

İmplantabl Kardiyoverter-Defibrilatör Takılan Hastalarda Şok Tedavisinin Hasta Sağlık İlişkili Yaşam Kalitesine Etkisi

The Effect of Shock Therapies on Health-Related Quality of Life in Patients with Implantable Cardioverter-Defibrillator

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ÖZ

GİRİŞ ve AMAÇ: İmplantabl kardiyoverter-defibrilatörler (İKD'ler) ani kardiyak ölümün önüne geçerek, mortaliteyi etkin bir şekilde azaltmaktadır. Bununla birlikte, uygun ya da uygunsuz, İKD şoklaması, özellikle aşılması zor psikolojik süreçlere yol açar ve de kötü yaşam kalitesi ile ilişkilidir. Çalışmamızda, şoklama ile sağlık ilişkili yaşam kalitesi arasındaki ilişkiyi göstermeyi amaçladık.

YÖNTEM ve GEREÇLER: Tek, iki ya da üç odacıklı (Kardiyak resenkronizasyon tedavisi-defibrilatör (KRT-D)) İKD implante edilmiş hastalar dahil edildi. Kliniğimize rutin cihaz kontrolü için başvuran hastalar, başvuruda ve 12. ayda Kısa Form-36 sağlık anketini tamamladılar. Klinik parametreler ve cihaz ölçümleri kayıt altına alındı.

BULGULAR: Yaş ortalaması 62±12 olan, 161'i (74%) erkek toplam 217 hasta çalışmaya dahil edildi. Takiplerde ölüm gerçekleşen 10 (4.6%) hasta çalışma dışına alındı. Kalan 207 hastanın yaş ortalaması 62±12 idi. Takiplerde 26 (12.6%) hasta şoklama tedavisi aldı. 16 hasta uygun; 10 hasta is uygunsuz şok tedavisi aldı. 18 hastada 2 ya da daha fazla şok tedavisi saptandı. Sağlık durumu parametreleri, şoklama tedavisi gören hastalarda daha kötü saptandı.

TARTIŞMA ve SONUÇ: İKD şoklama tedavisi, kötüleşmiş hasta yaşam kalitesi ile ilişkilidir. Dolayısıyla, rutin psikolojik durum değerlendirmesi, İKD hastalarının klinik takiplerine dahil edilmelidir.

Anahtar Kelimeler: İmplantabl kardiyoverter defibrilatör, şok tedavisi, yaşam kalitesi

ABSTRACT

INTRODUCTION: Implantable cardioverter defibrillators (ICDs) reduce mortality from sudden cardiac death (SCD) effectively. However, ICD discharge, whether appropriate or inappropriate, represents a particularly challenging psychological event and is associated with poor quality of life (QoL). We aimed to investigate the association of shock and the health-related QoL.

METHODS: Patients implanted with either single, dual chamber ICDs or CRT-D devices were included. When they presented at our clinic for regular device follow-up, they completed the Short-Form Health Survey 36 (SF-36) at baseline and 12 months. Clinical parameters and device measurements were recorded.

RESULTS: A total of 217 patients, including 161 (74%) males with a mean age of 62±12 years, were included in the study. We excluded 10 (4.6%) patients that died during the follow-up. The mean age of the remaining 207 patients (53 female and 154 male) was 62±12 years. During the follow-up, 26 (12.6%) patients experienced shock therapy. Sixteen of them had appropriate and 10 of them had inappropriate shocks. Two or more shocks were delivered in 18 (8.7%) patients. Health status patterns were poor in patients received shock therapies during follow-up period.

DISCUSSION and CONCLUSION: ICD shocks were associated with impaired health-related QoL. So, routine consideration of psychosocial situation needs to be integrated into the clinical care of ICD patients.

Keywords: Implantable cardioverter-defibrillator, shock therapy, quality of life

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Başvuru Tarihi: 18.12.2017

Kabul Tarihi: 05.02.2018

INTRODUCTION

ICDs have been the cornerstone treatment modality in patients who have a potential risk of ventricular arrhythmia with or without heart failure and for the prevention of SCD related with VF or hemodynamically unstable ventricular tachycardia (VT). Reliability and effect of ICD have been proven widely in several randomized controlled trials and shown to reduce mortality (1-3). Therefore, recently, the number of patients with implanted ICD has been rising significantly. Progressively increased number of ICD implantation brings about many problems. Concerns about the potential harmful effects of appropriate and inappropriate ICD shock therapy is increasing day by day.

Patients receiving ICD shocks are often exposed to physical and psychological trauma and this situation is among the most frequently encountered and difficult conditions to be solved for both patients and physicians concerning the ICD therapy. Anxiety disorder is found at rates ranging from 24-87% in patients who received shock therapy (4). In the SCDHeFT trial, which included primary prevention patients, patients administered shock therapy within 1 month of assessment (n = 49) had considerably reduced health-related quality of life when compared to those not received shocks in the previous month (5). In the AVID (Antiarrhythmics Versus Implantable Defibrillators) trial, secondary prevention patients receiving at least one shock had substantially weaker mental wellbeing and physical functioning (6). In the PainFREE Rx II (Pacing Fast Ventricular Tachycardia Reduces Shock Therapies). It was found that QoL was developed in patients with fast ventricular tachycardia in both arms but even more in the ATP arm. The ATP arm showed a significant improvement in 5 subscales - physical functioning, role physical, bodily pain, social functioning and role emotional, whereas the shock arm had improvement in only bodily pain score (7).

The level of psychological damage based on the number of shocks varies from severe disorders such as posttraumatic stress disorder to a low level. With the manifestation of psychological distress, problems occur impairing quality of life, such as avoidance behaviors, sedentary lifestyle, sexual disorders (8). The number and appropriateness of

the shock therapy act in a different manner to the patient's distress and acceptance of the device. The development of awareness in patients receiving inappropriate shock therapy increases the psychological stress twofold and reduces the patient's confidence to the device (9). Therefore, when the patient's psychosocial condition and QOL were provided, the full advantage of ICD could only be reached. In our study, we aimed to compare the QOL in patients receiving an ICD shock with patients not using SF-36 questionnaire.

METHODS

We included 217 primary prevention patients implanted with either single, dual chamber ICDs or CRT-D devices.

Study design

This prospective study enrolled patients with ICD who came for routine follow-up at our clinic. The inclusion criteria were that the ICD patients ≥ 18 years of age, willing and capable of giving informed consent. The patients received shock therapies until initial assessment, having a psychiatric disorders and using medications, and with major mental or physical disabilities were excluded. All the patients completed the SF-36 questionnaire at baseline and 12 months after to assess the QOL. After that, they were classified into two groups to compare the QOL. The patients who received at least one or more ICD shocks after implantation were classified into the shock group and who did not receive ICD shocks after implantation were classified into the non-shock group.

QOL measurement

The quality of life SF-36 questionnaire was used as an instrument of data collection to assess the QoL. SF-36 was the most common instrument used for QoL assessment across the studies. It is a generic instrument and not disease specific. It consists of 36 items covering eight domains: physical functioning (performance of daily activities, such as limitations in self-care, dressing, bathing and climbing flights of stair), physical (physical health impact on the performance of daily activities and/or professional), pain (pain level and the impact on performance of daily activities and/or professional), general health (subjective perception of general

health), social (reflecting the condition of physical health on social activities), emotional (emotional reflection of the conditions in the performance of daily activities and/or professional), and mental health (mood scale and well-being). Each domain is examined individually and receives a score from 0 to 100 (from worst to best health status), mean 50 and standard deviation of 10 (10,11). Many studies on patients with ICDs reported data on QoL and most of them used SF-36 questionnaire for assessment of QoL.

Statistical Analysis

Patients' characteristics were described using descriptive statistics, including frequencies and percentage for categorical variables. Continuous variables were reported as means, standard deviation of normally distributed variables and median, minimum and maximum of non-normally distributed variables. The normality of distribution of the variables was examined with the Kolmogorov-Smirnov test. The associations of normally distributed continuous variables were compared mean between three groups by using the One-way ANOVA. The associations of continuous variables were compared as the mean between two groups by using the independent t-test, and the Mann Whitney U test when there was no normal distribution. The associations of categorical variables were compared proportionally by using the Chi-square test or the Fisher exact test.

RESULTS

A total of 217 patients, including 161 (74%) males were included in the study. We excluded 10 (4.6%) patients who died during the follow-up. The mean age of the remaining 207 patients (53 female and 154 male) was 62.2±12 years. During the follow-up, 26 (12.6%) patients experienced shock therapy. Sixteen of them had appropriate and 10 of them had inappropriate shocks. Two or more shocks were delivered in 18 (8.7%) patients. 13 patients (6.3%) had ≥2 appropriate shocks and two or more inappropriate shocks were delivered in 5 patients (2.4 %). The median time between shock and subsequent QOL assessment was 7,38 ±2,95 months. The mean time since ICD implantation date was 2,42±1,94 years in shock group versus 2,37±1,51 years in non-shock group ($p > 0.05$). The

mean numbers of shocks received per patient in shock group were 6.2±15.8. The demographics and clinical variables are shown in Table 1.

Table 1. Characteristics of patient population

	Shock therapy group (n=26)	No Shock Therapy group (n=181)	P values
Mean age (years)	58.7±12.3	62.7±11.9	0,109
Gender			
Female	3 (11.5%)	50 (27.6%)	0,08
Male	23 (88.4%)	131 (72.3%)	
BMI (kg/m ²)	27±4.9	28±4.9	0,320
QRS Width (msec)	105.7±18.8	108.7±19	0,455
NYHA status	2.15±0.7	2.3±0.56	0,199
EF (%)	32.3±21.7	26.7±14.4	0,09
Time since implantation (years)	2.4±1.9	2.3±1.5	0,873
Comorbidity			
Diabetes	7 (26.9 %)	53 (29.3%)	0,805
Hypertension	15 (57.7%)	94 (51.9%)	0,585
Coronary artery disease	17 (65.4%)	86 (47.5%)	0,09
Medication			
Beta blockers	25 (92.2%)	158 (87.3)	0,189
CCB	3 (11.5%)	26 (14.4%)	0,700
ACEI/ARB	23 (88.5%)	152 (84%)	0,557
Spirolactone	10 (38.5%)	72 (39.8%)	0,898
ASA	19 (73.1%)	26 (69.6%)	0,720
Warfarin	5 (19.2%)	29 (16%)	0,681
Amiodrone	3 (11.5%)	22 (12.2%)	0,061
Digoxin	4 (15.4%)	22 (12.2%)	0,644

BMI: body mass index; EF:ejection fraction; NYHA:Newyork heart association classification; CCB: calcium channel blocker; ACEI/ARB: angiotensin converting enzyme inhibitors / angiotensin receptor blockers; ASA: acetylsalicylic acid

There was no difference between the two groups regarding NYHA class, age, LVEF or whether they were taking beta-blockers, calcium channel blockers (CCB) or anti-arrhythmic drugs. More patients in shock group had coronary artery disease ($p > 0.05$).

Health status patterns were poor in patients with shock during 12 month follow-up period. At one year after initial assesment, shock therapy was independently associated with all domains of the SF-36. Patients who received the shock had worse general health on the SF-36 scales compared with patients who had no shock (Table 2). When the we considered QOL in the shock group, there was no statistically significant difference in health status between appropriate and inappropriate shock.

Table 2. Mean scores on health status at 12 months

SF-36 questionnaire domains	Shocks (Any) During Follow-Up		p value
	Yes	No	
Physical functioning	48 ± 30	70 ± 20	0.001
Role functioning-Physical	41 ± 37	72 ± 29	<0.001
Bodily pain	66 ± 23	81 ± 21	0.002
Social functioning	64 ± 21	79 ± 22	0.002
Mental health	61 ± 20	70 ± 13	0.02
Role functioning-Emotional	34 ± 37	60 ± 28	0.001
Vitality	43 ± 23	64 ± 19	<0.001
General health	38 ± 18	55 ± 14	<0.001

DISCUSSION

Using of the ICD is mostly a standard therapy for life threatening ventricular arrhythmias since data derived from the clinical trials have consistently indicated its advantage over medical treatment in preventing SCD. While the clinical benefits of ICDs has been convincingly verified in clinical trials, the impact of ICDs on health care costs and patients' QoL is not completely obvious. After implantation, complications include lead fractures or dislodgement, infection, shocks that fail or are inappropriate, and the patient's psychological reaction to the device (12). Most researches have stated that ICD shock can be a primary culprit if reductions in quality of life take place. The occurrence of ICD shocks can affect psychological distress and quality of life through pain, fear, anxiety, avoidance behavior and family fear. These situations lead to lack of patient's confidence to the ICD device and misunderstanding such as ICD implantation is an improper treatment modality.

Our study demonstrates that the QoL of patients with ICD may be changed after ICD implantation, especially in patients receiving ICD shock. The patients in shock group had significantly worse general health than non-shock group whereas there was also statistically significant difference in mental health between the two groups. Sub-analysis of the present study did not demonstrate the differences of QoL in appropriate shock or inappropriate shock groups.

Some studies have shown a decrease in patients' QoL only above a certain number of shock therapy. CIDS (Canadian Implantable Defibrillator Study) study compared the QoL of patients between patients randomized to ICD therapy and patients randomized to amiodarone treatment. QoL is better with ICD therapy than with amiodarone therapy. QoL did not improve in the subgroup of patients in the ICD-treated group who received ≥ 5 shocks from their device (13). In the AVID trial, shocks associated with deterioration in physical and mental QoL and an increase in concerns. The development of more frequent shocks ≥ 3 versus < 3 was related to similar alterations in QoL (6). In the MADIT II trial, there was an impairment of PCS and MCS from baseline to 12 months in patients receiving appropriate ICD shocks. The number of shocks (0, 1, 2) was not significantly related to 12-month changes from baseline MCS score (14). In the SCD-HEFT trial the number of ICD discharges above an arbitrary number that range from 2 to 5 or more, did not show a significant effect on the subsequent quality of life (5). In our patients, analysis was stratified by the number of delivered shocks (0-1 vs ≥ 2) and we have not found an effect between number of shocks and impaired QoL. But, it is an acceptable reality that the mental QoL is more likely to be negatively affected in patients with greater numbers of shock at different times.

Duration of ICD implantation might affect the QoL. The patients who had been a longer time with ICD device might experience life style adaptation at the beginning of implantation and be familiar with ICD therapy. In our study population, implantation duration of ICD was found $2,42 \pm 1,94$ years in ICD shock group. Despite this condition, we have showed that pain and fear experienced after shock therapy could change the state of anxiety and depression. Also the time of ICD shock delivery influences the QoL. In a prospective study conducted by Kamphuis et al, patients divided into two groups, received shock during the first 6 months and in the last 6 months and patients were evaluated with the questionnaire form at 12th month. It was found that the patients experiencing ICD shock during the first 6 months of the study were more depressed and anxious than those in last 6 months (14). The median time between shock and

subsequent QOL assessment was $7,38 \pm 2,95$ months in our study and both physical and mental health scores were found lower in patients receiving ICD shocks. This results support that shock therapies continue to give harm both physically and mentally not only in acute phase but also in the chronic phase.

Avoiding the experience of shock is one of the most important goal for all ICD patients. Using new ICD shock reduction programming can lead to fewer shocks and improve life quality relatively. For instance, when compared to the SCDHeFT trial in which 20% of patients received inappropriate shocks in the first 5 years, with modern device programming this number can be reduced to at least 3–5% in 5 years (16,17). Using ATP alone diminishes shocks for fast VT by 75% (7). Besides, usage of longer detection times permits episodes of nonsustained VT to terminate spontaneously, thus avoiding therapy (18-20). Furthermore, remote monitoring has also lowered significantly the number of appropriate and inappropriate shocks. (21) During clinical cases remote monitoring data need to be aggressively prescribed, analyzed, and the results should be discussed. Nonsustained VT episodes predict sustained episodes. Episodes of atrial fibrillation with a rapid ventricular response, as well as lead noise predict shocks. Even without reaching alert threshold, gradual changes in impedance can still be a marker of lead failure (22).

STUDY LIMITATIONS

In our study, we used the SF-36 questionnaire. There were many QOL measurements, so, these results did not reflect all QOL measures of ICD patients. We studied only ICD patients in our region, and this population was a minority of ICD patients. Due to the socio-cultural variability, response to the ICD therapy may vary between individuals. Therefore, the results of the present study could not reflect the whole population.

CONCLUSION

ICD patients are at risk of psychological distress and adverse health outcomes due to the shock experience. So, routine consideration of psychosocial situation needs to be integrated into the clinical care of ICD patients. With regard to a impaired health-related QOL caused by delivery of

ICD shocks, we would recommend the shock reduction programming in all ICD patients.

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