The Quality of Life in Implantable Cardioverter Defibrillator Patients

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Background: *Implantable cardioverter defibrillators (ICD) are effective for reducing mortality in patients at high risk for sudden cardiac death (SCD). The effects of the devices on psychological status and quality of life were poor especially in the patients who received ICD shocks. This study compared quality of life (QOL) in a group who received an ICD shock with a group who did not receive an ICD shock.*

Material and Method: *A prospective study enrolled patients with implantable cardioverter defibrillator who came for follow-up at Siriraj's device clinic between June and December 2010. These patients completed the Medical Outcomes Study Short Form-36 Questionnaire (SF-36) to assess QOL.*

Results: *There were 138 patients, 105 men and 33 women with a mean age of 59 completed the Medical Outcomes Study Short Form-36 Questionnaire. Sixty-seven (48.55%) patients received an ICD shock. Patients who received the shock had worse general health on the Short Form-36 Questionnaire compared with patients who had no shock (Mean 57.2±21 in shock group vs. 66.1±18 in non-shock group, p = 0.011). There was no statistically significant difference in mental health between two groups (p = 0.63). In shock group, there was no statistically significant difference in health status between appropriate, inappropriate, and appropriate-inappropriate shock groups.*

Conclusion: *General health in patients who had ICD shock was significantly affected in a negative manner when compared to those who had no shock.*

Keywords: *Implantable cardioverter defibrillator, Quality of life, Device shock and non-shock*

J Med Assoc Thai 2014; 97 (Suppl. 3): S108-S114
Full text. e-Journal: *http://www.jmatonline.com*

There were multiple clinical trials, which proved that Implantable cardioverter defibrillators (ICD) could reduce mortality in patients at high risk for sudden cardiac death (SCD). ICD therapy was effective for primary and secondary prevention. In MADIT-II, patients with ICD had a 31% reduction in mortality, when compared to conventional therapy, in patients who had myocardial infarction and impaired left ventricular function[1]. In COMPANION trials, which randomized patients with ischemic or non-ischemic cardiomyopathy, New York Heart Association Class III or IV heart failure and QRS duration more than 120 milliseconds, were chosen to receive optimal pharmacological therapy alone or in combination with Cardiac resynchronization therapy (CRT) with either a pacemaker or a pacemaker-defibrillator. Cardiac resynchronization with the ICD significantly reduced all-cause mortality compared with pharmacological therapy alone in patients with DCM[2]. In Antiarrhythmics Versus Implanted Defibrillators (AVID), trials studied patients who had symptomatic sustained ventricular tachycardia with hemodynamic compromise or who were resuscitated from ventricular fibrillation. Three-year survival was significantly higher in the ICD group (84% in patients with ICD versus 76% in patients taking antiarrhythmic drugs)[3].

As a positive result of many clinical trials, the insertion of ICD was rapidly expanding in clinical practice. In the holistic approach, the occurrence of ICD shocks could affect psychological distress and quality of life through pain, fear, anxiety, avoidance behavior and family fear[4]. These processes contributed to cardiac morbidity and mortality. Thus, the full benefits of ICD could only be achieved when the patient's psychosocial status and QOL were maintained. Some studies reported that 20-50% of patients with cardiovascular disease were at risk for changes in physical or mental health outcomes in response to the new therapy[5]. Anxiety was common with

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approximately 24-87% of ICD patients and the depressive symptoms were reported in about 24-33% of ICD patients; this was consistent with other cardiac populations[6].

There were many studies which assessed QOL related to ICD. From Quality of Life and Psychological Status of Patients, the authors reviewed sixteen studies on psychological status and QOL of patients with ICD by searching PubMed to find the related articles. The QOL in patients with an ICD was often poor compared with those in the general population. The adverse consequences for psychological distress and QOL were discharges of the devices and the highest risk was for younger patients[7].

In Quality of Life and Psychological Functioning of ICD Patients reviewed four studies. The suspected risk factors that could serve as markers for psychosocial attention in patients with ICD were young patients (age <50 years), high rate of device discharges, poor knowledge of cardiac condition or ICD, significant history of psychological problems, poor social support and increased severity of medical conditions or comorbidity[4].

However, there were QOL sub-studies from large randomized clinical trials of ICD therapy, which demonstrated that the QOL was no different or was better in patients randomized to ICD therapy than those in control groups. The patients who received ICD shocks exhibited a decrease in physical, emotional, and psychological measures of health-related QOL[8-10].

In the PainFREE Rx II (Pacing Fast VT Reduces Shock Therapies II) trial, a prospective randomized trial of ATP or shocks for fast ventricular tachycardia, a comparison was made between appropriate and inappropriate ventricular therapies of ICD, QOL, and mortality. The results demonstrated that primary prevention patients were less likely to have appropriate therapies than secondary prevention patients. SVT was commonly found with therapies in both groups (1/3 in each group), but QOL and mortality were similar[11].

Costa et al studied QOL in young patients with ICD and demonstrated that high incidence of shocks interfered with QOL and adaptation to the device, but that there was no statistically significant difference in analysis of appropriate and inappropriate shock- free survival expectancy[12].

The purpose of the present study was to compare QOL in patients who received an ICD shock with patients who did not receive an ICD shock, from among those patients who came for follow-up at Siriraj's device clinic, by using Medical Outcomes Study Short Form-36 Questionnaire (SF-36).

Material and Method

Implantable Cardioverter Defibrillator (ICD) patients were defined as the patients who receive AICD or CRT-D for primary or secondary prevention.

Study design

A prospective study enrolled patients with ICD who came for follow-up at Siriraj's device clinic between June and December 2010. The research protocol was approved by Siriraj Institutional Review Board (SIRB), and the informed consent was obtained from all enrolled patients. The inclusion criteria were that the ICD patient should be able to speak and read Thai language, cognitively intact to provide informed consent, and should have a telephone at home to complete the follow-up data collection. This study excluded the ICD patients who had major mental or physical disabilities. All the patients had completed the Medical Outcomes Study Short Form-36 Questionnaire (SF-36) to assess 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 received ICD shocks after implantation were classified into the non-shock group. Primary end point of QOL was mental health and the secondary end points were physical health and their sub-concepts.

QOL measurement

The authors used SF-36 Questionnaire to assess the QOL. This instrument had established the validity and reliability to measure the QOL and health status. It is composed of two important health components, including physical and mental components. The physical components had four sub-concepts (physical functioning, role functioning (physical), bodily pain, and general health), and the mental components had four sub-concepts (vitality, social functioning, role functioning (mental), and mental health). Both composite summary scores and each sub-concepts score were reported on a scale from 0 to 100, with higher scores indicating improved physical and mental health.

Statistical analysis

Patient's 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

There were 138 patients, 105 men and 33 women with a mean age 59 years, who completed the SF-36 Questionnaire. Sixty-seven patients received an ICD shock (shock group) while 71 patients did not receive an ICD shock (non-shock group). The demographics and clinical variables for these two groups are displayed in Table 1.

Demographic and clinical variables

There was no difference between the two groups regarding education, occupation, living, employment, NYHA Class, LVEF or whether they were taking beta-blockers, calcium channel blockers (CCB), anti-arrhythmic or sedative drugs. In the non-shock

Table 1. Demographic and clinical variables

	Number (%) or mean ± SD		p-value
	Non-shock (n = 71)	Shock (n = 67)	
Age (years)	61.2±12.8	56.9±14.4	0.068
Gender			0.228
Female	20 (28.2)	12 (19.4)	
Male	51 (71.8)	54 (80.6)	
CAD risk factors			
Family history of CAD	18 (25.3)	9 (13.4)	0.078
Smoking	22 (31)	26 (38.8)	0.335
DM type II	14 (19.7)	14 (20.9)	0.864
Hypertension	35 (49.3)	18 (26.9)	0.007
Dyslipidemia	54 (76.1)	28 (41.8)	<0.001
LVEF, %	40.9±19.3	42.9±19.4	0.580
Cause of arrhythmia			
CAD	42 (59.2)	25 (37.3)	0.010
Non-CAD	31 (43.7)	43 (64.1)	0.016
Time since implantation, months	31±21.2	51.4±32.8	<0.001[a]
Number of shocks	0	2.9±3.1	
NYHC class			0.409[b]
Class I	53 (74.6)	44 (65.7)	
Class II	16 (22.5)	22 (32.8)	
Class III	2 (2.8)	1 (1.5)	
Current medications			
Antiarrhythmic drug	14 (19.7)	23 (34.3)	0.053
Beta-blocker	68 (95.8)	58 (86.5)	0.055
ACE inhibitor/ARB	48 (67.6)	34 (50.7)	0.044
Statin	56 (78.9)	31 (46.2)	<0.001
Anticoagulant	6 (8.4)	20 (29.8)	<0.001
Antiplatelet	56 (78.9)	38 (56.7)	0.005
Indication for ICD implantation			0.038
Primary prevention	25 (35.2)	13 (19.4)	
Secondary prevention	46 (64.8)	54 (80.6)	

[a] Mann-Whitney test; [b] Fisher exact test

group, there was more hypertension and dyslipidemia than in the shock group.

More patients in non-shock group had coronary artery disease (59.2% vs. 37.3%, p = 0.01). The mean time since ICD implantation in shock group was 51.4 months versus 31 months non-shock group (p < 0.001). For the ICD implantation indication, there were more secondary prevention patients in shock group (80.6% vs. 64.8%, p = 0.038). The mean numbers of shocks received per patient in shock group were 2.9±3.1 times.

Comparisons between the two groups (shock vs. non-shock) for QOL using the SF-36 scale

Patients who received the shock had worse general health on the SF-36 scales compared with patients who had no shock (Mean of SF-36 scales 57.2±21 in shock group vs. 66.1±18 in non-shock group, p = 0.011). There was no statistically significant difference in mental health between the two groups (p = 0.63) (Table 2).

When the authors considered QOL in the shock group, there was no statistically significant difference in health status between appropriate, inappropriate, and appropriate-inappropriate (combined) shock groups (Table 3).

In general health, the factor effected the QOL was employment. Retired patients no longer working had worse general health on the SF-36 scales compared with patient who worked full time (Mean of SF-36 scales 57.2±21 in retired patients vs. 67.4±19 in full time patients, p = 0.012) (Table 4).

Discussion

The present study demonstrates that the QOL of patients with ICD may be changed after

Table 2. SF-36 scales compared between the 2 groups in physical and mental health

	Non-shock group	Shock group	p-value
Physical health			
Physical functioning	84.22	81.81	0.494
Role-physical	98.59	94.40	0.166
Bodily pain	92.98	89.91	0.310
General health	66.15	57.23	0.011
Mental health			
Vitality	92.32	90.89	0.531
Social functioning	92.07	88.24	0.294
Role-emotional	98.59	92.53	0.070
Mental health	95.09	94.32	0.633

Table 3. SF-36 scales compared among 3 groups in appropriate and inappropriate and combined shock

	ICD shock group (n = 67): mean (SD)			p-value
	Appropriate shock (n = 42)	Inappropriate shock (n = 17)	Combined shock (n = 8)	
Physical health				
Physical Functioning	80.9 (24.8)	83.5 (16.9)	83.1 (14.1)	0.901
Role-Physical	94.6 (21.8)	91.2 (26.4)	100 (0)	0.640
Bodily Pain	92.1 (19.2)	90.1 (14.2)	78.1 (37.6)	0.591
General Health	57.1 (23.1)	55.6 (19.6)	61.4 (22.0)	0.833
Mental Health				
Vitality	92.3 (11.9)	87.1 (18.7)	91.9 (8.0)	0.584
Social Functioning	87.2 (26.4)	91.2 (21.5)	87.5 (23.1)	0.854
Role-Emotional	98.4 (10.3)	78.4 (40.7)	91.7 (23.6)	0.152
Mental Health	96.1 (7.5)	90.6 (14.1)	93.0 (7.9)	0.262

Table 4. General health was compared by sex, age, education, status, employment, living and occupation

	Mean ± SD	p-value
Sex		
Female	59.0±20.4	0.370
Male	62.7±20.8	
Education		
Less than high school	59.6±21.0	0.199
High school graduate	63.1±24.0	
Some college	60.2±19.5	
College graduate	71.5±14.1	
Advanced degree	84.5±10.6	
Status		
Married	62.0±20.9	0.721
Divorce	67.3±20.8	
Single	57.6±18.7	
Age_60 year		
>60 year	58.7±22.3	0.099
≤60 year	64.6±19.0	
Employment		
Full time	67.4±19.4	0.012*
Part time	54.0±20.1	
Retired	57.2±20.9	
Living		
Alone	78.0±13.5	0.172
With family/friend	61.5±20.7	
Occupation		
Professional	62.8±22.5	0.681
Managerial	62.2±19.6	
Clerical	60.7±21.6	
Craftsman	52.5±20.9	
Housewife	64.0±17.7	
Laborer	64.4±19.1	

ICD implantation, especially in patients who have experience of ICD shock. If the authors are not concerned about the QOL in these patients, ICD therapy may affect both morbidity and mortality. Previous studies had demonstrated variable results in those who received ICD shock; they found a decrease in both the mental and physical health composite summary scores, no decrease in either, and decrease in mental health scores[13-15].

In the present study, our research questions were answered. The patients in shock group had significantly worse general health than non-shock group whereas there was no statistically significant difference in mental health between the two groups. When the authors considered the sub-concepts of health, the patients in the shock group did insignificantly worse in all sub-concepts than in the non-shock group. Sub-analysis of the present study did not demonstrate the differences of QOL in appropriate shock, inappropriate or combined shock groups. The authors found the factor that affected the QOL was employment. The patients who retired from working had worse general health than the other groups; these results showed that many factors could affect the QOL.

Timing of ICD implantation and experience of shock might affect the QOL. In the present study, the authors collected the QOL only one time, and did not compare the timing of ICD implantation in each patient. Therefore, patients who had been a longer time with ICD implantation or who had more shock experiences might experience life style adaptation at the beginning of implantation and be familiar with ICD therapy. Since we collected the data only one time, it might not represent the real overall experiences in ICD therapy, which affect QOL. The QOL outcomes in these patients might be better than presented here.

Study limitation

There were many QOL measurements. In the present study, the authors used the SF-36 questionnaire that was the one instrument to measure the QOL and health status for ICD patients. Therefore, these results did not reflect all QOL measures of ICD patients. The authors studied only ICD patients in Siriraj Hospital, and this population was a minority of ICD patients. Therefore, the results of the present study could not reflect the whole population; these results, however, allow us to perceive the trend of QOL in ICD patients. In statistical analysis, we did not adjust p-value when we compared in eight components of QOL, so significant p-value did not influence the outcomes of either health component.

Application

When the patients have indications for ICD implantation, the authors should care for them with a holistic approach and identify the high-risk patients before or after ICD implantation. If we know the risk of patients, the authors may prevent excessive adverse change in QOL especially in patients who receive the ICD shock. The authors encourage psychosocial support by a multidisciplinary care teams to continue education for patients and their family. The authors know that the patients who are exposed to ICD shock may have poor QOL; thus, patients who received ICD shock should have all therapies assessed in order to improve the QOL. For example, in patients who have

inappropriate ICD therapies, the authors can optimize use of medications, interrupt AV conduction, ablate or adjust detection zones.

Conclusion

General health in patients who had ICD shock significantly declined when compared to those who had no shock. There was no statistically significant difference in health status between appropriate, inappropriate, and appropriate-inappropriate shock groups.

Potential conflicts of interest

None.

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การศึกษาคุณภาพชีวิตของผู้ป่วยที่ใส่เครื่องกระตุกหัวใจอัตโนมัติชนิดฝังไว้ในร่างกายของโรงพยาบาลศิริราช

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ภูมิหลัง: แม้ว่าเครื่องกระตุกหัวใจชนิดอัตโนมัติชนิดฝังในร่างกายสามารถลดอัตราการตายจากหัวใจเต้นผิดจังหวะชนิดรุนแรง และภาวะหัวใจล้มเหลวได้ แต่เมื่อเครื่องกระตุกไฟฟ้าหัวใจทำการช็อกผู้ป่วย อาจส่งผลกระทบต่อร่างกายและจิตใจ เช่น ความเจ็บปวด ความกลัว หลีกเลี่ยงพฤติกรรมบางอย่าง ตลอดจนต่อคนในครอบครัวและคุณภาพชีวิตตามมา

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบคุณภาพชีวิตของผู้ป่วยที่ใส่เครื่องกระตุกหัวใจอัตโนมัติชนิดฝังไว้ในร่างกาย (automatic implantable cardioverter defibrillator, AICD หรือ ICD) ในผู้ป่วยกลุ่มที่ได้รับการช็อกไฟฟ้าหัวใจ (shock group) และกลุ่มผู้ป่วยที่ไม่ได้รับการช็อก (non-shock group)

วัสดุและวิธีการ: ผู้ป่วยที่ใส่เครื่องกระตุกหัวใจอัตโนมัติทุกคนที่มารับการตรวจติดตามการรักษาที่คลินิก ตรวจเช็คเครื่องกระตุกไฟฟ้าหัวใจของโรงพยาบาลศิริราช โดยผู้ป่วยจะได้รับการสัมภาษณ์ประวัติเพื่อประเมินคุณภาพชีวิตด้วยแบบสอบถาม SF-36 เพียงครั้งเดียวแล้วแบ่งผู้ป่วยเป็น 2 กลุ่ม คือ ในผู้ป่วยกลุ่มที่ได้รับการช็อกไฟฟ้าหัวใจ (shock group) และกลุ่มผู้ป่วยที่ไม่ได้รับการช็อก (non-shock group) และนำผลที่ได้จากการสัมภาษณ์มาเปรียบเทียบคุณภาพชีวิตในแต่ละด้าน โดยมีระยะเวลาการศึกษาตั้งแต่ เดือนมิถุนายน ถึง เดือนธันวาคม พ.ศ. 2553

ผลการศึกษา: ผู้ป่วยทั้งหมดจำนวน 138 ราย ได้รับการสัมภาษณ์ประวัติด้วยแบบสอบถาม SF-36 เป็นเพศชาย 105 ราย และเป็นเพศหญิง 33 ราย ซึ่งอายุเฉลี่ยเท่ากับ 59 ปี เป็นผู้ป่วยที่ได้รับการช็อกไฟฟ้าหัวใจจำนวน 67 ราย คิดเป็น 48.55% พบว่ากลุ่มผู้ป่วยที่ได้รับการช็อกไฟฟ้าหัวใจ (shock group) มีคุณภาพชีวิตด้านสุขภาพทั่วไป (general health) แย่กว่ากลุ่มผู้ป่วยที่ไม่ได้รับการช็อกไฟฟ้าหัวใจอย่างมีนัยสำคัญทางสถิติ ($p = 0.011$) โดยคะแนนเฉลี่ยและค่าเบี่ยงเบนมาตรฐานของกลุ่มผู้ป่วยที่ได้รับและไม่ได้รับการช็อกไฟฟ้าหัวใจเท่ากับ 57.2 ± 21 และ 66.1 ± 18 ตามลำดับ ส่วนคุณภาพชีวิตด้านสุขภาพจิต (mental health) นั้นไม่มีความแตกต่างกันในทั้งสองกลุ่ม ($p = 0.63$) เมื่อพิจารณาเฉพาะกลุ่มผู้ป่วยที่ได้รับการช็อกไฟฟ้าหัวใจ (shock group) ไม่พบความแตกต่างของคุณภาพชีวิต ด้านสุขภาพกายและสุขภาพจิต ทั้งในกลุ่มผู้ป่วยที่ได้รับการช็อกไฟฟ้าหัวใจอย่างเหมาะสม (appropriate shock group) และไม่เหมาะสม (inappropriate shock group) หรือทั้งสองอย่าง (combined shock group)

สรุป: คุณภาพชีวิตด้านสุขภาพทั่วไป (general health) ของกลุ่มผู้ป่วยที่ได้รับการช็อกไฟฟ้าหัวใจแย่กว่ากลุ่มที่ไม่ได้รับการช็อกไฟฟ้าหัวใจ อย่างมีนัยสำคัญทางสถิติ