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Quality of life predicts one-year survival in patients with implantable cardioverter defibrillators

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Abstract
Purpose This study examines the contributions of known predictors of survival and quality of life (QOL) to 1-year survival in ICD recipients.
Methods This study used the data set from the antiarrhythmia versus implanted defibrillator (AVID) controlled clinical trial conducted by the National Institutes of Health, National Heart, Lung, and Blood Institute. The 507 patients randomly assigned to the ICD treatment were included in the analysis. Patients were mostly male (78.3%), with mean age of 64.85 ± 10.81 and mean left ventricular ejection fraction of 32.2 ± 13.45%. QOL was measured with the medical outcomes study 36-item short form health survey (SF-36) and quality of life index-cardiac version (QLI-CV). Data were analyzed with descriptive statistics and logistic regression.
Results Fifty-four (10.6%) patients died in the first year after ICD implantation. Angiotensin-converting enzyme inhibitor (ACE) medication, age, and QLI-CV were significant independent predictors of 1-year survival. The odds of survival of a younger patient with ACE medication and good QOL were approximately three times (OR = 3.96) greater than for an older patient, without ACE medication and with poor QOL.
Conclusion Quality of life is an important factor predicting 1-year survival in patients with ICDs. ACE medication and younger age also predict 1-year survival independent of QOL and each other.

Keywords Quality of life · Survival · Implantable cardioverter defibrillator · Antiarrhythmia versus implanted defibrillator clinical trial · Predictor

Abbreviations

ACE	Angiotensin-converting enzyme inhibitor
AVID	Antiarrhythmia Versus Implanted Defibrillator Study
CABG	Coronary artery bypass graft
EF	Left ventricular ejection fraction
HF	Heart failure
ICD	Implantable cardioverter defibrillator.
MCS	Mental component summary score from the SF-36
NYHA	New York Heart Association
PCS	Physical component summary score from the SF-36
QOL	Quality of life
QLI-CV	Quality of life index-cardiac version
SCD	Sudden cardiac death
SF-36	Medical outcomes study 36-item short form health survey
VF	Ventricular fibrillation
VT	Ventricular tachycardia

Introduction

Sudden cardiac death (SCD) is an important clinical and public health problem in the United States [1]. Approximately 85% of SCDs are caused by the first dysrhythmic

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event [2]. Implantable cardioverter-defibrillators (ICDs) are highly effective medical devices for terminating life-threatening ventricular arrhythmias. More than 80,000 ICDs were implanted in 2000 [3]. Several studies provided evidence that ICDs reduce mortality from SCD more than antiarrhythmic drug therapy [4–8].

Although ICD implantation increases life expectancy, it has a negative impact on patients' quality of life (QOL). Previous studies indicated that ICD implantation negatively affected patients' lives, and ICD recipients needed to adapt to these alterations [9, 10]. Evidence from a number of clinical studies in patient populations with cardiovascular disease revealed that poor QOL is a significant independent predictor of increased mortality [11–15]. No studies evaluate the relationship between QOL and mortality in patients who received ICDs. Among ICD recipients, left ventricular ejection fraction (EF) [4, 16–19], New York Heart Association (NYHA) classification [5, 16, 20, 21], ICD shocks [20, 22], a history of sustained ventricular tachycardia (VT) [23], age [22], and gender [20] predicted long-term mortality.

Patients with ICDs may be able to return to their normal way of life after 1 year [24–26]. When a device was implanted into patients, patients experienced a brief decline in QOL and returned to pre-implantation QOL in about 1 year [27]. The first year of ICD treatment probably is the critical period for patients. Most studies of mortality in ICD recipients investigated predictors of long-term mortality [4, 5, 16–23], but not of mortality in the first year. Identification of predictors of mortality in the first year after ICD implantation may assist in developing health care programs for patients who receive ICDs. This study was designed to evaluate the impact of QOL on 1-year survival of patients receiving ICDs. The aims of this study were to identify the demographic and clinical predictors of 1-year survival and to determine the impact of QOL on 1-year survival after adjusting for demographic and clinical characteristics that predict mortality in ICD recipients.

Methods

Study sample

The data for this study were obtained from the 507 patients who were randomly assigned to receive ICDs in the anti-arrhythmia versus implanted defibrillator (AVID) clinical trial [28, 29]. The AVID data base was obtained through the National Heart, Lung, and Blood Institute (NHLBI) limited access data set process [30].

The AVID study aimed to determine whether ICD placement reduced total mortality when compared to antiarrhythmic drug therapy and evaluate the relative cost-effectiveness and impact on QOL of the alternative treatment options for patients with ventricular fibrillation (VF) or symptomatic VT. Symptomatic VT was defined as sustained VT with syncope or hemodynamically compromising sustained VT with EF $\leq$ .40 [28]. The AVID study screened the first registry patient in June 1993, randomized its first patient into the trial on June 2, 1993, and terminated the follow-up for the remaining patients on August 31, 1998. Patients were enrolled from 56 hospital centers in United States and Canada. A total of 1,016 registry patients participated in the randomized clinical trial, with 507 patients randomly assigned to the ICD arm and 509 patients to the drug arm (amiodarone or sotalol) [29].

Patients signed the AVID Trial Informed consent prior to participation in the AVID Trial. Baseline data collected prior to randomization included arrhythmia history, clinical history, demographics, and current clinical assessment. Follow-ups were conducted by in-clinic evaluations at 1, 3 months, and every 3 months thereafter for the duration of follow-up until patients died or the end of the study. Quality of life was measured with medical outcomes study 36-item short form health survey (SF-36) at baseline, 3, 6 months, and 1 year and with the quality of life index-cardiac version (QLI-CV) at baseline and 1 year. Vital status was obtained through the National Death Index Service [29]. Complete information about AVID study design and procedures has been published previously [28, 29].

Instruments

In the current study, QOL was measured with the SF-36 and the QLI-CV. General QOL was assessed with the SF-36, and cardiac-specific QOL was assessed with the QLI-CV. The baseline QOL data were used as the predictor variables for 1-year survival.

Medical outcomes study 36-item short form health survey

The SF-36 is a norm-referenced measure of QOL. It contains 36 items to measure eight QOL components including physical functioning (10 items), role-physical (4 items), bodily pain (2 items), general health perceptions (5 items), vitality (4 items), social functioning (2 items), role-emotional (3 items), mental health (5 items), and one item asking a self-assessment of health change over the past year. Scores are calculated for each component and aggregated into two summary scores, a mental component summary score (MCS) and a physical component summary score (PCS). A higher score indicates better QOL [32, 33]. Reliability and validity of the SF-36 have been established in patients with heart disease [31]. In this current study, the

Cronbach's α for each component and both summary scales were greater than .75, indicating acceptable internal consistency reliability.

Quality of life index-cardiac version

The Cardiac Version of the QLI-CV was used as a measure of cardiovascular health-related QOL. The QLI was developed by Ferrans and Powers to measure the QOL of healthy individuals, and those who are experiencing an illness. The QLI is comprised of two sections: one measures satisfaction with various domains of life and the other measures the importance of the domain. Each section consists of 32 items within four domains: health and functioning, psychological/spiritual, socioeconomic, and family [34]. The QLI-CV is based on the same core items as the QLI but has six additional items specific to cardiac patients in each section [35]. Each item is rated on a six-point Likert-type scale with responses ranging from "very satisfied" to "very dissatisfied" for the satisfaction items and from "very important" to "very unimportant" for the importance items. To calculate scores, satisfaction responses are weighted by the paired importance responses. Highest scores are obtained for items that have both high satisfaction and high importance. Scores on each subscale and overall scale ranges from 0 to 30 [34]. Previous studies indicated acceptable reliability and validity of the QLI-CV [36, 37]. In this current study, the Cronbach's α for the total scale was greater than .9, indicating high internal consistency reliability.

Statistical analyses

The statistical package for the social science (SPSS 13.0) was used for data analysis. Prior to analysis, raw data were screened and cleaned by examining the missing values, outliers, normality, and multicollinearity. Negative skewed predictor variables including age, MCS, and QLI-CV were reflected before they were transformed with the square root transformation; indicated by (rsqrt) after the variable name in the text. Descriptive statistics comprising frequency, range, mean, standard deviation, and percentage were used to summarize the predictor and outcome variables.

Logistic regression analyses were used to evaluate the contributions made by each predictor over and above that of the other predictors to 1-year survival status. The interval between ICD implantation and patient death was calculated by subtracting the date of ICD implantation from the date of the patient's death. Patients were categorized as alive or dead 1 year after ICD implantation. The 1-year survival status was entered as the dependent variable with 1 = alive 1 year after ICD implantation and 0 = death within 1 year after ICD implantation. Three steps of analysis were as follows: (1) separate logistic regression analysis for the contribution of each predictor variable to 1-year survival status was performed; (2) all predictor variables with $P < .2$ in step 1 were combined into a simultaneous logistic regression analysis with 1-year survival as the outcome [38]. The criterion of $P < .2$ was chosen to identify potential confounding variables while minimizing the bias that occurs with automatic stepwise selection and avoiding the under-selection of variables that occurs with a smaller criteria (i.e., $P < .05$) [39].

Results

Sample characteristics

Table 1 summarizes the demographic and clinical characteristics of the participants. The mean age of the ICD recipients ($N = 507$) was 64.85 (SD = 10.81). Most of the patients with ICD were male ($n = 397$, 78.3%), white ($n = 442$, 87.2%), and married or living with a partner ($n = 228$, 45%). The index arrhythmia type was VF in 44.6%, documented sustained primary VT with syncope in 20.3%, and documented sustained primary VT with significant cardiac symptoms in 35.1% of the sample. Over half (55%) of the participants had heart failure (HF) and 36% had angina. Approximately 4.1% of patients with ICD had prior VF, 13.8% had prior VT, 66.9% had prior MI, 55.6% had hypertension, 24.5% had diabetes, 31.8% had hyperlipidemia, and 1.8% had hypertrophic cardiomyopathy. During the first year after ICD implantation, 56.4% of ICD recipients did not receive ICD shocks, 24.5% experienced 1–4 shocks, and 19.1% experienced five or more shocks. A total of 54 patients with ICD (10.6%) died in the first year after ICD implantation. The mean of total survival time for the patients with ICD was 2.61 years (SD = 1.24).

Quality of life at baseline

The scores on the SF-36 at baseline for the PCS ranged from 11.5 to 64.9 (mean = 37.15, SD = 11.01) and for the MCS ranged from 19.6 to 68.1 (mean = 46.23, SD = 11.45; see Table 2). Comparing the actual scores of the baseline SF-36 to the normative scores derived from the patients with heart disease in the 1998 National Survey of Functioning Health Status [33], the PCS and MCS scores at baseline in the AVID ICD recipients were significantly better than those of the patient group with normative heart disease [$t(341) = 4.325$, $P < .001$; $t(341) = 11.402$, $P < .001$].

Table 1 Demographic characteristics of participants ($N = 507$)

Variable	Mean (SD)	Range	Frequency	Percent
Age	64.85(10.81)	32–87		
Gender (male)			397	78.3
Race (white)			442	87.2
Index arrhythmia type				
VF			226	44.6
VT with syncope			103	20.3
VT with symptom			178	35.1
Clinical history				
Hypertension			282	55.6
Hyperlipidemia			161	31.8
Heart failure			233	46.0
Myocardial infarction			339	66.9
CABG			150	29.6
Medication treatment				
β-blocker			211	41.6
Diuretic			241	47.5
ACE			344	67.9
Lipid-lowering medication			68	13.4
Heart failure status				
No heart failure			229	45.2
NYHA class I			100	19.7
NYHA class II			144	28.4
NYHA class III			34	6.7
Angina status (CCSC)				
No angina			327	64.5
Class I			118	23.3
Class II			51	10.1
Class III			9	1.8
Class IV			2	.4
ICD shocks (during 1 year)				
No shock			286	56.4
1–4 shocks			124	24.5
≥5 shocks			97	19.1
Ejection fraction	32.2 (13.45)			
Total survival time (year)	2.61 (1.24)			

ACE angiotensin-converting enzyme inhibitor, *CABG* coronary artery bypass graft, *CCSC* Canadian cardiovascular society classification for Angina, *ICD* implantable cardioverter defibrillator, *NYHA* New York Heart Association, *VF* ventricular fibrillation, *VT* ventricular tachycardia

The scores on the QLI-CV at baseline ranged from 5.7 to 30 (mean = 22.01, SD = 4.84; see Table 2). The baseline QLI-CV score in the AVID ICD recipients was similar to those obtained in a longitudinal study on patients with HF who had life-threatening arrhythmias and received ICDs (mean = 22.19, SD = 2.96) [40] and a descriptive correlation study on patients with life-threatening arrhythmias undergoing ICD therapy (mean = 24.89, SD = 3.9) [41].

Predictors of one-year survival

Univariate demographic and clinical predictors of the likelihood of surviving 1 year after ICD implantation include age (rsqrt; OR = 1.605, $P < .001$), race (OR = .463, $P = .032$), EF (OR = 1.421, $P = .011$), NYHA class (OR = .548, $P = .038$), history of HF (OR = .551, $P = .042$), history of hyperlipidemia (OR = 2.260, $P = .025$), β-blocker medication (OR = 1.985, $P = .044$), and diuretic medication (OR = .457, $P = .015$). Patients with ICD who were younger, white, with higher EF, without HF or NYHA class I HF, having history of hyperlipidemia, undergoing β-blocker medication treatment, and without using diuretic medication were more likely to be alive 1 year after ICD implantation.

All demographic and clinical characteristics that predicted survival at $P < .2$ in univariate analysis and the three QOL variables MCS, PCS, and QLI-CV were combined in a simultaneous logistic regression analysis with 1-year survival as the outcome. The demographic and clinical predictor variables included age, race, EF, NYHA class, history of HF, history of hypertension, history of hyperlipidemia, history of CABG (pre index event), β-blocker medication, diuretic medication, ACE medication, and lipid-lowering medication. The overall predictive model was statistically significant [model $\chi^2(16, N = 308) = 33.248$, $p = .007$] (see Table 3). The Hosmer and Lemeshow test revealed that the predictive model fit the data well [$\chi^2(8, N = 308) = 7.091$, $P = .527$]. Three of the predictor variables were significant independent predictors of surviving 1 year after ICD implantation: age (rsqrt) (OR = 1.7, p = .008), ACE medication (OR = 4.478, p = .005), and QLI-CV (rsqrt; OR = .48, $P = .047$). This finding indicated that patients with ICD, who were younger, took ACE medication, and who had better QOL at baseline, had higher probability of surviving more than 1 year after ICD implantation.

Estimated odds of survival status were computed for patient whose ages were one standard deviation (SD) below and above the mean age, whose QLI-CV scores were one SD above and below the mean, and with and without ACE medication (See Fig. 1). Odds of 1-year survival increased by 50% for older patient with low QOL when ACE were added (OR = 1.499). Improving QOL of this patient in addition to adding ACE improved odds of survival further (OR = 2.73). A younger patient with poor QOL with ACE had approximately the same odds of survival as an older patient with ACE and good QOL (OR = 2.73). By comparison, the odds of survival of a

Table 2 Summary of SF-36 and QLI-CV Scores at baseline for all ICD recipients and according to one-year survival status

Subscale and overall	All ($N = 507$) Mean (SD)	Survived ($n = 453$) Mean (SD)	Died ($n = 54$) Mean (SD)
SF-36—physical functioning subscale	56.30(27.82)	57.28(27.36)	45.84(30.44)
SF-36—role-physical subscale	32.99(40.25)	34.33(40.95)	23.57(32.05)
SF-36—bodily pain subscale	59.12(30.99)	59.16(31.11)	60.2(30.38)
SF-36—general health perception subscale	51.28(21.14)	51.61(21)	47.14(21.01)
SF-36—mental health subscale	68.57(19.85)	68.17(20.16)	73.33(16.11)
SF-36—role-emotional subscale	54.40(43.51)	55.48(43.42)	46.08(44.21)
SF-36—social functioning subscale	64.38(29.86)	65.08(29.55)	58.93(32.31)
SF-36—vitality subscale	46.12(23.28)	46.25(23.26)	43.14(22.66)
SF-36 PCS	37.15(11.01)	37.50(10.94)	33.66(10.79)
SF-36 MCS	46.23(11.45)	46.25(11.63)	46.50(9.46)
QLI-CV—health and functioning subscale	19.58(5.8)	19.72(5.82)	18.48(5.30)
QLI-CV—psychological-spiritual subscale	23.65(5.75)	23.68(5.72)	23.82(5.74)
QLI-CV—socioeconomic subscale	24.00(5.16)	24.07(5.19)	23.22(4.94)
QLI-CV—family subscale	25.06(5.69)	25.11(5.66)	24.88(5.57)
QLI-CV—overall	22.01(4.84)	22.11(4.86)	21.30(4.35)

SF-36, medical outcomes study short form -36; *MCS,* mental component summary score; *PCS,* physical component summary score; *QLI-CV,* quality of life index-cardiac version

Table 3 Logistic regression using biomedical, demographic and quality of life variables simultaneously to predict one-year survival ($N = 308$)

Predictor variables	*B*	Wald	Odds ratio	95% Confidence interval	*P*
EF	.206	.741	1.229	.768–1.966	.389
NYHA class	−.556	.928	.573	.185–1.779	.335
History of hypertension	−.337	.478	.714	.275–1.856	.489
History of hyperlipidemia	1.326	3.270	3.767	.895–15.862	.071
History of HF	.129	.049	1.137	.363–3.566	.825
History of CABG	.316	.377	1.371	.501–3.756	.539
β-blocker medication	.868	2.728	2.383	.85–6.677	.099
Diuretic medication	−.813	1.887	.444	.139–1.414	.170
ACE medication	1.499	7.839	4.478	1.568–12.789	.005
Lipid-lowering medication	.03	.001	1.03	.165–6.427	.975
Non-white race	−1.052	2.294	.349	.089–1.363	.130
Gender	−.364	.289	.695	.185–2.618	.591
Age*	.531	7.079	1.7	1.15–2.513	.008
PCS	−.007	.067	.993	.945–1.044	.796
MCS*	.206	.984	1.229	.818–1.848	.321
QLI-CV*	−.733	3.958	.48	.233–.989	.047
Constant	−.095	.002			
−2 Log Likelihood = 140.226, $\chi^2(16) = 33.248$, p = .007					

* Before square root transformation, variables were reflected. The interpretation of relationship between variables should be reversed, for example a higher average in age* means younger. The higher score in MCS* indicated worse mental health status. The higher scores in QLI-CV* indicated poor quality of life. B: unstandardized logistic regression coefficients; EF: left ventricular ejection fraction; NYHA: New York Heart Association classification; ACE: angiotensin-converting enzyme inhibitor; PCS: physical component summary score; MCS: mental component summary score; QLI-CV: quality of life index-cardiac version. Gender, female was referant group (female = 0); Race, white was referant group; History, no history was referant group; Medication, no use was referant group

younger patient with ACE medication and good QOL improved approximately three times (OR = 3.96) compared with the older patient, without ACE medication and with poor QOL. Improving QOL had the potential to improve survival meaningfully for both younger and older patients with ICDs.

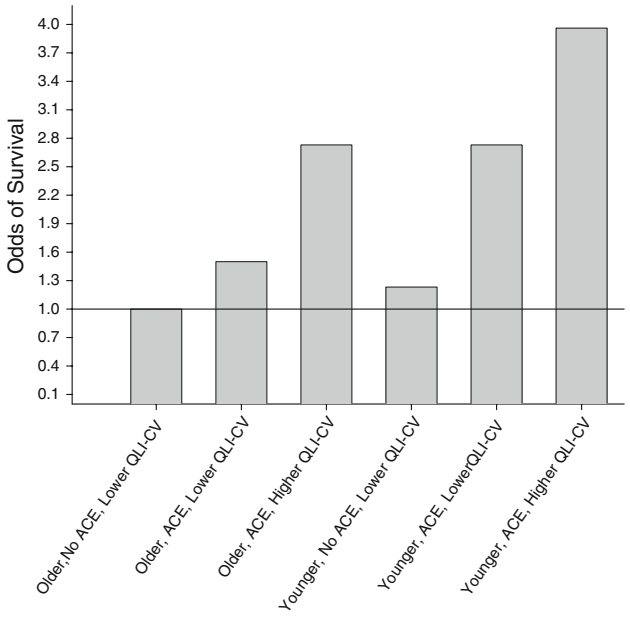

Fig. 1 Comparison of estimated odds of survival for patients with ICDs according to age, quality of life (*QOL*), and angiotensin-converting enzyme inhibitor (*ACE*) use. Younger age is 1 SD below the mean; older is 1 SD above the mean. Poor quality of life is 1 SD below the mean score on the QLI-CV, and good quality of life is 1 SD above the mean

Quality of life predicts one-year survival

A hierarchical approach was used to force the clinical and demographic variables into the model first and then evaluate whether adding the QOL variables added to the predictor of survival. Gender, age, race, EF, NYHA class, Hx of CHF, Hx of hypertension, Hx of hyperlipidemia, Hx of CABG, β-blocker medication, diuretic medication, ACE medication, and lipid-lowering medication were entered as the first block and PCS, MCS, and QLI-CV were entered as a second block. After adjusting for other predictor variables, the combination of PCS, MCS, and QLI-CV did not add significantly to the prediction of surviving 1 year after ICD implantation [$\chi^2(3,\ N = 308) = 4.531,\ P = .21$]. However, QLI-CV remained a significant independent predictor of 1-year survival after ICD implantation (OR = .48, $P = .047$). After adjusting for other predictor variables, patients with ICD who had better QOL had higher probability of surviving more than 1 year after ICD implantation.

Discussion

The demographic and clinical characteristics of the AVID ICD recipients were similar to those of studies conducted in the patient population with ICD [42–50]. Most participants were married men with a mean age of 64.85. The mean EF in this study (32.2%) was lower than in other ICD patient population studies [42, 43, 49–52]. Like previous studies, patients in this study underwent ICD therapy after they were resuscitated from near fatal VF or symptomatic VT [6, 47, 49, 51, 53, 54].Approximately 44.6% of the patients with ICD in this study had an index arrhythmia as VF and 55.4% had sustained primary VT.

In this study, during the first year after ICD implantation, 24.5% of patients with ICD experienced 1–4 shocks, 19.1% experienced more than five shocks, and 56.4% did not experience any shock. The percentage of patients with ICD (44%) experiencing shock was higher than in three studies (26, 39, 27%, respectively) [40, 45, 47] and lower than in one prospective longitudinal study [49], in which 57% of patients with ICD experienced shocks during the first year after ICD implantation. The percentage of patients with ICD who had shocks may be due to differences in the percentage of patients with AF. In the study that included description of AF [49], both percent of patients with AF (73%) and percent of patients who received shocks were higher than in the current study.

Most studies investigated the determinants of long-term mortality in patients with ICDs. Few studies focused on 1-year survival. The patients with ICD may be able to return to their normal way of life after 1 year [24–26]. During the first year after ICD implantation, patients face complex life situations. This is a critical period for patients.

Three variables were significant independent predictors of 1-year survival in ICD recipients. They were younger age, receiving ACE medication, and better QOL. A previous study also found that younger age was a significant independent predictor of long-term mortality [22]. Patients with ICD who received ACE medication had higher probability of surviving more than 1 year after ICD implantation. The rennin-angiotensin system facilitates norepinephrine release from sympathetic nerve endings and inhibits norepinephrine reuptake by nerve endings, thereby enhancing sympathetic adrenergic function. This may stimulate the pathogenesis of arrhythmias and poor prognosis [55]. Therefore, patients receiving ACE medication which interrupts the function of rennin-angiotensin system by blocking the transformation from angiotensin I to angiotensin II may decrease this risk and mortality. Finally, patients with ICD who had better QOL at baseline had a higher probability of surviving more than 1 year after ICD implantation. Even after adjusting for demographic and clinical predictor variables, QOL-CV remained a significant independent predictor of survival. This finding was consistent with two studies in the patient population with HF [11, 12], one study in patient population with ischemic

heart disease [13], and one study of patients eligible to receive ICDs for ventricular arrhythmia enrolled in the AVID study [56]. In these studies, QOL was identified as a significant independent predictor of mortality.

Previous studies of survival in ICD recipients found that EF [4, 16–19], NYHA classification [16, 17, 20, 21], ICD shocks [20, 22], gender [20], and history of sustained VT [23] predicted mortality. In this study, EF was a significant predictor in univariate analysis, however, in the multivariate analysis, EF did not have a significantly independent relationship to survival. This was consistent with the findings of two other studies of ICD recipients [16, 18]. NYHA classification also achieved a significant association with survival in univariate analysis, but not in multivariate analysis in this study. This finding was different from two studies [20, 21] in which NYHA classification (worse HF) was a significant independent predictor of mortality after adjusting for the clinical and demographic predictor variables such as EF, history of coronary artery disease, VT, VF, dilated cardiomyopathy, cardiac arrest, gender, and age.

Conclusion

Overall, the findings provide new information documenting the relationship between QOL and survival in patient with ICD. The result of this analysis indicated that younger patients with ICDs undergoing ACE medication treatment and with better QOL have a higher likelihood of surviving for more than 1 year after ICD implantation. After adjusting for other predictor variables, better QOL predicts more than one-year survival. AVID has already made significant contributions to the understanding of QOL of patients with ventricular arrhythmias [57]. The AVID study data set provided an excellent opportunity to examine the influence of QOL on survival in a well conducted and well controlled intervention environment of an internationally respected clinical trial.

Quality of life significantly influences the prognosis of patients receiving ICD treatments. When assessing patients with ICDs, the focus is not only on physiological status, but also on psychological conditions. An interventional program could be developed to improve the QOL and decrease the psychological distress in patients with ICDs and possibly improve their survival.

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