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Original Article

An Evaluation of the Association between Quality of Life and Psychological Issues in Patients with Automated Implantable Cardioverter Defibrillator

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Abstract

Introduction: Implantable cardioverter defibrillator (ICD) plays a life-saving role via controlling malignant dysrhythmias. However, it may result in the incidence of psychological tensions in patients' lives, eventually leading to changes in their quality of life (QoL). To date, this association has remained unclear among Iranian population. Therefore, the present study aimed to determine the association between QoL and psychological issues in patients with ICD.

Methods: Using convenience sampling method, this cross-sectional study was conducted on 96 patients referred to the pacemaker clinic of Shahid Faghihi hospital and Kowsar heart hospital affiliated to Shiraz University of Medical Sciences, Iran from September 2016 to January 2017. The data were collected using Depression, Anxiety, Stress Scale (DASS-21) and the Short Form-36 (SF-36) questionnaire, and analyzed in SPSS software version 13 using independent t-test, Pearson's correlation test, and ANOVA.

Results: The mean (SD) score of patients' QoL was found to be 1672.02 (43.43). Moreover, the mean (SD) scores of depression, anxiety, and stress were 4.69 (0.46), 5.6 (0.47), and 7.51 (0.05), respectively indicating moderate depression, anxiety, and stress levels among the patients. A significant association was found between the patients' QoL and depression, anxiety, and stress.

Conclusion: As an association was observed between the patients' QoL and depression, anxiety, and stress, performing some interventions to reduce the patients' psychological issues might improve their QoL.

Introduction

Important progresses in diagnostic technologies and medical and surgical therapies have caused changes in the concept of healthcare during the past 20 years.[1] Implantable cardioverter defibrillator (ICD) is among such progresses in therapeutic technologies.[2] Evidence has indicated that ICD is superior to antidysrhythmic medications in reducing deaths resulting from cardiac dysrhythmias, as well as the risk of sudden cardiac death.[3] Moreover, ICD implantation has undergone considerable progresses in the recent years.[4] This device returns the cardiac rhythm to normal status by identifying the potentially dangerous cardiac rhythms and discharge of shock.[5] However, it might lead to psychosocial distresses in patients and, in case of inability to adapt with the device, affect their quality of life (QoL).[6]

Evidence has shown that almost half of patients experience discharge of shock within the first year after ICD implantation. Due to anxiety and fear from the probable discharge of shock, these patients severely restrict their daily activities, particularly sport activities, get depressed, and are not able to adapt with the device.[7] Hence, although ICD has a life-saving role,[8] it can lead to psychological vulnerability and social restrictions.[3] In this context, patients usually experience significant impairments in psychological status,[9] such as depression, anxiety,[10] fear, anger, and distress.[11] Fear and worries about physiological stimuli are among the psychological signs that are highly experienced by such patients.[12] In this respect, approximately 44% of patients experienced some degrees of shock anxiety, associated with cardiac fear, physical inactivity, and increased morbidity and mortality.[5]

Additionally, survival after sudden cardiac arrest,[13] frequent hospitalizations,[14] and invasive electrophysiological examinations[15] result in patients' instability.[16] The most common feelings include negative feelings due to unpredictability of the number

of shocks,[17] dependence on ICD, weak psychosocial adaptation, worries about one's status after cardiac arrest, depression, anger, and anxiety.[4] In fact, patients have to adapt with their lifestyle modifications, including driving limitations and reduction of ability to do hard work and sexual activities.[18] Moreover, recurrent shocks exert negative effects on patients' QoL. Researchers believe that discharge of shock is accompanied with negative mental outcomes and lower QoL.[6] In addition, reduction of energy, sleep problems, physical disorders, reduced physical contact with partners, and reduction of sport activities due to unpredictable shock discharges increase patients' concerns.[19] These may result in the onset of new life-threatening dysrhythmias, which can affect patients' survival.[20] Inadequate social support[21] and psychosocial factors (personal characteristics) are also effective in low QoL among ICD patients.[22] Furthermore, researchers believe that psychological attitudes, such as anxiety and depression, towards receiving shock play a critical role in prognosis of such patients' QoL.[14] In this regard, psychosocial variables, including optimism,[23] depression, anxiety, and social support[24] are effective in patients' QoL after ICD implantation.

Accordingly, treatment with ICD can be accompanied with mental distresses and psychological disorders in patients.[25] Indeed, such patients experience great discomfort due to treatment with shock,[4] and they may suffer from psychological distresses, such as anxiety, fatigue, and tensions.[26] In fact, these patients have problems in adapting with the device. Thus, they have to be examined with respect to the incidence of mental distresses.[14]

It was reported that emotional disorders,[27-29] anxiety,[30] pain,[30,31] fatigue, sleep disturbance,[31] and poor QoL[32,33] were common in some adult patients. So far, limited quantitative and qualitative[17,18,34] studies have been conducted on ICD patients in Iran. The association between QoL and psychological issues was obvious in a sample of the Iranian population. Therefore, identifying this association is so important. Psychological issues such as depression, anxiety, stress, and implantable shock anxiety might affect QoL in this group of patients.[35-37] Hence, the present study aimed to determine the association between QoL and psychological issues in patients with ICD. In this way, deeper insight can be gained regarding such patients' mental health issues and their needs, eventually promoting their QoL.

Materials and Methods

The population of this cross-sectional study included ICD patients referred to the pacemaker and ICD clinics of Shahid Faghihi hospital and Kowsar heart hospital affiliated to Shiraz University of Medical Sciences (SUMS), Iran. Using convenience sampling method, 96 patients referred to the mentioned clinics for device analysis from September 2016 to January 2017 were included. All participants signed a written informed consent.

The inclusion criteria were: living with ICD for more than one year, age above 18 years, speaking and understanding Persian, and not suffering from cognitive disorders. Totally, 96 patients (37 females and 59 males) with an age range of 18-78 years were enrolled.

The data were collected using the Short Form-36 (SF-36) questionnaire and the Depression, Anxiety, Stress Scale (DASS-21), and analyzed in SPSS software version 13 using independent t-test, Pearson's correlation test, and ANOVA. The first questionnaire included demographic information, such as age, sex, marital status, education level, occupation, living status (alone or with one's family), type of ICD, number of received shocks, date of device implantation, and name of the hospital.

In order to determine depression, anxiety, and stress levels, the DASS-21 was used.[38] This standard instrument has been used and its reliability and validity have been confirmed in studies conducted in Iran.[27,39] In the present study, the reliability of the questionnaire was approved by Cronbach's alpha ($\alpha = 0.93$). In 21-item questionnaire, seven items per subscale were allocated to assessing 3 subscales of depression, anxiety, and stress symptoms. The items were responded based on a 4-point Likert scale with the following options: 'not at all', 'mild', 'moderate', and 'high'. In addition, the minimum and maximum scores of each item were 0 and 3, respectively. Thus, after summing up the scores of the seven items related to each part, the patients' mental health status was categorized as 'normal', 'mild', 'moderate', 'severe', and 'extremely severe'[40] (Table 1).

The patients' QoL was evaluated using SF-36 questionnaire.[41] The Persian version of this questionnaire contained 36 items divided into eight dimensions as follows: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health perception. The items of this questionnaire were responded through either yes/no options or six options including 'always', 'usually', 'often', 'sometimes', 'rarely', and 'never'. Accordingly, the scores of each dimension ranged from 0 to 100, representing the most inappropriate and appropriate states, respectively. The reliability and validity of the original[42] and Persian[43] versions of the questionnaire were confirmed.

It should be noted that all research processes were done in accordance with the Declaration of Helsinki after gaining the approval of the Ethics Committee of Shiraz University of Medical Sciences (ethics code: EC-P-9368-6068). Prior to beginning the research, the study objectives were explained to all patients and they signed a written informed consent. They were also reassured about the confidentiality of their data.

Finally, the data were entered into the SPSS software version 13 and analyzed using descriptive and inferential statistics mean (SD), independent t-test, Pearson's correlation test, and ANOVA.

Table 1. The characteristics of the participants

Demographic characteristics	No. (%)
Gender	
Male	59 (61.5)
Female	37 (38.5)
Marital status	
Single	11(11.5)
Married	78 (81.2)
Divorced	7 (6.3)
Type of living	
Living with family	90 (93.8)
Living alone	6 (6.2)
Education level	
Illiterate	21 (21.9)
High school	57 (59.4)
College degree	18 (18.7)
Employment status	
Student	6 (6.4)
Employee	14 (15.0)
Home maker	28 (30.1)
Disabled	21 (22.8)
Retired	24 (25.7)
First hospital for ICD insertion	
Nemazi	3 (3.1)
Kowsar	43 (44.8)
Faghihi	42 (43.8)
Others	8 (8.3)

ICD, implantable cardioverter defibrillator.

Results

The patients' age was 51.1(26.57) years. Among the participants, the majority of subjects were male, married, lived with family, and had high level of education (Table 1). Based on the results of echocardiography, the mean (SD) of Ejection Fraction (EF) was 37.23 (4.09). Besides, an average of 2.47 (0.27) years had passed from ICD implantation and the patients had received shocks for an average of 2.16 (0.42) times.

The results revealed that the majority of patients had normal mental health status. However, the mean (SD) scores of depression and stress were 4.69 (0.46) and 7.51 (0.05), respectively, indicating mild levels of depression, and stress. The mean (SD) score of anxiety was 5.6 (0.47), indicating a moderate level of anxiety among the patients (Table 2).

The results demonstrated no significant association between depression, anxiety, and stress scores and gender, marital status, living status (alone or with one's family), education level, employment status, and first hospital for ICD insertion (Table 3).

The participants' scores of QoL ranged from 705 to 2550 with the mean (SD) score of 1672.02 (SD = 43.43). The reduction in QoL was particularly related to physical functioning with the mean score of 184.14 (8.91) (Table 4).

The results revealed no significant correlation between QoL and gender, marital status, living status, education level, employment status, and first hospital for ICD insertion (Table 5).

Moreover, the association between various dimensions of QoL and age, EF, and date of ICD implantation was assessed using Pearson's correlation test, the results of which revealed a significant association between pain and patients' age ($r = 0.29$, $P = 0.004$) (Table 6).

The results also indicated a significant negative association between depression, anxiety, and stress levels and various dimensions of QoL. Nonetheless, no significant correlations were observed between depression, anxiety, and stress levels and physical functioning dimension (Table 7).

Discussion

The results of this study revealed a significant reverse association between depression, anxiety, and stress scores and the patients' QoL. Moreover, the majority of patients had a normal mental health status. However, the mean scores of depression, anxiety, and stress showed mild depression and stress levels and moderate anxiety levels. Similarly, researchers reported anxiety in 46% and depression in 41% of the ICD patients.[44] Shiga et al also stated that 30% of ICD recipients showed depression, and ICD shocks might contribute to the persistence of depression. Anxiety was common in ICD patients.[45] Similarly, it was reported that a large number of patients had degrees of anxiety and depression before cognitive-

Table 2. Frequencies and mean (SD) of depression, anxiety, and stress

Mental health status (range)	No. (%)	Mean (SD)
Depression level		
Normal (0-4)	52 (54.2)	
Mild (5-6)	17 (17.7)	
Moderate (7-10)	17 (17.7)	4.69 (0.46)
Sever (11-13)	4 (4.2)	
Extremely severe (+14)	6 (6.2)	
Anxiety level		
Normal (0-3)	45 (46.9)	
Mild (4-5)	13 (13.5)	
Moderate (6-7)	14 (14.6)	5.6 (0.47)
Sever (8-9)	9 (9.4)	
Extremely severe (+10)	15 (15.6)	
Stress level		
Normal (0-7)	53 (55.2)	
Mild (8-9)	13 (13.6)	
Moderate (10-12)	15 (15.6)	7.51 (0.05)
Sever (13-16)	15 (15.6)	
Extremely severe (+17)	0 (0.0)	

Table 3. The association between depression, anxiety, and stress level in patients and demographic and clinical characteristics

Variable	Mean (SD)		
	Depression	Anxiety	Stress
Gender			
Male	4.84 (0.61)	5.35 (0.64)	7.55 (0.74)
Female	4.45 (0.7)	4.59 (0.67)	7.43 (0.59)
P value[a]	0.68	0.43	0.90
Marital status			
Single	3.81 (0.96)	3.9 (1.09)	6.63 (0.74)
Married	4.97 (0.54)	5.37 (0.54)	7.74 (5.21)
Divorced	2.66 (2.33)	2.83 (1.94)	5.16 (2.31)
P value[b]	0.59	0.46	0.38
Living status			
Living with family	4.73 (0.48)	5.04 (0.49)	7.5 (0.51)
Living alone	4.16 (1.13)	5.33 (1.7)	7.66 (2.67)
P value[a]	0.76	0.88	0.37
Education level			
Illiterate	6.28 (1.13)	6.57 (1.15)	9.42 (1.3)
High school	4.84 (0.58)	5.33 (0.60)	7.65 (0.58)
College degree	2.66 (1.15)	2.22 (1.13)	5.5 (1.44)
P value[b]	0.10	0.06	0.11
Employment status			
Students	3.66 (0.88)	3.16 (1.32)	7.83 (1.49)
Employee	3.07 (0.75)	3 (0.70)	5.42 (1.15)
Home maker	4.78 (0.89)	5.25 (0.81)	7.75 (0.71)
Disabled	5.64 (1.51)	5.85 (1.27)	8.71 (1.87)
Retired	5.58 (0.95)	4.83 (0.95)	6.95 (0.94)
P value[b]	0.61	0.19	0.28
First hospital for ICD insertion			
A	7 (1.00)	8 (3.21)	5.66 (0.66)
B	4.11 (0.6)	5.04 (0.75)	7.65 (0.80)
C	4.61 (0.74)	4.54 (0.60)	7.26 (0.71)
D	7 (2.13)	6.75 (2.08)	8.75 (2.20)
P value[b]	0.33	0.42	0.79

[a] Independent t-test; [b] ANOVA.

behavioral interventions.[46] Others reported depression among patients after ICD implantation.[47]

The mean score of QoL was 1672.02, which was more than one third (M = 1200) of expected score. It showed that the mean score of QoL was in moderate level. This study also indicated that the lowest reduction in mean QoL score was related to physical functioning. The results showed a significant association between pain subscale of Qol and patients' age. Researchers indicated that experience of shock discharge, age, gender (female), and clinical features (diabetes and coronary artery disease) could affect patients' QoL.[22] In this regard, younger patients might face more problems in adapting with ICD, experience anxiety, depression, and sleep disorders, and have lower QoL in comparison to elderly ones.[48] However,

Table 4. Mean (SD) and maximum of quality of life (QoL) and each dimension

QoL	Max in QOL and each dimension	Mean (SD)
Total	3600	1672.02 (43.43)
Dimensions		
Physical functioning	1100	184.14 (8.91)
Role limitations due to physical health	400	151.06 (15.48)
Role limitations due to emotional problems	300	160.63 (13.46)
Energy/fatigue	300	186.38 (6.82)
Emotional well-being	500	316.8 (11.10)
Social functioning	200	154.09 (4.47)
Pain	200	151.7 (5.11)
General health perception	600	358.24 (10.90)

Table 5. The association between QoL level in patients and demographic and clinical characteristics

Variable	QoL Mean (SD)	*P* value
Gender		
Male	1674 (57.46)	0.94[a]
Female	1668 (66.05)	
Marital status		
Single	1741.11(131.86)	0.66[b]
Married	1668.2 (47.90)	
Divorced	1821 (185.96)	
Living status		
Living with family	1666.37 (45.17)	0.37[a]
Living alone	1841 (214.61)	
Education level		
Illiterate	1480.25 (100.8)	0.01[b*]
High school	1656 (53.57)	
College degree	1862 (110.29)	
Employment status		
Students	1808 (215.74)	
Employee	1753 (101.31)	0.37[b]
Home maker	1624.42(82.62)	
Disabled	1569.58(145.84)	
Retired	1454.28(161.86)	
First hospital for ICD insertion		
A	1526.66(105.29)	
B	1708.25 (62.62)	0.67[b]
C	1677.02 (73.26)	
D	1553.18(132.02)	

[a] Independent t-test; [b] ANOVA; *Statistically significant.

some studies including the one performed by Carroll and Hamilton have shown that physical QoL was higher in younger patients with ICD compared to older ones, while no significant difference was observed between the two groups with respect to mental QoL. Carroll and Hamilton also assessed QoL in patients with ICD and came to the

Table 6. Association between QoL and three demographic and clinical characteristics in patients with ICD using Pearson correlation coefficient

Dimensions	Age	Ejection fraction	Date of ICD implantation
Physical functioning	r=0.03, *P*=0.73	r=0.03, *P*=0.91	r=0.09, *P*=0.37
Role limitations due to physical health	r=0.03, *P*=0.76	r=-0.21, *P*=0.49	r=-0.07, *P*=0.94
Role limitations due to emotional problems	r=0.08, *P*=0.43	r=- 0.09, *P*=0.77	r=-0.15, *P*=0.15
Energy/fatigue	r=0.01, *P*=0.92	r=-0.37, *P*=0.23	r=0.02, *P*=0.79
Emotional well-being	r=0.03, *P*=0.73	r=0.19, *P*=0.54	r=- 0.12, *P*=0.22
Social functioning	r=0.15, *P*=0.15	r=-0.35, *P*=0.26	r=0.14, *P*=0.18
Pain	r=0.29, *P*=0.004*	r=0.12, *P*=0.69	r=0.03, *P*=0.73
General health perception	r=0.03, *P*=0.72	r=0.22, *P*=0.49	r=-0.06, *P*=0.54

*Statistically significant.

Table 7. Correlations between QoL dimensions with depression, anxiety, and stress in patients with ICD using Pearson's correlation coefficient

QoL	Depression	Anxiety	Stress
Total	r=-0.71*, *P*<0.001	r=-0.62*, *P*<0.001	r=- 0.68*, *P*<0.001
Dimensions			
Physical functioning	r=0.09, *P*=0.34	r=0.12, *P*=0.21	r=0.63, *P*=0.54
Role limitations due to physical health	r=-0.31*, *P*=0.002	r=-0.32*, *P*=0.002	r=-0.34*, *P*=0.001
Role limitations due to emotional problems	r=-0.43*, *P*<0.001	r=-0.40*, *P*<0.001	r=-0.29*, *P*=0.003
Energy/fatigue	r=-0.64*, *P*<0.001	r=-0.53*, *P*<0.001	r=-0.58*, *P*<0.001
Emotional well-being	r=-0.60*, *P*<0.001	r=-0.46*, *P*<0.001	r=-0.65*, *P*<0.001
Social functioning	r=-0.43*, *P*<0.001	r=-0.39*, *P*<0.001	r=- 0.50*, *P*<0.001
Pain	r=-0.41*, *P*<0.001	r=-0.52*, *P*<0.001	r=-0.32*, *P*=0.001
General health perception	r=-0.49*, *P*<0.001	r=-0.39*, *P*<0.001	r=-0.51*, *P*<0.001[a]

*Statistically significant.

conclusion that the patients who had experienced shock discharge had lower mental health, vitality, and physical health.[49] Similarly, it was reported that increase in the number of received shocks decreased the patients' QoL.[50] On the other hand, Herman et al referred to the life-saving role of the device as well as its role in improvement of the patients' feeling of safety. In this regard, 95.8% of patients in secondary prevention group and 89.4% of patients in the primary prevention group reported feeling safer following ICD implantation.[51] Yet, Pasyar et al pointed to fear from unknown feelings and unpredictable discharge of shock.[52] Tripp et al also referred to fear from life status.[5] Similarly, Mohammadi et al reported an increase in anxiety levels among the patients with the experience of shock discharge.[53]

The findings of this study revealed a significant association between depression, anxiety, and stress levels and the patients' QoL. Mental imbalance could strengthen the pathological process in patients and increase the risk of sudden death.[48] Therefore, psychosocial cares have been recommended to be applied for patients routinely.[25] In addition to utilization and monitoring of psychological medications with respect to intensification of ventricular dysrhythmias,[2] cognitive-behavioral therapies have been suggested to reduce negative mental pressures among patients.[54] In this context, it was mentioned the necessity for multi-professional healthcare teams including cardiologists, nurses, mental health specialists, and rehabilitation specialists in treatment of patient.[55] Such teams could help patients perceive their emotions and reactions. It also indicated the patients' need for management skills and social support for adaptation with ICD. This could be achieved by providing patients with the required information, creating motivation towards how to behave in the new life conditions and promote their mental adaptation.[4]

As mentioned, our study results showed moderate level of QoL and the lowest reduction of QoL was reported in physical functioning. This emphasizes the necessity to eliminate barriers against providing the patients with continuous, comprehensive, and holistic care services and to improve team approach in holistic care to promote the patients' QoL.

One of the limitations of the current study was dependence of QoL on individuals' experiences and expectations, which could fluctuate over time depending on developmental, environmental, and seasonal factors. Other limitation was the small sample size and cross-sectional design of the study. Thus, further longitudinal studies with larger sample sizes are recommended to be conducted on the issue. This study can be effective in providing the patients with training and consultation in physical, mental, and social dimensions and play a key role in their experience of the device's positive impacts on their lives. Qualitative studies on patients' experiences can add to the existing knowledge in this field.

Research Highlights

What is the current knowledge?

The patients with ICD might suffer from psychological issues.

QoL of patients with ICD might be different compare to other people.

What is new here?

The patients with ICD reported moderate stress, depression, and anxiety levels.

The mean score of QoL was 1672.02, which was more than one third (M = 1200) of expected score.

An association was between QoL and depression anxiety, and stress.

Conclusion

The findings of this study revealed a significant reverse association between depression, anxiety, and stress scores and the patients' QoL. Therefore, strategies such as training, consultation, and supportive groups are recommended to improve the patients' mental health. Supportive groups can be considered as an adjuvant therapy for patients with ICD.

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Authors' Contributions

NP, MR, PM: Conceptualization, methodology, analysis, supervision; NP, MR, PM, MHN: Data collection, study validation, writing original draft preparation, writing-review and editing, project administration. All the authors have read and agreed to the published version of the manuscript.

Ethical Issues

This study was approved by the University's Ethics Committee (ethics code: EC-P-9368-6068).

Conflict of Interest

The authors declare no conflict of interest in this study.

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