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# Assessment of Anxiety Level in Patients Receiving Implantable Cardioverter Defibrillator

**Nooreddin Mohammadi[1], Shahin Askari[2*], Mansooureh Ashghali Farahani[2], Azam Ghorbani[3], Rezvan Ghafarzadegan[4], Nasrin Masuomi[5]**

## Abstract

**Objectives:** The implantable cardioverter-defibrillator (ICD) is a device that is used for patients who suffer from dangerous ventricular dysrhythmia like ventricular tachycardia or ventricular fibrillation by preventing them from sudden cardiac death. Our knowledge about psychological reactions and adaptability after insertion of ICD is not enough, so we did this study to assess and compare anxiety level in patients before and after ICD implantation.

**Materials and Methods:** In this comparative cross-sectional study, after providing written informed consent, 95 eligible patients (30 females and 65 males) were selected through convenience sampling in Shahid Rajaee heart hospital and the medical centers related to Tehran Arrhythmia Clinic. A demographic questionnaire and HADS (Hospital Anxiety and Depression Scale) questionnaire were used to measure anxiety level before and 4 weeks after implantation of ICD. In this study, data were collected and analyzed using SPSS software version 14.0.

**Results:** The mean ± SD of anxiety was significantly lower in male patients than in females prior to inserting ICD device (M=7.55±4.95 vs. F=10.93±5.34, $P$=0.003) and also after insertion (M=7.76±5.76 vs. F=12.06±6.68, $P$=0.001).

**Conclusions:** We found that women had a higher level of anxiety before and after ICD implantation. Since sex is a predisposing factor for encountering a higher level of anxiety, health care providers need to notice the role of gender when providing psychological support for patients with ICD.

**Keywords:** Anxiety, Implantable cardioverter defibrillator, Gender

## Introduction

More than 80% of cardiac arrest cases are initiated by a sudden onset of ventricular tachycardia which swiftly makes progress toward ventricular fibrillation. Since the spontaneous cessation of ventricular fibrillation is a rare phenomenon, it should be treated as soon as it occurred. The best treatment methods for this group of patients involve cardiopulmonary resuscitation and defibrillation. The time gap between the onset of a heart attack and the initiation of attempts to defibrillate the cardiac muscle is regarded as an important determining factor for patient's survival. Therefore, the mortality rate in the patients who suffer from cardiac arrest outside of the hospital is too high because patients are unable to receive emergency medical care and this delay may cause sudden cardiac death (1). Implantable cardioverter-defibrillator (ICD) is a valuable device that was invented for saving patients who confront life-threatening dysrhythmia related to ventricles by preventing them from sudden cardiac death.

ICD is a device that doctors use for monitoring patients who suffer from life-threatening dysrhythmia (2). If there is a ventricular dysrhythmia, ICD delivers electrical impulses to the cardiac muscle in order to regulate the heart rhythm. The delivered energy can be customized according to the individual patient's need. ICD delivers a variable range of electrical energy to the cardiac muscle within 10 to 20 seconds of dysrhythmia onset. This period of time is considered as the valuable time for treating fatal ventricular dysrhythmia. ICD is implanted in the left pectoral region by a method which is the same as implantation of a permanent pacemaker (Table 1). The device is implanted in a patient either as single chambered or dual chambered (3).

ICD was implanted for the first time in a human body by Mirowski and his colleagues in John Hopkins Hospital in 1980 (3). The Food and Drug Administration (FDA) approved using ICD for the treatment of patients who suffer from ventricular dysrhythmias in 1985. Thereafter, it has been generally used in a wide range and was implanted globally in over 50 000 cases (3). In 2009, a published report showed that there are approximately 100 000 patients who have been cured by ICD and there

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[1]Nursing Care Research Centre, Iran University of Medical Sciences, Tehran, Iran. [2]Faculty of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran. [3]Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran. [4]Faculty of Nursing, Khomein University of Medical Sciences, Khomein, Iran. [5]Faculty of Nursing, Zanjan University of Medical Sciences, Zanjan, Iran.
*Corresponding Author: Shahin Askari, Tel: +982435277745, Email: Shahin.askary@yahoo.com

are also 20 000 to 40 000 new ICD implantations each year (4).

Today, ICD is used as a standard treatment in high-risk patients for life threatening dysrhythmia (5). ICD is applied as a primary treatment of fatal ventricular dysrhythmia or as a preventive treatment in the patients who suffer from cardiomyopathy and are at high risk for developing ventricular dysrhythmia and sudden cardiac death (3). Meta-analysis of primary prevention ICD trials suggests that ICDs could decline sudden cardiac death by nearly 60% (6).

Despite the medical benefits of ICD, it imposes some problems on the patient and may influence their daily lives (7). The most important disadvantages of ICD are inappropriate electrical discharge in absence of constant ventricle arrhythmia and its high cost. In addition to these disadvantages, Dunbar et al reported that patients experience a high level of anxiety, exhaustion and psychological stress immediately and in a period of 3 months after ICD implantation (8). According to the results of past studies, the level of anxiety is partly higher in those patients who have had an experience of an electrical shock discharge (8,9).

Considering the inadequacy of the studies in relation to patient's psychological response before and after ICD implantation and the importance of screening for psychological morbidity after the insertion of ICD, this study was conducted to evaluate and compare the level of anxiety in patients before and after implantation of ICD.

## Materials and Methods

This comparative cross-sectional study was conducted in Heart Center of Shahid Rajaee hospital and hospitals affiliated to Tehran Arrhythmia Clinic, Tehran, Iran from January 2009 to December 2010. The study participants were patients (≥18 years old) who had any heart conditions that caused them to be an ICD candidate. During a convenience sampling and after obtaining informed consent, a total of 95 patients (65 males and 30 females) were participated according to inclusion criteria such as: not having a history of narcotic and sedative drug use, having cardiac defibrillators for the first time, according to the patient statements, not suffering from incurable mental illness and mental health and not experiencing stressful events (such as relatives' death, bankruptcy, divorce, marriage, having children, leave home by children in recent months) in the three months before participating in the study. The exclusion criteria were as follows: patient's death, patient's unwillingness to continue, prolonged hospitalization, psychotropic medications during the study, not answering the phone, worsening of the clinical condition of the patient and stressful events experienced during the study except the present illness.

The data were collected by the questionnaire persistently. The questionnaire consisted of 2 parts. The first part was used to collect demographic and health-related information including age, gender, education, and marital status, number of children, financial status, medication and background history. The second part was a self-reported questionnaire named the Hospital Anxiety and Depression Scale (HADS). HADS is a tool for self-assessment which contains 14 questions (7 questions about anxiety and the other 7 questions about depression). HADS was designed to assess the existence and intensity of anxiety and depression in patients over the past few weeks. In this study, we measured the anxiety level. The anxiety components have a 4-point (0-3) scale, and the total score is between 0 and 21. A score of <7 is in the normal range, between 8 and 10 shows us low anxiety, between 11 and 14 suggests mild and between 15 and 21 suggests severe anxiety. The validity of HADS was determined by content validity and its reliability was affirmed by determining Cronbach alpha co-efficient via a pilot study ($\alpha = 0.75$).

Participants completed the instruments in the day before ICD implantation. They also completed HADS four weeks after implanting. The data were analyzed using SPSS software, version 14.0.

### Statistical Analysis

In this study, we analyzed our data using SPSS software, version 14.0. Descriptive statistics were used to describe the characteristics of the samples. In addition, dependent and independent *t* tests were used to analyze the data collected to compare anxiety and depression in men and women before and after cardiac implantable defibrillator devices.

## Results

Means of age among male and female patients were 55.7±13.36 and 56±15.26, respectively. 80% of participants were married. 63.3% of women and only 24.6% of men were uneducated. Other demographic characteristics are listed in Table 1.

Based on Table 2, the level of anxiety before implantation was significantly lower in male patients (7.55±4.95 vs. 10.93±5.34, $P=0.003$). After insertion, the anxiety in female patients increased significantly (10.93±5.34 vs. 12.06±6.68, $P=0.0001$) but in males, no significant increase was observed (7.55±4.95 vs. 7.76±5.76, $P>0.05$).

## Discussion

In our study, we did a survey concerning the average rate of anxiety men and women suffer before the defibrillator device was implanted within the heart. The result obtained by us shows that the degree of anxiety among men and women participants differs in level from the statistical viewpoint ($P=0.003$).

Gender was considered as a determining important factor in anxiety rate in patients in the present study, and women compared to men were observed to experience a higher rate of anxiety before and after cardioverter

**Table 1.** Characteristics of the Patients in Terms of Gender

| | | Male | | Female | |
|---|---|---|---|---|---|
| | | No. | % | No. | % |
| Age | <40 | 12 | 18.5 | 4 | 13.3 |
| | 40-49 | 5 | 7.7 | 2 | 6.7 |
| | 50-59 | 19 | 29.2 | 11 | 36.7 |
| | 60-69 | 16 | 24.6 | 8 | 26.7 |
| | >70 | 13 | 20 | 5 | 16.7 |
| Marital status | Single | 9 | 13.8 | 2 | 6.7 |
| | Married | 54 | 83.1 | 24 | 80 |
| | Widow | 2 | 3.1 | 4 | 13.3 |
| Educational status | Un Read | 16 | 24.6 | 19 | 63.3 |
| | <Diploma | 18 | 27.7 | 5 | 16.7 |
| | Diploma | 14 | 21.5 | 1 | 3.3 |
| | Bachelor and upper | 17 | 26.2 | 5 | 16.7 |
| Economic status | Weak | 33 | 50.8 | 21 | 70 |
| | Moderate | 23 | 35.4 | 7 | 23.3 |
| | Good | 9 | 13.8 | 2 | 6.7 |
| The number of children | <2 | 20 | 30.8 | 6 | 20 |
| | 3-6 | 37 | 56.9 | 16 | 53.3 |
| | 7-11 | 8 | 12.3 | 6 | 20 |
| | >12 | 0 | 0 | 2 | 6.7 |
| Side effects | Yes | 21 | 32.3 | 10 | 33.3 |
| | No | 44 | 67.7 | 20 | 66.7 |
| Defibrillator use | Yes | 10 | 15.4 | 6 | 20 |
| | No | 55 | 84.6 | 24 | 80 |

**Table 2.** Comparison of Anxiety in Patients Before and After the Insertion of Cardioverter Defibrillator in Terms of Gender

| | | Female | | Male | |
|---|---|---|---|---|---|
| | | No. | % | No. | % |
| Before Insertion | 0-7 | 10 | 33.3 | 36 | 55.4 |
| | 8-10 | 6 | 20 | 13 | 20 |
| | 11-14 | 6 | 20 | 9 | 13.8 |
| | 15-21 | 8 | 26.7 | 7 | 10.8 |
| After Insertion | 0-7 | 10 | 33.3 | 37 | 56.9 |
| | 8-10 | 2 | 6.7 | 10 | 15.4 |
| | 11-14 | 4 | 13.3 | 7 | 10.8 |
| | 15-21 | 14 | 46.7 | 11 | 16.9 |

defibrillator implantation within the heart. In their study, Starrenburg et al found that women had higher levels of anxiety which is in line with our study (10). In addition, the education level in women was significantly lower compared to men ($P=0.002$). Comparing the rate of anxiety in both genders, education obviously is thought to play an important part in controlling the increase and decrease of the level of anxiety, for it helps patients to learn and grasp the instructions imparted to them by the health care personnel. In fact, a lack of education leads to a lack of understanding of written and oral instructions conveyed by the health care personnel. Then improper or ineffective compatibility and fear of the shock delivery by the implanted defibrillator doubtlessly raise the anxiety rate in ICD participants either before or after implantation of ICD (11,12). Bilge et al in a study concluded that family responsibility is generally a primary source of concern especially if the victim with the first attack of ventricular fibrillation is a woman. Therefore, they regarded gender basically as an important initiating factor of anxiety based on the findings of their study (9).

In the present study, the estimated rate of anxiety was significantly higher ($P<0.001$) in females after cardioverter defibrillator implant than in male patients, which is statistically similar to the findings of the studies by Bilge et al (9) and Spindler et al (13).

In a study which was carried out by Dunbar, it was indicated that the level of anxiety after cardiac defibrillator implant in young adults was higher in comparison with elderly patients (14). Although the age was recognized by Dunbar as an effective factor of anxiety in patients after insertion of cardiac defibrillator device, our study from statistical standpoint revealed no significant differences regarding the anxiety increase in participants in different age groups after ICD implant ($P<0.05$). In fact, in women who experienced intense anxiety before defibrillator implantation, the degree of intensity generally did not vary even in the stage after the defibrillator was implanted within the heart.

In our study, the variation in the anxiety rate among

men before and after ICD implantation statistically was very slight and insignificant. In 1982, Vlay et al carried out a similar study, the results of which are rather different from ours. Because they indicated that anxiety level in men after defibrillator implantation decreases (15). This decrease in anxiety level may be primarily due to the improvement of insufficient outflow of the left ventricle contents after a defibrillator was implanted and secondly because of the emotional and social support of family members and close acquaintances. Contrary to this, Kapa et al and Duru et al in their studies found no significant decrease in anxiety rate among male participants after insertion of ICD or among those who were in the control group (16,17).

Bilge et al in 2006 indicated that a rise in anxiety level in patients after ICD implant primarily could be due to fear concerning an occurrence of electric shock and pain induced after ICD implantation, failure to predict the approximate onset of shock and pain after ICD insertion, fear of reactions of relatives and close friends, inability to control dysrhythmia and fear of an unexpected defect in the defibrillator device and lack of activation of the implanted ICD device operation in time to control cardiac dysrhythmia (9). Study findings have also indicated that a psychological problem, particularly anxiety is principally an important prevailing cause which leads to increase of dysrhythmia and multiple shocks which eventually is observed to increase the level of anxiety inpatients (11). The above-mentioned finding signifies that those who had experienced shocks or multiple electrical shocks were more concerned than those who had not experienced any of the mentioned instances which occur either before or after ICD implant (18).

Considering the results of this research, the psychosocial effects of the present treatment method should be taken into account in designing the nursing care programs by paying more attention to psycho-social problems among female patients, for they are more prone to psychosocial harm.

We, therefore, suggest that coping skills training should be designed for all specifically for the female participants to teach the techniques of relaxation and measures of proactive coping to reduce anxiety level before and after ICD implant. Similarly, we also recommend that special training courses should be designed for the nursing staff to instruct them to consider and pay more attention to the psychosocial need of the female patient before as well as after the ICD is implanted. Moreover, during follow-up visits, the research nurse, first of all, should provide necessary information and explanation about the normal feeling and fear of the reaction to the delivery of ICD shocks the patient is going to experience after device insertion. Patients should also be encouraged to express their feelings and experience they go through to the research nurse. Studies have also shown that families do play a vital role in decreasing the level of anxiety in their patient (16). Since half of the problems and fears of a patient can mainly be solved by the support of family members, we suggest they form a group composed of trained research team members and the patient's close family members in order to solve the psycho-social problems of the patient before and after ICD implantation.

Since the use of other noninvasive procedures like relaxation, breathing, hypnotic, intense relaxation and thought strengthening techniques are considered to have a powerful effect on decreasing the anxiety rate; we suggest that a study should be done to verify the efficacy of these techniques specifically with regard to the reduction of the anxiety level in ICD recipients. In addition, since group and individual meetings are found to be helpful and effective in solving problems connected with anxiety and depression, we suggest that a study about the effect of arranged meetings between the research team and patients should be undertaken to assess the beneficial effects of arranged meetings on anxiety rate reduction and depression in ICD recipients before and after device implantation. Since our study is conventional with time limitations, we hopefully anticipate doing another research in the same field if a reasonable length of time is allocated to conclude the benefits of meetings between a trained research nurse and single or a group of patients.

## Limitations

Some patients had excessive distress that affected their anxiety. On the other hand, some patients had unknown mental disorders that could change the level of anxiety during research. Both of the following issues were completely uncontrollable for the researcher.

Most of the patients had a wide range of worries about economic problems related to the cost of device and hospitalization. Unfortunately, we could not do anything about these problems.

## Conflict of Interests

Authors have no conflict of interests.

## Ethical Issues

This study was confirmed by Ethic committee of Tehran University of Medical Science (No. IR.IUMS.REC.1387.8711196023) . Before we started the research, we completely explained the research processes to every patient and described what we wanted to do. Then, we asked them to sign the questionnaire if they agreed to participate. We assured them that all the information would be kept confidential and they can withdraw from the research at any time without any consequences.

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