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Shoulder problems and related conditions in patients with implantable cardioverter defibrillators

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Abstract

Aim: Shoulder pain and disability is a complication that can be seen frequently after implantable cardioverter defibrillator (ICD) implantation. The aims of this study were to determine the causes of shoulder problems and related factors in patients with ICD implantation and to investigate the effects of shoulder problems on quality of life and psychological status.

Material and Methods: A total of ninety-four consecutive patients (average age 59.38±10.75 years) who admitted to ICD follow up clinic were included in the study. Patients who had shoulder problems were referred to our physical therapy and rehabilitation outpatient clinic for further evaluation. The Shoulder Pain and Disability Index (SPADI), Short Form-36 (SF-36) and The Hospital Anxiety and Depression Scale (HADS) were used as the clinical assessment scales.

Results: Thirty-nine (41.5%) patients had shoulder complaints. The patients were divided into two groups according to presence of shoulder problem. The statistical analysis revealed no significant differences between the groups in terms of the socio-demographic and clinical characteristics. None of these characteristics was demonstrated as a risk factor for the development of shoulder problem ($p>0.05$). There were significantly lower SF-36 subgroup scores and higher HADS depression and anxiety scores in patients with shoulder complaints. The SPADI scores also showed significant correlations with shoulder pain VAS score, several subgroups of SF-36 and HADS scores ($p<0.05$).

Conclusion: Our study revealed that patients with shoulder complications had decreased quality of life and deteriorated psychological status. In patients with ICD, awareness should be increased in terms of shoulder problems and appropriate management strategies should be determined.

Keywords: Disability; implantable cardioverter defibrillator; shoulder; pain; psychological status.

INTRODUCTION

Implantable cardioverter defibrillator (ICD) has been the main treatment to prevent sudden cardiac death in patients with known ventricular tachycardia or fibrillation. ICD implantation is also recommended in selected patients who are at a high lifetime risk for ventricular tachycardia. ICD devices are mostly placed in the pectoral area of the non-dominant side either subcutaneously or subpectorally. The patients with ICD most likely may resume normal lifestyle but sometimes ICD implantation can be associated with complications which significantly influence the patient's comfort. (1-4) These complications may be related to implantation procedure, type and size of the inserted generator, number of the leads implanted and presence of inappropriate shocks. (5) Incidence of serious adverse events like pneumothorax and cardiac arrest ranged from 1.2 to 1.4% (6).

Shoulder problem is also an important complication that may occur after ICD implantation. Ignorance of shoulder complication may lead to pain, disability and decreased quality of life. Several factors such as prolonged immobilization of the shoulder and physical trauma

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caused by the generator and/or catheters may lead to this outcome. (2) There is no consensus on the limitation period of upper extremity movements after implantation. Some physicians suggest early mobilization, as well as some recommend to limit excess movements for a few weeks. The general approach is to extend the limitation period until the device and leads are fixed with fibrosis in the subcutaneous tissue, pectoralis muscles and/or the endocardium. But sometimes patients can keep this time longer with the concern of the dislocation of the ICD and/or leads. (4,7,8)

In the literature, the studies evaluating the shoulder problem as an ICD-related complication are limited. These studies mostly focused on the effects of ICD implantation on shoulder pain and disability. (1,2,4,9) The aims of this study were; to determine shoulder problems and related factors in patients with ICD implantation and to investigate the effects of shoulder problems on quality of life and psychological status.

MATERIAL and METHODS

A total of one hundred thirty-five consecutive patients with ICD were evaluated between February 2015 and January 2016 in ICD follow up clinic of the cardiology department. Patients with the history of ipsilateral shoulder injury and surgery, previous shoulder disease, inflammatory rheumatic diseases, neuromuscular disease, and cognitive impairment were excluded. Therefore, 41 patients were excluded and consequently 94 patients with ICD implantation were eligible for the study (Figure 1). Patients who had shoulder problems were referred to our physical therapy and rehabilitation outpatient clinic for further evaluation and examination. All patients were questioned about socio-demographic characteristics, systemic diseases, drug use, smoking, place of implantation (subpectoral/subcutaneous), indication of ICD (ischemic and non-ischemic causes), ejection fraction of heart, duration of implantation, implantation related complications, and number of the electrodes. Detailed physical examination (inspection, palpation, muscle strength testing, and evaluation of shoulder range of motion with goniometer and special tests for shoulder), imaging methods [radiography (posterior-anterior and lateral view), ultrasonography] and laboratory assessment methods were applied when needed for diagnosis. The severity of shoulder pain was assessed by visual analog scale (VAS). VAS scores ≤ 3 corresponded to mild, scores of 4-6 to moderate and scores ≥7 to severe pain. (10) Type of pain, factors that increase and decrease the pain and the treatment approaches were also questioned. This study was approved by the local ethics committee and we received informed consent from all patients.

ICD implantation

All ICDs were implanted subcutaneously or subpectorally under local anesthesia in the cardiac catheterization laboratory. A 5–7 cm skin incision for the subcutaneous pocket is made in the infraclavicular area on the left side. Dissection is performed until pectoral facia with the use of electrocautery or blunt dissection. The dissection is enlarged to accommodate to the size of the battery. All leads were inserted via subclavian vein puncture or cephalic vein cut-down. Single-lead, two-leads or three-leads (biventricular) ICD systems were used according to the clinical indication with respect to the left ventricular systolic function and present conduction abnormality of the heart. After proper placement, leads were tested for impedance and capture thresholds. Routine high output pacing was performed to be sure that phrenic nerve stimulation was absent. The leads were usually secured to pectoralis muscle with silk suture and then connected to the pulse-generator. In subpectoral implantation, the ICD device secured to the prepectoral facia or pectoralis muscle with non-absorbable suture. Skin and subcutaneous layers are then sutured with absorbable thread.

Evaluation of shoulder pain and disability

The Shoulder Pain and Disability Index (SPADI) is a self-administered instrument that assesses pain and functional status of the shoulder. SPADI contains 13-items to evaluate 2 subscales; 5-items measures the severity of an individual's pain and 8-items measures disability in term of the degree of difficulty on various daily living activities. (11) It's Turkish validity and reliability study was conducted by Bumin et al. (12) A 10 cm visual analog scale is used for each question and patients place a mark on it according to the severity of pain or difficulty. The total score is calculated by averaging the subscale scores. Higher scores indicate more severe pain and disability. (13)

Evaluation of health-related quality of life

Short Form-36 (SF-36) was used to assess the functional health and well-being of the patients. This questionnaire consists of 8 subscales including 36 questions. These scales investigate physical and social function, emotional and physical role, bodily pain, general health, vitality, and mental health. Each scale is transformed into a score between 0 and 100, and higher scores indicate better health status. (14)

Evaluation of Anxiety and Depressive Symptoms

The Hospital Anxiety and Depression Scale (HADS) is a 14-item measure designed to evaluate depression, anxiety, and emotional distress. It has two subscales for anxiety and depression each containing 7-items. Items are rated on a 4-point Likert scale ranging from 0 to 3. The entire scale (emotional distress) ranges from 0 to 42 and higher scores indicate more symptom severity. 7 point is used as the cut-off score for depression subscale and 10 point for anxiety subscale. (15)

Statistical analysis

SPSS software package (version 20.0, SPSS Inc., Chicago, IL) was used for statistical analysis. Distributions of continuous variables were evaluated with the Shapiro-

Wilk test. Continuous variables were presented as mean±standard deviation and discrete variables as median (minimum-maximum). Categorical variables expressed as number (n), and percentage (%) and the differences between the groups were compared with the chi-square test or Fisher Exact test. The significances of the difference in mean values between the two groups were analyzed with Student T-test. The linear relationship between SPADI scores and other clinical assessment scale scores were evaluated with Pearson correlation analysis. A backward stepwise logistic regression analysis was used to assess independent predictors associated with shoulder problem development (dependent variable) in patients with ICD implantation. Variables which were found to be significantly different between the groups (patients with and without shoulder problem) were included as candidate risk factors to the multivariate logistic regression model and evaluated with univariate analysis. Variables, for which the unadjusted p-value was < 0.10 in univariate analysis were incorporated into the full model. The result of the power analysis according to the logistic regression model was 0.70.

RESULTS

The average age of all 94 patients with ICD implantation was 59.38±10.75 (37-88). Thirty-nine patients (41.5%) had shoulder pain with/without limitation. The patients were divided into two groups according to presence of a shoulder problem. Ten patients had mild pain, 19 had moderate and 10 had severe pain. Twelve patients had a limitation of the range of shoulder joint. The socio-demographic and clinical characteristics of the groups (39 patients with a shoulder problem and 55 patients without a shoulder problem) and the comparisons were shown in Table 1. The statistical analysis revealed no significant differences between the groups. We also performed multivariate logistic regression analysis and it was found that none of the clinical and socio-demographical characteristics was a risk factor for the development of shoulder problem in patients with ICD implantation after adjustment for confounding variables

Table 1. Evaluation of socio-demographic and clinical characteristics in patients with and without shoulder problem

Variables	shoulder problem+ (n=39)	shoulder problem- (n=55)	p
Age, years	59.3±10.4	59.4±11.1	0.91
Gender, female/male	11/28(28.2/71.8)	8/47(14.5/85.5)	0.10
BMI, kg/m2	28.31±4.9	28.36±4.9	0.91
Educational status, low/high	35/4 (89.8/10.2)	47/8 (85.5/14.5)	0.40
Marital status, married/unmarried	34/5 (87.1/12.9)	53/2 (96.4/3.6)	0.07
Working status,working/not-working	31/8 (79.5/20.5)	48/7 (87.3/12.7)	0.31
Income, low /medium	9/30 (23.1/76.9)	6/49 (10.9/89.1)	0.11
Active smoking	3 (7.7)	5 (9.1)	0.23
Comorbidities			
DM	15 (38.5)	13 (23.6)	0.12
HT	35 (89.7)	49 (89.1)	0.87
Dislipidemia	17 (43.6)	29 (52.7)	0.38
Place of implantation			
Subpectoral / subcutaneous	4/35(10.3/89.7)	7/48(12.7/87.3)	0.71
Indication of ICD			
Ischemic HF/non-ischemic HF	23/16(59/41)	33/22(60/40)	0.68
Duration of implantation, month	35.9±21.5	30.1±19.7	0.10
Number of the electrodes (1/2)	29/10(74.3/25.7)	48/7(87.2/12.7)	0.07

Values are mean± SD or n (%) Significance at P<.05
Abbreviations: BMI: Body Mass Index, DM: Diabetes Mellitus HF: Heart Failure HT: Hypertension
ICD: Implantable cardioverter defibrillator
The educational status low: earlier than high school, high: high school and university

(p>0.05). (Table 2).

Table 2. Pain assessment in patients with shoulder problems, n=39

Variables	
Pain VAS, mean±SD (min-max)	5.25±1.96 (1-8)
Severity of pain, n(%)	
Mild	10(25.6)
Moderate	19(48.7)
Severe	10(25.6)
Duration of pain, month, mean±SD (min-max)	17.47±17.11 (1-72)
Acute, n(%)	4 (10.3)
Subacute, n(%)	3 (7.7)
Chronic, n(%)	32 (82.1)
Side of the body, n(%)	
Unilateral	28 (69.2)
Bilateral	11 (28.2)
Quality of pain, n(%)	
Sharp and stabbing	13(33.3)
Dull	12 (30.8)
Aching	1(2.6)
Throbbing	3(7.7)
Burning	6(15.4)
Numbness and Tingling	4(10.2)
Frequency, n(%)	
Continuous	5(12.8)
Intermittent	34 (87.2)
Type of pain, n(%)	
Nosiseptive	33(84.6)
Neuropathic	2(5.12)
Mixed	4(10.3)
Presence of limitation, n(%)	12(30.8)

VAS: Visual analog scale

Among the patients with shoulder problems, the average pain VAS score was 5.25±1.96 and total SPADI score was 42.53±21.34 (0.05-83.07) [pain subscale 48.86±20,69 (0,12-88); disability subscale 37.5±24,71(0-95)].The detailed assessment of shoulder pain was shown in Table 3. As a result of clinical evaluation; 32 of the patients (82%) had rotator cuff lesion, 21(53.8%) had degenerative joint disease, 17 (43.6%) had bicipital tendinitis and 9 of the patients (23%) had myofascial pain syndrome. Besides, 8 patients (20.5%) had rotator cuff lesion, degenerative joint disease, and bicipital tendinitis together. Patients were also questioned whether they had received any treatment for shoulder pain and/or limitation.

Table 3. Evaluation of clinical assessment scales in patients with and without shoulder problem

Variables	shoulder problem+ (n=39)	shoulder problem- (n=55)	p
HADS			
HADS-A	9.1±4.6	3.6±3.2	<0.001
Anxiety+	14(35.9)	3(5.5)	<0.001
HADS-D	8.2±4.1	5.1±3.2	<0.001
Depression+	19(48.7)	12(21.8)	0.006
SF-36			
Physical function	38.5±15.7	59.9±12.8	<0.001
Physical role limitation	32.8±10.5	72.1±10.1	<0.001
Bodily pain	54.1±22.8	84.2±20.5	<0.001
General health	42.8±17.5	56.2±15.4	<0.001
Vitality	38.3±18.1	66.7±17.1	<0.001
Social function	64.7±27.1	82.5±22.3	0.001
Emotional role limitation	41.8±13.74	83.0±10.6	<0.001
Mental health	52.4±21.3	81.09±16.2	<0.001

Values are mean+ SD or n (%)
HADS: The Hospital Anxiety and Depression Scale. SF-36: Short Form-36

Table 4. Correlations between SPADI -total and clinical assessment scales

Variables	r	p
Shoulder pain VAS	0.76	**<0.001**
HADS-A	0.53	**<0.001**
HADS-D	0.31	**0.04**
SF-36		
Physical function	0.09	0.56
Physical role limitation	-0.009	0.95
Bodily pain	-0.46	**0.003**
General health	-0.29	0.06
Vitality	-0.47	**0.003**
Social function	-0.41	**0.008**
Emotional role limitation	-0.33	**0.03**
Mental health	-0.57	**<0.001**

HADS: The Hospital Anxiety and Depression Scale
SF-36:Short Form-36 VAS: Visual analog scale

It was revealed that 24 (61.5%) patients did not receive previous treatment, while 12 (30.7%) of them received only medical treatment.Our study also revealed significantly lower SF-36 subgroup scores and higher HADS depression and anxiety scores in patients with shoulder problems

(p<0,05). Taking 10 as a cut off point for HADS anxiety subscale and 7 point for depression; we found that the rate of the patients at risk for anxiety and depression were significantly higher in patients with shoulder problem. (Table 4)

We also investigated the correlations of SPADI total scores with sociodemographic properties and clinical scale scores. We demonstrated significant relations between SPADI and shoulder pain VAS score, SF-36-pain, vitality, social function, emotional role limitation and mental health subgroups , HADS anxiety and depression subgroups. (p<0.05) (Table 5).

Table 5. The results of multivariate logistic regression analysis to detect the risk factors for the development of shoulder problems

Variables	Odds Ratio	%95 CI	p-value
Age	0.996	0.95-1.04	0.84
Sex	2.008	0.81-6.98	0.13
Place of implantation	0.634	0.15-2.66	0.53
Duration of implantation	0.847	0.56-1.28	0.43
Number of the electrodes	0.14	0.25-1.97	0.14

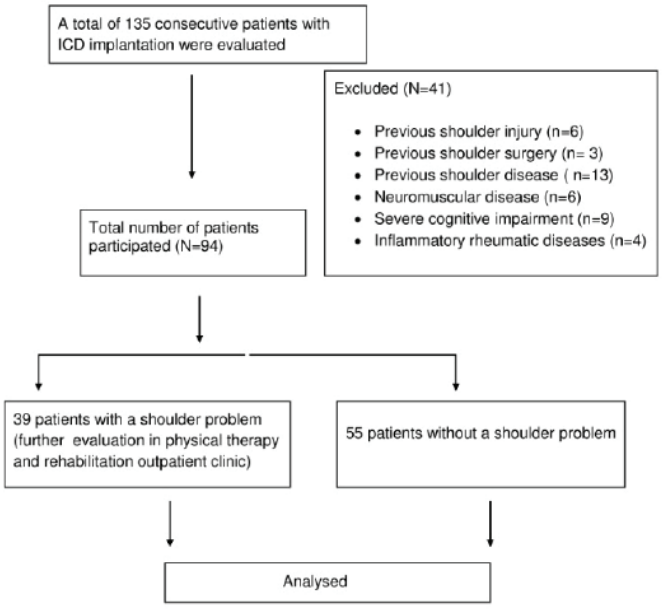

Figure 1. Flow diagram for subject enrollment in this study

DISCUSSION

Implantable cardioverter defibrillator is used in primary and secondary prevention of sudden cardiac death and its use has become widely increased in recent years. Shoulder pain and disability is a complication that can be seen frequently after implantation and adversely affects daily living activities. In our study, we aimed to determine the shoulder problems in patients with ICD implantation and examine the risk factors that may lead to the development of shoulder pain and/or limitation. In addition, we evaluated its effects on quality of life and psychological status. As a result, 41.5% of the patients with ICD had shoulder complaints. Among the socio-demographic and clinical factors, none of them was found to be the risk factor for the development of shoulder problems. The patients with shoulder complications also had a markedly decreased level of quality of life and an increased rate and severity of anxiety and depression compared to patients without shoulder complications.

In the literature, the number of studies examining shoulder problems after ICD implantation is limited. These studies usually focused on the occurrence and course of the shoulder pain and disability after implantation. (1,2,4,9) In Korte et al.'s study, shoulder problems and functions were evaluated within the first year of the subpectoral ICD implantation. At the third month assessment, they revealed that 60% of the patients had shoulder limitation which decreased during follow up with the rate was only 8% at the 12 month visit. Similarly, they demonstrated that having ipsilateral pain was dropped from 62% to 10% at the one-year evaluation.(1) In another study, Diemberger et al. investigated the patients with subcutaneous ICD implantation during 3 months. In the evaluation of the quality of life, physical and mental component scores decreased at 2 weeks evaluation but physical component scores recovered in the 3rd month follow-up. Similarly, upper extremity functions improved and pain intensity decreased at 3rd month assessment. (2) These studies show that most of the parameters improved over time and the rate of disability in patients who underwent subcutaneous ICD implantation was lower compared to subpectoral implantation at the 3rd month evaluation. Our study has a cross-sectional design and does not examine the changes in shoulder pain and limitation at the post-implantation period. We included patients with both subpectoral and subcutaneous ICD implantation and there was no significant difference between the groups of patients with and without shoulder problems in terms of implantation location.

In our study, we evaluated 94 consecutive patients referred to the ICD follow-up outpatient clinic and found that 41.5% had shoulder complaints. The detailed evaluation showed that these complaints were due to rotator cuff lesion, degenerative joint disease, bicipital tendinitis, and myofascial pain syndrome and several combinations of these diseases. Although shoulder problems were frequently seen; the majority of patients (61.5%) had received no treatment for these complaints. Thirty percent of the patients received only medical treatment but no physical treatment approach was applied. Since patients prioritize cardiac problems in the post-implantation period, they do not care about shoulder problems and therefore do not receive adequate evaluation and treatment. However, as our study revealed, there was a significant deterioration in the quality of life and psychological status in patients with shoulder problems. This study also demonstrated that disability of shoulder (SPADI scores) was correlated with the severity of pain, anxiety and depression and several subgroups of SF-36. Although the cause-effect relationship could not be established due to the design

of our study; we think that anxiety and depression may have triggered pain and disability, as well as shoulder disabilities, may have a negative effect on psychological status.

In the literature, limited studies exist evaluating predictors of shoulder-associated problems in patients with ICD implantation. (1,2,4,9) Among them, Diemberger et al. revealed that post-procedure pain was the most important independent predictor of short-term shoulder impairment and they emphasized the importance of good pain management. (2) In another study, Celikyurt et al. demonstrated that patients with three-leads ICD have significantly higher SPADI scores than patients with single-lead ICD and the number of leads correlated with pain, disability subscales, and total SPADI scores. They demonstrated that number of lead was the only predictor of shoulder pain and disability. (9) They explained this result with the greater dimensions of the three-leads ICDs compared to two-leads and single-lead ICDs. ICD devices could lead imbalances in shoulder complex muscles by the restriction of the pectoralis fascia with the effects of both volume and related inflammation of the device. (9,16) Differently, Korte et al. analyzed sex, age, body height, body weight, and body surface area as possible predictors of shoulder-associated problems after subpectoral ICD implantation but none of these factors was able to predict the shoulder complication. (1) Similarly, in our study, we couldn't demonstrate significant risk factor for the development of shoulder problems. A limited number of participants may have contributed to this outcome.

Several mechanisms have been proposed for the development of shoulder problems in patients with ICD implantation. The direct effects of ICD device and catheters and prolonged immobilization of the shoulder joint as a physician's advice or patient's fear of lead dislodgement may lead to this result. (2,4) Appropriate exercise programs including range of motion, stretching and strengthening should be applied to this patient group to prevent or to treat shoulder pain and disability. (17,18) In the literature, there is no consensus on the immobilization duration after implantation. Some physician suggest early mobilization, while others suggest a few weeks of movement limitation in order to wait for the formation of fibrosis around the device and lead to reduce the risk of dislodgement . (4,7,8)

Study limitations

Our study is a cross-sectional observational study and does not reveal a cause-effect relationship. The detailed evaluation of the shoulder had led to a limited number of patients admitted to this study. The majority of patients underwent implantation subcutaneously, and no patients had 3-lead ICD. These might cause limitation when evaluating risk factors for pain and disability.

CONCLUSION

Shoulder problems were frequently seen in patients with ICD but they were not treated adequately. As shown in our study, patients with shoulder pain and limitation had decreased quality of life and deteriorated psychological status. In patients with ICD, awareness should be increased in terms of shoulder problems and appropriate treatment approaches should be determined. There is need for prospective studies in this area with larger populations to evaluate the effects of shoulder management on quality of life and psychological status.

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