-0.90; for the triggers is between 0.48-0.59. The AVE explained by the result size is 0.49; and by the triggers size is 0.34. The construct reliability coefficients respectively are 0.86 and 0.60. For the trigger size, the construct reliability coefficient of AVE is 0.34. For the model it is χ^2_{34} =81.48; p<0.001; normed χ^2=2.44; CFI=0.93; RMSEA=0.09 (GA: 0.07-0.11); SRMR=0.06. The correlation between the result and the triggers size is 0.86. When the analysis was repeated by

making the parameter between these two sub-scales as (correlation)=1, it has been found as χ^2_{35}=91.47; p=0.00. The difference between the two models is χ^2_{35}=9.99, it is greater than the chi-square table value 3.84.

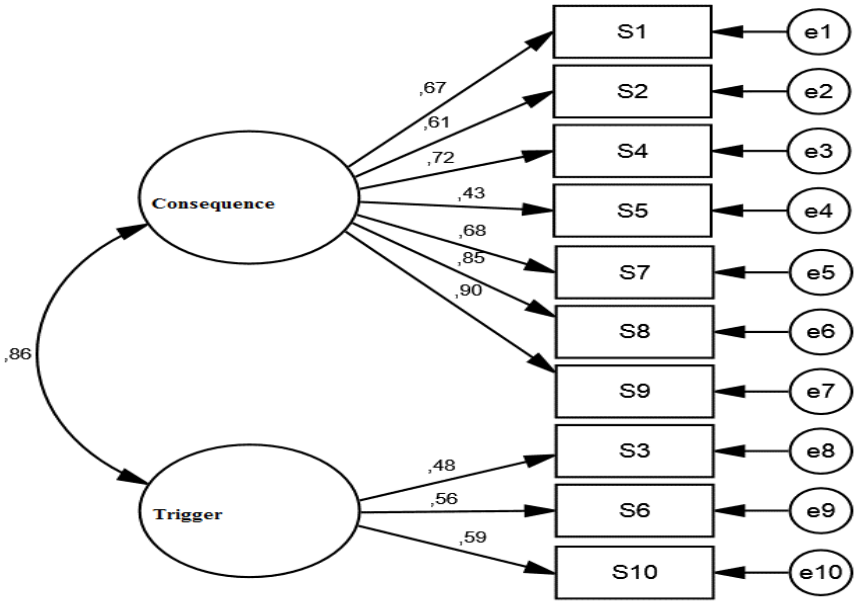

Figure 2 Measurement model of Florida Shock Anxiety Scale

Convergent-divergent validity

The simultaneously correlation of FPAS, Florida shock anxiety scale, STAI- TX1, STAI-TX2 and BAI. The Pearson correlation coefficients are given in Table 2.

Table 2 The Pearson correlation coefficients between FPAS, FSAS, STAI- TX1, STAI-TX2 and BAI

Scales	FPAS	FSAS	SAI	TAI	BAI
FPAS	-	-0.54*	-0.54*	-0.59*	-0.47*
FSAS	-	-	0.40*	0.51*	0.60*
SAI	-	-	-	0.74*	0.40*
TAI	-	-	-	-	0.59*
BAI	-	-	-	-	-
*p<0.001 BAI: Beck Anxiety Inventory, FPAS: Florida Patient Acceptance Scale, FSAS: Florida Shock Anxiety Scale, STAI-TX1: State Anxiety, STAI-TX2: Trait Anxiety Inventory					

When the correlation between FPAS, State anxiety inventory (STAI-TX1), Trait anxiety inventory (STAI-TX2) and BAI are examined (Table 2); statistically significant negative correlation was found between FPAS, STAI-TX1, STAI-TX2 and BAI (p<0.01). While the scores of individuals for device acceptance increase, their trait/state anxiety and anxiety scores reduce.

Statistically significant expected positive correlation was found between Florida shock anxiety scale, STAI-TX1, STAI-TX2 and BAI (p<0.01). Individuals While the ICD shock anxiety scores of the individuals increase, their trait /state anxiety and anxiety scores also increase (p<0.01) (Table 2).

The Reliability of Florida Patient Acceptance Scale and Florida Shock Anxiety Scale

The internal consistency coefficients (Cronbach's alpha) of the measurements obtained from the Turkish Form of FPAS were found as for the return to function 0.74, for device-related stress 0.81, for positive assessment 0.74, and for body image concerns 0.56. The reliability coefficient for the whole of the scale is 0.81 (Table 3).

Table 3 The Cronbach's alpha coefficients of FPAS, FSAS, STAI- TX1, STAI-TX2 and beck anxiety inventory

Scales	Cronbach's Alpha Coefficients
FPAS	0.81
Return to Function (sub-scale)	0.74
Device-Related Stress (sub-scale)	0.81
Positive Appraisal (sub-scale)	0.74
Body Image Concerns (sub-scale)	0.56
FSAS	0.87
Result (sub-scale)	0.87
Triggers (sub-scale)	0.57
STAI- TX1	0.9
STAI-TX2	0.88
BAI	0.92
BAI: Beck Anxiety Inventory; FPAS: Florida Patient Acceptance Scale; FSAS: Florida Shock Anxiety Scale; STAI- TX1: State Anxiety Inventory; STAI-TX2: Trait Anxiety Inventory	

The reliability coefficient for the result size of Cronbach's alpha value of FSAS was found as 0.87, for triggers size as 0.57, for the whole of the scale as seen in Table 3 found as 0.87.

DISCUSSION

Language and content validity

According to the content validity index of FPAS and FSAS adapted to Turkish by standard forward-back translation it has been determined that the validity of language and content of these scales at satisfactory level. In the Chinese version of the Florida patient acceptance, the content validity index scale was found as 0.80, and in the Chinese Version of Florida shock anxiety the content validity index scale was found as 0.90 [25].

Construct validity

Some complex psychological characteristics that cannot be identified in one size (dimension), with a particular theoretical approach and in a conceptual framework, are described as a construct. Construct validity of a scale, allows the explanation of outcomes and the explanation of what the outputs are in connection with [30].

The construct validity of the FPAS was examined by confirmatory factor analysis. According to the results of this analysis, for the sub-scales of FPAS, it can be said that their validity of the similarities is at low levels. On the other hand, MSV and ASV are lower than the AVEs. This means the sizes (dimensions) measure different or independent characteristics, therefore, separation validity of the FPAS is high.

As it can sufficiently explain the variance-covariance matrix obtained from the data set of proposed models of FPAS, Hair, et al. [31] have indicated that in case the item number is 12-30; number of people <250, even the χ^2 result is statistically significant, the CFI should be greater than 0.95; SRMR and RMSEA should be smaller than 0.08. Beside normed for the badness of fit indices (RMSEA and SRMR) being low indicates the well-adjustment (adaptation) of the model; the lowness of CFI, which is the goodness of fit index, indicates that this adjustment (adaptation) is not high enough. As a result, the coefficients of similarities, validity and general adjustment - non- adjustment show that the total scores of sub-scales of FPAS should be used cautiously. Apart from this analysis, when it is examined that to what extent the variance and covariance between the items existing in FPAS by a one-dimensional construction (if considered that the scale is one-dimensional) is explained, the standardized regression weights and general adjustment (overall compliance) coefficients indicate that the FPAS does not consist of a single size, and the four-dimensional construction explains the data better in comparison with the one-dimensional ($\Delta\chi^2_6$ =247.7; p=0.00). As another proof of this result, the correlations between the sub-factors being between 0.22-0.57 can be given figure. Among the 6-correlation coefficient only the two of them being greater than 0.30, means that the correlation between the sub-scales is not high, and the dimensions (sizes) measure the characteristics which are independent from each other.

For the FPAS, in the validity study by Burns et al. [1], throuhout the principal component analysis it has been determined that the scale consists of 4 sub-scales. By Pedersen, et al. [5], the study of reliability and validity of FPAS has been conducted in Denmark. By making the Varimax rotation principal component analysis, it has been revealed

that the scale consists of 4 sub-scales and these sub-scales explained the 64% of the variance. In the study of validity and reliability by Versteeg, et al. [32], in the explanatory and confirmatory analysis it has been determined that the scale displayed a 3-factor construction. In this research, the 4th Factor (body image anxiety) explains only 7.4% of the variance. Thus, 3 items with low factor loads [1) I am careful while hugging or kissing my loved ones, 2) I feel that others see me as disfigured by my device, 3) I feel less attractive because of the device] have been excluded from the scale, the construction of the factor has been examined again and it has been determined that the scale as being a 3-factor scale, explained 63.6% of the variance.

Within the scope of construct validity of Florida shock anxiety scale, for the result size, the standard regression weights being greater than 0.50, and the reliability coefficients being greater than 0,70 great and the AVE being close to 0.50, indicates that the validity of similarities is ensured. For the trigger size that the AVE is 0.34, can be due to the rarity of the number of items in this sub-scale. However, the standard regression weight and reliability coefficient are higher than the acceptable limit value 0.50. Thereby, it can be asserted that validity of similarities is partially ensured. The correlation between the sizes (dimensions) of results and triggers is relatively high. When the analysis is repeated by making the parameter between these two (dimensions) sizes as (correlation)=1, the difference between the two models and the chi-square table value reveals that the two-factor model fits (adapts) the data better than the single factor model.

The Original FSAS has been examined by explanatory factor analysis and it has been revealed that it displayed two-factor structure. The 1st factor has been grouped as outcome factor, and the 2nd factor has been grouped as triggering factors. The factor loads of the 1st factor ranged between 0.56 and 0.82; the factors loads of 2nd factor ranged between 0.46 and 1.02. In the expression "I do not get angry or upset because it may cause my ICD to fire" factor load is insignificant (the factor loads of items that are not included in either of the 2 factors are under 0.40). These two factors explain the 66% of the variance [24].

By Ford, et al. [26], with 443 patients, the study of large-scale reliability and validity of FSAS has been performed. In this study, the confirmatory factor analysis has been compared with the single-factor construction and two-factor construction of the scale, and it has been determined that the 2-factor model was more suitable for the data compared to the single-factor model (χ^2_{34} =75.34; p<0.0F; CFI=0.98; RMSEA=0.05].

What should be the general adjustment coefficients in the confirmatory factor analysis?

While the validities of FPAS and of Florida shock anxiety scale, which were adapted within the scope of the study, are examined the views of Hair et al. [31] are taken regarding the coefficients of general adjustment. However, for the last 25 years it has been observed that there is difference of opinion about which fit coefficients should be used and what should be the size of these coefficients. [33].

Browne and Cudeck [34] indicate that the coefficient of RMSEA should be smaller than 0.05; and that the values over 0.10; show bad adjustment. MacCallum, et al. [35] have expressed that a value to be obtained between 0.05-0.10 shows that the model is good, if it is between 0.08-0.10 this shows an intermediate level of adjustment (fit), if the RMSEA upper limit is greater than 0.10 the model has a bad adjustment. In an acceptable model, again for the RMSEA, it has been expressed that according to Hu and Bentler [36] it should be close to 0.06; according to Schumaker and Lomax [37] it should be 0.05; according to Brown [38] it should be smaller than 0.06; and according to Steiger [39] it should be smaller than 0.07, and the values over 0.10 indicate that the model did not adjust well.

Byrne [40] says that the coefficient of SRMR should be smaller than 0.05 to be small; Hu and Bentler [36] say that the coefficients up to 0.08 are acceptable. For a good fit, for the CFI it is proposed not to be under 0.90 [41,42] and is proposed to be 0.95 and over [33,36,38,43].

Tabachnick and Fidelle [44] indicate that the CFI and RMSEA are affected by the estimation method used; Kline [43] indicates that when the number of parameters and number of people are more, the SRMR is found lower. Randall, et al. [37]; Brown [38] say that unless n is large and the model is complex, the confidence interval of RMSEA will be large. Accordingly, it can be said that the sample size of each adjustment (fit) coefficient item varies depending on the conditions such as number of items and paths.

The fact remains that there is no consensus on the cut-off point of the coefficients of general adjustment, a common thought comes in that in the evaluation of the adjustment of a model the coefficients of general adjustment is just one

of the criteria, in other words, other criteria should also be taken into consideration [31,33,37,38,44,45] These are: the standard residues are small, the direction and magnitude of the estimates for the parameter are in the expected direction and they are statistically significant, the model contains too little or too much factors (for this reason the Heywood case problem), reliability coefficients of the factors are high, the inconvenient definition of correlated or uncorrelated measurement errors in the model.

When considered in terms of these criteria, as almost all factors are defined by more than three indicators during the analysis, the direction and magnitude of the index weights (factor loads) are in the expected direction and are statistically significant, each factor has greater reliability coefficient than 0.50 [46] show that the scales adapted within the scope of the research can be used to compare the groups.

Convergent validity

It is specified that for the validity of the measurements, it is not enough to use only the factor analytic methods; also, evidence should be collected about the validity by using different methods such as content, validity based on the measurements convergent validity. Considering this idea, the correlations of the scales, which have been adapted within the scope of the research, with the other measurement tools have been examined within the scope of validity based on criteria. As the device acceptance scores of the individuals increase, their trait/state anxiety scores decrease. As the ICD shock anxiety scores of the individuals increase, their trait/state anxiety and anxiety scores increase ($p<0.01$) (Table 2).

In the study by Burns, et al. [1] the FPAS displayed a significant correlation with SF-36 quality of life scale and its subscales, with anxiety scale and with depression scale. In the study by Pedersen, et al. [5], it has been determined that the FPAS displayed a significant correlation with the scales of anxiety, depression, and ICD anxiety. In the study of Versteeg, et al. [32], a correlation has been set forth between Florida patient acceptance and anxiety, depression, and distress.

In the study by Kuhl, et al. [24] the correlations between the original FSAS and the fear of death scale have been examined and, it has been found as –0.65. The low scores of the fear of death scale indicate that more fear of death has been developed. In the study by Ford, et al. [26] the FSAS displayed a negative correlation with emotional wellbeing scale, sense of safety scale and scales of perceived general health and quality of life.

In the study by Udlis, et al. [47], the levels of patient acceptance and shock anxiety are correlated and the shock anxiety is correlated with the mental dimension of the quality of life. In the study by James, et al. [2], in patients with anxiety and depression, the scores of patients' acceptance is correlated. In the study by Wilson [48], it has been found that for the patients whose shock anxiety levels were high, the patient acceptance levels were lower. Besides, for the patients with less depressive symptoms, the patient acceptance levels were also higher. In the study by Chair, at al. [25], also for the patients whose shock anxiety scores were higher, the patient acceptance level and the quality of life were lower.

Reliability

The methods improved for the purpose of evaluating the reliability of measuring instruments are called reliability analysis and the reliability coefficients are calculated in order to analyze the reliability of the tests.

The reliability of the measurements being low also reduces the validity. In connection with the validity of the adapted scales, the reliability coefficients of other scales implemented in connection with the validity of the adapted scale is smaller than 1. This shows that the measurement errors are involved in measurements. By making a correction for measurement errors, the corrected validity coefficients were calculated (Table 3).

The internal consistency coefficients (Cronbach's alpha) of the measurements obtained from the Turkish Form of FPAS have been found sub-scales; ranged between 0.56-0.81. The reliability coefficient for the whole scale is 0.81.

The reliability study of FPAS has been conducted by Burns et al. [1]. In this study, it has been determined that the internal consistency coefficients (Cronbach's alpha) for the sub-scales of the measurements obtained from validity research, ranged between 0.74-0.89; and the reliability for the whole scale was determined as 0.83. In the study by Pedersen, et al. [5], it has been determined that the Cronbach's alpha coefficient of the sub-scales of the scale ranged between 0.73-0.79, and the Cronbach's alpha for the whole scale was found as 0.85. In the Chinese version of the

scale, it has been found that the Cronbach's alpha coefficient of the sub-scales of the scale ranged between 0.40-0.82, and the Cronbach's alpha for the whole scale was found as 0.54 [25].

In this study, the reliability coefficient for the outcome size of Cronbach's alpha value of FSAS has been found as 0.87, for the triggers size found as 0.57, and for the whole scale found as 0.87. In the study by Kuhl, et al. [24], the coefficient of Cronbach's alpha of FSAS has been determined as 0.91. In the Chinese version of the scale [25], the Cronbach's alpha value for the sub-scale of the outcome has been found as 0.46. Scale, for the triggers found as 0.79 and for the whole scale found as 0.81. In the study by Ford, et al. [26], the Cronbach's alpha value has been found as 0.89.

Study limitations

Because the research is conducted in one center, the results of the research are not generalizable for all ICD patients, can be generalized to those who have similar characteristics to the research group. Data were obtained through interviews. For this reason, the reliability of data is limited to the notification of participants.

CONCLUSION

In the sequel of the analysis, the scales used in the research were determined to be valid and reliable that they can be used in Turkey for the evaluation of ICD patients. FPAS and FSAS is a useful tool in research and clinical practice to examine the process of device adjustment and to identify patients at the high-risk device-specific anxiety is associated with worse emotional wellbeing after ICD implantation.

DECLARATIONS

Acknowledgement

The authors wish to express their appreciation to Prof. Dr. Samuel Sears for giving the permission to use FPAS and FSAS in this study. The present work was supported by the Research Fund of Istanbul University.

REFERENCES

[1] Burns, Jason L., et al. "Measuring patient acceptance of implantable cardiac device therapy." *Journal of Cardiovascular Electrophysiology* Vol. 16, No. 4, 2005, pp. 384-90.

[2] James, Cynthia A., et al. "General and disease-specific psychosocial adjustment in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy with implantable cardioverter defibrillators: a large cohort study." *Circulation: Cardiovascular Genetics* Vol. 5, No. 1, 2012, pp. 18-24.

[3] Morken, Ingvild M., et al. "Shock anxiety among implantable cardioverter defibrillator recipients with recent tachyarrhythmia." *Pacing and Clinical Electrophysiology* Vol. 35, No. 11, 2012, pp. 1369-76.

[4] Shea, Julie B. "Quality of Life Issues in Patients with Implantable Cardioverter Defibrillators Driving, Occupation, and Recreation." *AACN Advanced Critical Care* Vol. 15, No. 3, 2004, pp. 478-89.

[5] Pedersen, Susanne S., et al. "Correlates of Patient Acceptance of the Cardioverter Defibrillator: Cross-Validation of the Florida Patient Acceptance Survey in Danish Patients." *Pacing and Clinical Electrophysiology* Vol. 31, No. 9, 2008, pp. 1168-77.

[6] Lemon, Jim, and Sarah Edelman. "Psychological adaptation to ICDs and the influence of anxiety sensitivity." *Psychology, Health & Medicine* Vol. 12, No. 2, 2007, pp. 163-71.

[7] van Ittersum, Miriam, et al. "Fear of exercise and health-related quality of life in patients with an implantable cardioverter defibrillator." *International Journal of Rehabilitation Research* Vol. 26, No. 2, 2003, pp. 117-22.

[8] Whang, William, et al. "Depression as a predictor for appropriate shocks among patients with implantable cardioverter-defibrillators: results from the Triggers of Ventricular Arrhythmias (TOVA) study." *Journal of the American College of Cardiology* Vol. 45, No. 7, 2005, pp. 1090-95.

[9] Bilge, Ahmet Kaya, et al. "Depression and anxiety status of patients with implantable cardioverter defibrillator and precipitating factors." *Pacing and Clinical Electrophysiology* Vol. 29, No. 6, 2006, pp. 619-26.

[10] Luyster, Faith S., et al. "Resource loss predicts depression and anxiety among patients treated with an implantable cardioverter defibrillator." *Psychosomatic Medicine* Vol. 68, No. 5, 2006, pp. 794-800.

[11] Passman, Rod, et al. "Implantable cardioverter defibrillators and quality of life: results from the defibrillators in

nonischemic cardiomyopathy treatment evaluation study." *Archives of Internal Medicine* Vol. 167, No. 20, 2007, pp. 2226-32.

[12] Costa, Roberto, et al. "Incidence of shock and quality of life in young patients with implantable cardioverter-defibrillator." *Arquivos brasileiros de cardiologia* Vol. 88, No. 3, 2007, pp. 258-64.

[13] Johansen, Jens B., et al. "Symptomatic heart failure is the most important clinical correlate of impaired quality of life, anxiety, and depression in implantable cardioverter-defibrillator patients: a single-centre, cross-sectional study in 610 patients." *Europace* Vol. 10, No. 5, 2008, pp. 545-51.

[14] Pedersen, Susanne S., et al. "Clustering of device-related concerns and Type D personality predicts increased distress in ICD patients independent of shocks." *Pacing and Clinical Electrophysiology* Vol. 31, No. 1, 2008, pp. 20-27.

[15] Jacq, Fanny, et al. "A comparison of anxiety, depression and quality of life between device shock and nonshock groups in implantable cardioverter defibrillator recipients." *General Hospital Psychiatry* Vol. 31, No. 3, 2009, pp. 266-73.

[16] Thomas, Sue A., et al. "Changes in psychosocial distress in outpatients with heart failure with implantable cardioverter defibrillators." *Heart & Lung: The Journal of Acute and Critical Care* Vol. 38, No. 2, 2009, pp. 109-20.

[17] Van den Broek, Krista C., et al. "Risk of ventricular arrhythmia after implantable defibrillator treatment in anxious type D patients." *Journal of the American College of Cardiology* Vol. 54, No. 6, 2009, pp. 531-37.

[18] Pedersen, Susanne S., et al. "Shock and patient preimplantation type D personality are associated with poor health status in patients with implantable cardioverter-defibrillator." *Circulation: Cardiovascular Quality and Outcomes* Vol. 5, No. 3, 2012, pp. 373-80.

[19] Dunbar, Sandra B., et al. "Educational and psychological interventions to improve outcomes for recipients of implantable cardioverter defibrillators and their families." *Circulation* Vol. 126, No. 17, 2012, pp. 2146-72.

[20] Fritzsche, Kurt, et al. "Depressive coping is a predictor for emotional distress and poor quality of life in a German–Austrian sample of cardioverter-defibrillator implant recipients at 3 months and 1 year after implantation." *General Hospital Psychiatry* Vol. 29, No. 6, 2007, pp. 526-36.

[21] Sears, Samuel F., et al. "The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients." *Pacing and Clinical Electrophysiology* Vol. 30, No. 7, 2007, pp. 858-64.

[22] Kuhl, Emily A., et al. "Patient-assisted computerized education for recipients of implantable cardioverter defibrillators: a randomized controlled trial of the PACER program." *Journal of Cardiovascular Nursing* Vol. 24, No. 3, 2009, pp. 225-31.

[23] Lewin, Robert J., et al. "A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions." *Heart* Vol. 95, No. 1, 2009, pp. 63-69.

[24] Kuhl, Emily A., et al. "Measurement of patient fears about implantable cardioverter defibrillator shock: an initial evaluation of the Florida Shock Anxiety Scale." *Pacing and Clinical Electrophysiology* Vol. 29, No. 6, 2006, pp. 614-18.

[25] Chair, Sek Y., et al. "Quality of life outcomes in Chinese patients with implantable cardioverter defibrillators." *Pacing and Clinical Electrophysiology* Vol. 34, No. 7, 2011, pp. 858-67.

[26] Ford, Jessica, et al. "The Florida Shock Anxiety Scale (FSAS) for patients with implantable cardioverter defibrillators: testing factor structure, reliability, and validity of a previously established measure." *Pacing and Clinical Electrophysiology* Vol. 35, No. 9, 2012, pp. 1146-53.

[27] Akgül, A, Cevik, O. *Statistical Analysis Methods: SPSS Business Management Applications*. Ankara: Emek Ofset Ltd. Şti, 2013.

[28] Spielberger, C.D., et al, "Manual for the State-Trait Anxiety Inventory (Form Y)" Consulting Psychologists Press, Inc., Palo Alto, 1983.

[29] Beek, A.T., et al. "An inventory for measuring clinical anxiety: Psychometrie properties." *Journal of Consulting and Clinical Psychology* Vol. 56, No. 6, 1988, pp. 893-97.

[30] Tavşancıgil, E. *Data Analysis and Measurement of Attitudes with SPSS*. Ankara: Nobel Yayın Dağıtım, 2005.

[31] Hair, Joseph, et al. *Multivariate Data Analysis*. Upper Saddle River NJ: Prentice Hall, 1998.

[32] Versteeg, Henneke, et al. "Monitoring device acceptance in implantable cardioverter defibrillator patients using the Florida Patient Acceptance Survey." *Pacing and Clinical Electrophysiology* Vol. 35, No. 3, 2012, pp. 283-93.

[33] Raykov, Tenko, and George A. Marcoulides. *A first course in structural equation modeling*. Routledge, 2nd ed. Mahwah (NJ): Lawrence Erlbaum, 2006.

[34] Browne, Michael W., and Richard Cudeck. "Alternative ways of assessing model fit." *Testing structural equation models,* edited by Kenneth A. Bollen and J. Scott Long, SAGE publications, 1993, pp. 136-162.

[35] MacCallum, Robert C., Michael W. Browne, and Hazuki M. Sugawara. "Power analysis and determination of sample size for covariance structure modeling." *Psychological Methods* Vol. 1, No. 2, 1996, p. 130.

[36] Hu, Li-tze, and Peter M. Bentler. "Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives." *Structural Equation Modeling: A Multidisciplinary Journal* Vol. 6, No. 1, 1999, pp. 1-55.

[37] Schumacker, Randall E. and Richard G. Lomax. *A Beginner's Guide to Structural Equation Modeling, Volume 2*, Lawrence Erlbaum Associates, 2004.

[38] Brown, Timothy A. *Confirmatory Factor Analysis for Applied Research*, 2nd ed., Guilford Publications, 2015.

[39] Steiger, James H. "Understanding the limitations of global fit assessment in structural equation modeling." *Personality and Individual differences* Vol. 42, No. 5, 2007, pp. 893-98.

[40] Byrne, Barbara M. *Structural equation modeling with LISREL, PRELIS, and SIMPLIS: Basic concepts, applications, and programming*. Psychology Press, 1998, New Jersey: Lawrence Erlbaum Associates, 1998.

[41] Bentler, Peter M. "Comparative fit indexes in structural models." *Psychological bulletin* Vol. 107, No. 2, 1990, p. 238.

[42] Kelloway, E. Kevin, *Using LISREL for Structural Equation Modeling: A Researcher's Guide*, SAGE Publications, 1998.

[43] Kline, Rex B. *Principles and Practice of Structural Equation Modeling*, 3rd ed., Guilford Publications, 2011.

[44] Tabachnick, Barbara G. and Linda S. Fidell. *Using Multivariate Statistics*, 5th ed., Pearson Education Inc, 2007.

[45] Harrington, Donna. *Confirmatory Factor Analysis*. Oxford University Press, USA, 2009.

[46] Frary, Robert B. *Reliability of test scores*. http://ericae.net/ft/pug/reliabil.txt.

[47] Udlis, Kimberly A. "The impact of technology dependency on device acceptance and quality of life in persons with implantable cardioverter defibrillators." *Journal of Cardiovascular Nursing* Vol. 28, No. 6, 2013, pp. E65-E73.

[48] Wilson, Mary H., et al. "Disease-specific quality of life-Patient acceptance: Racial and gender differences in patients with implantable cardioverter defibrillators." *Journal of Cardiovascular Nursing* Vol. 28, No. 3, 2013, pp. 285-93.