Quality of life in patients with an implantable cardioverter-defibrillator – the significance of clinical factors

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Abstract

Introduction: Implantable cardioverter-defibrillators (ICD) in patients exposed to the risk of lethal malignant ventricular arrhythmia proved to be the most effective method for preventing sudden cardiac death. The remaining problem is the tolerance of painful ICD discharges and patients' quality of life (QOL). The results of the study on quality of life after implantation of an ICD were unequivocal. The aim of the research presented in this paper was to verify some discrepancies, in particular in the area of relationships between QOL and clinical factors.
Material and methods: Eighty ICD patients were included in the research. The following tools were used in the assessment of QOL: the questionnaire by Kochańska, and the American questionnaire FPAS (Polish adaptation: Kochańska).
Results: A negative correlation of ICD shocks with QOL was proven. This applies in particular to multiple inappropriate and recently experienced discharges. The incidence of complications related to the ICD as well as the experience of additional invasive procedures correlated negatively with QOL. The period of life spent with an ICD also proved to be significant. The lowest QOL was observed in patients who were 1-2 years after the procedure, and the highest among those who were at least 5 years after the procedure.
Conclusions: Implantable cardioverter-defibrillators discharges reduce QOL and this pertains in particular to multiple and inappropriate shocks. Patients with an ICD who underwent additional procedures and invasive examinations, who experienced losses of consciousness after ICD implantation and those who had complications related to the ICD are at increased risk of reduced QOL. When interpreting the results of the research into QOL it is necessary to take into account the period of time since the first ICD implantation.

Key words: quality of life, implantable cardioverter-defibrillator, clinical factors.

Introduction

Implementation of implantable cardioverter-defibrillators (ICD) in clinical practice has contributed to the improvement of prognosis in patients with recurrent malignant ventricular arrhythmia [1]. The effectiveness of the ICD in preventing sudden cardiac death (SCD) has been confirmed by abundant research, inter alia AVID, CIDS MADIT, MUST, MADIT II, COMPANION, SCD HeFT [2-6].

Psychological consequences of the treatment, however, especially those connected with the tolerance of electric discharges, remain a problem.

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Typically, the energy of ICD discharges is 8-40 J. Shocks are usually accompanied by unpleasant sensations, as the pain threshold is normally ca. 1 J. More and more often, issues related to the tolerance of treatment, to the subjective perception of the state of health, to the satisfaction level, to the acceptance of the ICD and the disease are studied by means of the QOL assessment [7]. According to the definition by the World Health Organisation QOL is referred to as "individuals" perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' [8]. Different areas of QOL, including the physical, psychological and socioeconomic areas, may be affected due to the specific operation of an ICD.

Hence, patients with an ICD are continuously subject to a specific stress factor, i.e. painful unpredictable electric shock delivery. 50 to 70% of patients experience interventions within the first 2 years after ICD implantation [9, 10]. In the majority of cases, one shock is sufficient to terminate arrhythmia. Some of them (20-30%), however, experience "electrical storm", i.e. multiple ICD shocks (at least 3) within a 24-h period. Accumulated interventions can affect patients' emotional domain, causing fear and depression, and sometimes even post-traumatic stress disorder [10].

The assessment of QOL in ICD patients is therefore focused on the consequences of an unpleasant and unpredictable electrical shock delivery, on symptoms of heart disease, and, in a positive dimension, on the assessment of hope and of the sense of security of life [11, 12]. The results of previously conducted research into QOL are unequivocal [13]. Abundant research confirms high QOL, estimated in particular dimensions, and high ICD tolerance, especially in view of sudden cardiac death [14-17]. Nevertheless, some researchers confirm a negative correlation between QOL and ICD interventions [18-20]. In the research carried out by Hamilton et al. [21] and in the CABG-PATCH randomized study [18], the ICD associated negatively with QOL, especially in the physical and psychological dimension. On account of the above, it seems that the relationship between ICD implantation and patients' QOL is a complex problem and it does not depend only on electric shocks.

The aim of the study was to specify clinical correlates of the sense of the patients' QOL after implantation of an ICD. The following clinical factors were included: ICD shocks, supraventricular arrhythmias, complications related to ICD implantation, cardio-surgical procedures, invasive examinations, the period of life with the ICD, type of organic disease (coronary artery disease, heart failure), and pharmacological treatment (amiodarone, β-adrenolytics).

Material and methods

Participants

The research was carried out on 80 consecutive Polish patients with an ICD implanted at the Department of Cardiology and Electrotherapy, Medical University of Gdansk, Poland. 78.8% of the general sample were men, mean age was 56.3±14.8; mean left ventricular ejection fraction (LVEF) was 41.0±18.3; 42% of patients were classified as NYHA class II and 53% were patients with coronary disease. The period of life with an ICD ranged from 2 months to 9 years. Individuals with insufficient verbal-logical contact after neurological incidents, and individuals who did not give consent to participation in the research, were excluded from the study (5 patients in total). The investigation was granted the agreement of the Scientific Committee of the Bioethical Committee at the Medical University of Gdansk.

Methods

The research was a cross-sectional analysis. Quality of life in patients with ICDs was evaluated by means of a validated device-specific metric of patient acceptance, the Florida Patient Acceptance Survey (FPAS, 15-item version) [22-24]. The method facilitates measurement of general QOL (total score) and measurement of results in 4 sub-scales: Return to Life, Device-Related Distress, Positive Appraisal and Body Image Concerns. Quality of life is associated with the level of acceptance of the implanted device. Polish adaptation of the method was carried out by Kochańska [25] (reliability consistency of the Polish FPAS version was measured with Cronbach's coefficient α=0.70; other psychometric indicators of this version are available upon request). The correlation between QOL measurement and clinical factors was measured. Data concerning the occurrence of the factor and its intensity were gathered by means of the questionnaire by Kochańska, using the 5-point Likert scale. The questionnaire consisted of two parts: part "A" was filled in by patients, part "D" by the investigator, according to the patient's medical record. See the samples in Table I.

Statistical analysis

Statistical analysis was carried out by means of the SPSS-12 software. The r-Pearson and the rho-Spearman correlations were applied. Groups with normal distribution were compared by means of the t-test; in other cases, non-parametric tests were used: the Mann-Whitney U-test and

Table I. Sample questionnaire questions (authors' questionnaire)

Question	Numbers assigned to answers				
	1	2	3	4	5
Did you lose consciousness after ICD implantation?*	Yes – I was resuscitated because of it	Yes – I experienced losses of consciousness	No – but I fainted	No – I felt non-specifically 'dizzy'	I didn't lose consciousness/faint
How long have you been living with an implanted ICD?*	2-6 mths	6-12 mths	1-2 yrs	3-5 yrs	>5 yrs
When did you experience the most recent ICD shock?*	Less than 7 days ago	7-30 days ago	1-6 mths ago	6-12 mths ago	>12 mths
Symptoms of HF assessed according to the NYHA class.**	No heart failure	Class I	Class II	Class III	Class IV
Angina symptoms according to the CCS class.**	No coronary disease	Class I	Class II	Class III	Class IV
Have any ICD shocks occurred?**	Yes	No			

*Part "A" of the questionnaire, filled in by the patient
**Part "D" of the questionnaire, filled in by the investigator according to the patient's medical record
HF – heart failure

the Kruskal-Wallis test. In post hoc analyses, the Tukey test and the Dunn test were used. Statistical significance was set at the level of P<0.05.

Results

The majority of patients (85%) felt more secure with an ICD. Only 11.3% held the view that negative consequences of the implantation outnumbered its advantages. Twenty-two of the study population considered ICD shocks as the main problem in their life after implantation. Five percent of the investigated patients would not give consent for the implantation again.

The level of QOL was measured on a 100-point scale with the FPAS total score and it ranged from 33 to 97 (Me = 68).

The results of the correlation between the QOL measurement and the occurrence of clinical factors are described below. Particular correlations are presented in Tables II-IV and Figures 1, 2.

Implantable cardioverter-defibrillator shocks

Approximately 39% of the sample had experienced no shocks. Pain caused by an ICD shock was evaluated by patients as shock intensity on the 10 cm scale, where 0 stands for no unpleasant feelings, and 10 for unbearable pain. The distress associated with the shock ranged from 0.2 to 10 (M=6.12±3.07).

Patients with frequent shock deliveries perceived them as less painful. More intensive, more frequent,

Table II. Period of life with an ICD vs. FPAS total score. The Tukey B test

Period of life with an ICD	N	P<0.05
1-2 yrs	16	57.18
7-12 mths	16	61.12
3-5 yrs	22	61.54
2-6 mths	12	64.58
More than 5 yrs	9	66.66

recent, as well as inadequate discharges, were related to lower QOL. Patients who had experienced an electrical storm (22.5%) demonstrated much lower results in the FPAS in comparison to patients without defibrillations, in particular in the sub-scale Return to Life. See Tables III and IV.

Period of life with an implantable cardioverter-defibrillators

Quality of life was also related to the period of life with an ICD – the lowest within 1-2 years since the first implantation. See Table II and Figure 1.

Complete losses of consciousness and syncopes

Patients with losses of consciousness after implantation of an ICD demonstrated reduced QOL, in particular in the sub-scale Return to Life. See Table III and Figure 2.

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Table III. Correlations of selected clinical factors with FPAS results

Clinical factor	FPAS subscale scores and the total score					Correlation
	Return to life	Device-related distress	Positive appraisal	Body image concerns	Total score	
Self-reported shock intensity	−0.283*	0.194	0.038	0.225*	−0,254*	r Pearson
Length of time since the last shock	0.307**	−0.165	−0.083	−0.184	0,238*	rho Spearman
Shock frequency	−0.379**	0.185	−0.048	0.286*	−0,315**	rho Spearman
Loss of consciousness (after ICD implantation)	0.287*	0.139	0.025	0.128	0,218*	rho Spearman
Ejection fraction (LVEF)	0.239*	−0.209	−0.102	0.082	0,136	r Pearson
Pain intensity (CCS class.)	0.079	−0.014	−0.173	0.101	−0,060	r Pearson
Heart failure (NYHA class.)	−0.216*	0.072	0.103	0.118	−0,136	r Pearson

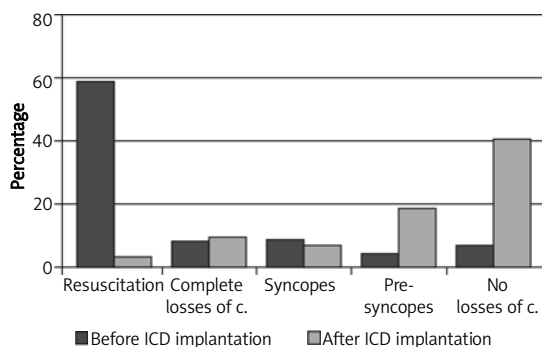*$P<0.05$, **$P<0.01$ significant correlations are marked in bold

LVEF – left ventricular ejection fraction, CCS scale – Canadian Cardiovascular Society classification, NYHA class. – New York Heart Association classification

Procedure-related and distant ICD-related complications

Complications, including haematoma around the implantation site, lead failures, dislocations of an ICD, and local and general infections, occurred in 22.5% of the sample. The presence of complications reduced QOL significantly ($P<0.05$) and caused high distress. See Table IV.

Additional procedures, cardiological and cardiosurgical invasive examinations

All patients had ICDs implanted, and almost all of them (95%) had coronarography performed. Approximately 67% of patients were subject to additional procedures: RF ablation, electrophysiological study, coronary artery bypass graft (CABG), valve replacement, left ventricular plasty, percutaneous transluminal coronary angioplasty. Patients who were subject to additional procedures have significantly lower QOL. See Table IV.

Coronary artery disease

Patients with a diagnosed coronary artery disease (53%) did not differ in QOL from other patients with the ICD. An escalating stenocardia in the CCS classification did not differentiate QOL of the patients significantly. See Table III.

Heart failure

Lower LVEF and a higher functional NYHA class correlated with lower QOL. See Table III.

Supraventricular arrhythmias (atrial fibrillation and flutter, atrial tachycardia)

Supraventricular arrhythmias occurred in 34% of the ICD patients. Their presence did not differentiate the sample group regarding QOL.

Pharmacological treatment

Individuals treated with beta-adrenolytics (90%) showed lower QOL than individuals who did not

Figure 1. Percentage of patients with losses of consciousness before and after ICD implantation
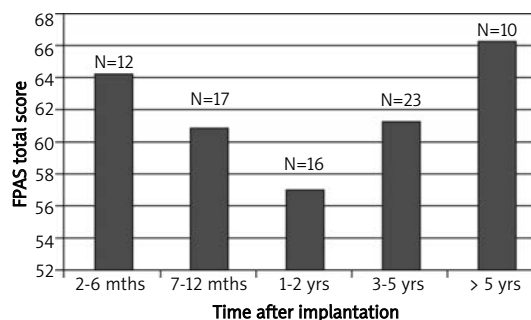
Figure 2. Period of life with ICD and the FPAS total score (mths – months, yrs – years)

Table IV. Influence of selected clinical factors on QOL in individual FPAS subscales and in the total score

Clinical factor		N	FPAS subscale scores and the total score									
			Return to life		Device-related distress		Positive appraisal		Body image concerns		Total score	
			M	SD	M	SD	M	SD	M	SD	M	SD
Frequency of ICD shocks	No shocks	31	16.63	2.88	10.86	5.25	18.06	2.86	3.90	2.02	64.93	8.85
	Multiple shocks	18	13.80	2.67	12.86	5.09	16.80	4.90	5.42	2.40	57.14	9.89
	P-value		<0.01		SI		SI		<0.05		<0.05	
Shock adequacy	Inadequate shocks	17	13.94	2.81	14.41	6.23	17.11	4.68	5.06	2.40	56.46	11.75
	Adequate shocks	16	16.14	2.24	12.42	6.28	18.00	2.82	3.92	2.20	62.78	7.26
	P-value		<0.05		SI		SI		SI		SI	
Complications	Presence of complications	18	14.64	3.01	15.64	4.80	17.47	3.04	4.82	2.24	56.64	8.03
	No complications	62	15.06	2.91	11.29	5.32	18.23	3.04	4.54	2.15	63.08	9.40
	P-value		SI		<0.01		SI		SI		<0.05	
Additional invasive procedures	Yes	54	13.95	2.08	15.59	5.81	17.09	4.34	4.90	2.50	55.54	10.30
	No (only ICD)	26	16.00	3.10	10.94	4.88	18.45	2.30	4.46	2.05	64.19	8.04
	P-value		<0.01		<0.001		SI		SI		<0.001	
Necessity to apply psychotropic drugs	Yes	42	14.29	2.65	14.09	5.73	17.68	3.60	4.74	2.26	58.15	10.29
	No	38	16.63	2.78	10.18	4.43	18.50	2.22	4.45	2.06	65.38	6.80
	P-value		<0.001		<0.001		SI		SI		<0.001	

M – mean, SD – standard deviation, N – number, SI – statistically insignificant

receive such medication (P<0.05, Mann-Whitney U-test). Amiodarone treatment (37%) did not change QOL significantly in the sample. As many as 52% of the sample received psychoactive drugs (sleeping pills, tranquillisers and anxiety-relieving drugs), and this sub-group was characterized by reduced QOL. See Table IV.

Discussion

The results of previous studies on QOL in patients with an ICD lead to unequivocal conclusions [13]. The aim of the research presented in this paper was to verify some discrepancies, in particular with regard to the relationships between QOL and clinical factors.

In the assessment of QOL, the American Florida Patient Acceptance Survey (FPAS), the visual analogue scale of assessment of the pain caused by the ICD shock delivery, and the Cantril Ladder were applied.

In this study, the average FPAS result was 68 and it was significantly lower than in the Burns et al. study, in which the general result was M=76 [22]. Similarly, in the Groeneveld et al. study, patients achieved the average FPAS result of M=80 [23]. An even higher mean of M=86 was demonstrated in the study by Birnie et al. [26] These results suggest lower QOL among Polish patients. However, it is worth noting that in patients studied by Burns, ICDs had not been implanted more than 3 months before the study. In Groeneveld's sample, 45.7% did not experience any ICD shocks, whereas in the Polish group only 38.8% did not experience any defibrillations and 20% experienced an electrical storm.

The presence of multiple and high-energy ICD interventions correlates negatively with QOL in our study. This is confirmed by other authors [3, 12, 10, 26, 27]. The results of our study indicate that higher frequency of ICD shocks is associated with subjective perception of the shocks as more powerful and more painful. Moreover, it was not only the fact that there had been ICD discharges that was significant, but also the period since the last shock delivery. Quality of life was higher in patients in whom the interventions occurred a long time before. Appropriate discharges were of positive significance. Inappropriate shocks, i.e. not associated with a ventricular arrhythmia, influenced QOL negatively. Quality of life was also significantly lower in patients who had experienced a loss of consciousness or circulatory arrest, the ICD notwithstanding. Similar reservations were expressed by Chevalier et al. [12] and by Lüderitz et al. [28]. These authors proved that the fact that the shocks are appropriate and effective in terminating arrhythmia is of great importance to patients.

The most difficult period for our patients was 1-2 years after the implantation of an ICD, when QOL was at the lowest level. The highest QOL was recorded in patients with at least 5-year experience of life with an ICD. This result is explained by some researchers as a process of adaptation to life with the implanted ICD [29, 30]. Nevertheless, there are also researchers who see no relationship between QOL and the passage of time [24, 31]. We assume that only the healthiest patients have survived more than 5 years with the device. This issue should be set as the subject of further research.

The QOL of patients with coronary artery disease did not differ from patients with other aetiology rhythm disorders. On the other hand, in scientific reports it was shown that even mild stenocardia influences QOL negatively [32, 33]. However, this concerned patients without an implanted ICD. We presume that the awareness that the device provides protection gives a feeling of security to patients after myocardial infarction, and in particular after circulatory arrest.

According to our study, heart failure classified in a higher NYHA class, as well as lower LVEF, correlated negatively with QOL. A similar association of symptomatic heart failure with the FPAS results was demonstrated in the study by Pedersen et al. [34]. In addition, we observed that some patients with a higher NYHA class limited physical exertion because of fear of ICD shocks. According to Godemann et al. [35] even severe heart failure influences QOL after ICD implantation only insignificantly, and 30% of the symptoms leading to the decrease of QOL in the dimension of physical function are a result of fear somatisation.

The occurrence of supraventricular arrhythmias did not differentiate our population significantly, although, as confirmed in the Swerdlow et al. study [36], they might be the cause of 30% of in-appropriate shocks. We observed that patients who, apart from ICD implantation and coronarography, underwent additional invasive procedures (of cardiological and cardiosurgical nature), demonstrated significantly lower QOL. Similarly, patients with distant and procedure-related complications, which were directly associated with the implanted cardioverter-defibrillator, indicated reduced QOL.

In the assessment of the relationships of pharmacological treatment and QOL in our sample, only β-blockers correlated negatively with QOL. However, we paid attention to the significant and also negative correlation between taking sleeping pills, tranquillisers, and anxiety-relieving drugs in patients with an ICD and their QOL. This result suggests the presence of quite significant emotional problems in this group of patients.

In conclusion, ICD shocks reduce QOL, but this applies in particular to multiple and inappropriate

shocks; the group which is especially put at risk of reduced QOL comprises patients with ICD-related complications who undergo additional procedures and invasive examinations, and with losses of consciousness after ICD implantation; in the interpretation of the results of the QOL research it is also necessary to take into account the period of time since the first ICD implantation.

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