Quality of life in patients with a subcutaneous vs. transvenous implantable cardioverter-defibrillator

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ABSTRACT

Background: The implantable cardioverter-defibrillator (ICD) and subcutaneous ICD (S-ICD) are well-accepted life-saving devices for treating potentially lethal ventricular arrhythmia, but little is known about quality of life (QoL) in patients with S-ICD and ICD.

Aims: Our study aimed to compare QoL in patients with S-ICD and ICD.

Methods: All consecutive patients who had S-ICD implanted between October 2015 and September 2021 were included in the study. A cohort of transvenous ICD (TV-ICD) patients was matched to S-ICD subjects by sex, age, indications for the device, and type of prevention. All patients were requested to fulfill two standardized questionnaires to assess QoL: 36-Item Short Form Health Survey (SF-36) and Minnesota Living with Heart Failure Questionnaire (MLHFQ) 6 months after device implantation.

Results: Patients with S-ICD (n = 49) and TV-ICD (n = 49) did not differ regarding baseline characteristics. There were no statistically significant differences between S-ICD and TV-ICD subgroup, both for mental and physical QoL assessed in SF-36 and MLHFQ (all P = NS). The median MLHFQ total score was 24 (9–41) for S-ICD and 28 (14–43) for TV-ICD (P = 0.83). The median total score for the SF-36 questionnaire was 62.5 (29–86) vs. 59 (38–77) for S-ICD and TV-ICD, respectively (P = 0.78).

Conclusions: Quality of life after device implantation does not differ significantly between the groups of patients with subcutaneous and conventional implantable cardioverter-defibrillator.

Key words: quality of life, implantable cardioverter-defibrillator, subcutaneous cardioverter-defibrillator, prognosis

INTRODUCTION

The implantable cardioverter-defibrillator (ICD) is a well-accepted life-saving therapy for lethal ventricular arrhythmias. It has an undeniable advantage over antiarrhythmic drugs for the primary and secondary prevention of sudden cardiac death (SCD) [1]. While clinically effective, ICDs carry short- and long-term complications associated with intracardiac leads, such as lead failure occurring with the upward trend linked to the longer follow-up. Indeed, this complication reaches 20% of 10-year-old leads [2]. To overcome lead-related issues, the subcutaneous ICD (S-ICD) was created. S-ICD is a class IIa indication when pacing therapy for bradycardia, anti-tachycardia, or resynchronization therapy is not required, and a class IIb indication in patients with inadequate vascular access, prone to infections, especially after transvenous ICD (TV-ICD) removal and in young patients [1]. Throughout the last years, the importance of S-ICD has been increasing

WHAT'S NEW?

Physical and mental quality of life (QoL) in patients with subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous ICD (TV-ICD) did not differ 6 months after device implantation. The data about QoL in patients with TV-ICD compared to S-ICD are important for clinicians and patients, especially in cases of similar indications for S-ICD and TV-ICD implantation.

in Poland, and the main selection factor is the young age of a patient [3, 4].

Therapy with ICD successfully enabled prolonging patients' life; however, symptoms of anxiety affect around 24%–87% of ICD recipients, and approximately 13%–38% of ICD patients suffer from significant anxiety disorders [5]. Regardless of a decrease in lead-related complications both perioperative and long-term, little is known about S-ICDs' psycho-social impact. Thus, this study aimed to compare the quality of life (QoL) in patients with S-ICD and TV-ICD.

METHODS

Study population

The study population consisted of consecutive patients who had S-ICD implanted between October 2015 and September 2021 in a tertiary cardiology center in Poland. All patients were observed prospectively in a single-center S-ICD registry.

Subjects with S-ICD were matched with TV-ICD recipients by age, sex, indications for the device, and type of prevention in the same time interval.

All patients met the criteria for ICD implantation, in line with the current European Society of Cardiology guidelines [1]. Patients were informed about the procedure and potential complications and signed informed written consent. The study was conducted in compliance with recognized international standards, i.e., the Declaration of Helsinki.

Implantation of S-ICD

Each recipient received the EMBLEM™ MRI S-ICD Device (Boston Scientific, Natick, MA, US). All implantations of S-ICD were performed under general anesthesia using the three-incision technique. Fluoroscopy was used to determine the intended device and lead locations. The first incision was made to accommodate the pulse generator at the mid-axillary line between the 5th and 6th intercostal spaces under the latissimus dorsi muscle. Two other parasternal incisions were made to enable lead tunnelization. A defibrillation threshold test (DFT) was made to test the device's functionality. The optimal localization of the S-ICD was assessed with the post-implant X-rays.

Implantation of TV- ICD

The implantations of TV-ICD were performed under local anesthesia. The subclavian vein was accessed by venesection of a cephalic vein or a puncture of the subclavian vein or axillary vein, depending on favorable anatomical conditions and operators' decisions.

The right ventricular pacing/defibrillation lead was inserted with fluoroscopy. The pulse generator was implanted into a subcutaneous pocket. A prophylactic dose of antibiotic was given pre-procedurally to all the ICD recipients (cefazolin single dose iv; or clindamycin single dose iv in the case of allergy to cephalosporins).

Follow-up

Patients were followed 1 week, 1 month, 6 months post-implantation, and every 6 months subsequently. Clinical assessment was performed during post-implantation hospitalization and the whole follow-up. Data was collected from appointments, hospital files, telemonitoring of the devices, and available sources.

Quality of life

Health-related QoL was evaluated *via* Minnesota Living with Heart Failure Questionnaire (MLHFQ) and Medical Outcomes Study 36-Item Short-form General Health Survey (SF-36), completed by two groups of patients 6 months after implantation. MLHFQ is dedicated to heart failure (HF) patients and is used to screen daily the impact of their condition which cannot be received directly from clinical measurements. The questionnaire consists of 21 questions, each ranked on a six-point Linkert scale. A final score ranges from 0 to 105 and represents general wellbeing. This questionnaire also provides scores for two dimensions: physical (8 items, range 0–40) and emotional (5 items, range 0–25).

To screen for potential variations between groups in an aspect of generic measure for health-related QoL, the SF-36 was evaluated. SF-36 measures eight scales divided into two concepts: the mental dimension, comprising vitality, emotional role, social functioning, mental health; and the physical dimension comprising bodily pain, physical functioning, physical role, and general health. SF-36 total score ranges from 0 to 171 with the mental dimension (0–68) and the physical dimension (0–103).

Statistical analysis

The continuous parameters were expressed as median (interquartile range [IQR]), whereas categorical variables as numbers and percentages. The groups were compared using the χ^2, Student t-test, or Mann–Whitney U tests, as appropriate.

Table 1. Baseline characteristics of the study population

	Whole population (n = 98)	TV-ICD (n = 49)	S-ICD (n = 49)	*P*-value
Age, years	44 (32–55)	48 (37–56)	36 (28–54)	0.06
Male sex, n (%)	63 (64.3)	32 (65.3)	31 (63.3)	0.83
NYHA class III or IV, n (%)	15 (15.3)	7 (14.3)	8 (16.3)	0.78
Primary prevention, n (%)	58 (59.2)	30 (61.2)	28 (57.1)	0.68
Ischemic cardiomyopathy, n (%)	36 (36.7)	22 (44.9)	14 (28.6)	0.09
LVEF, %	33 (25–53)	32 (25–46)	37 (25–55)	0.15
Comorbidities, n (%)				
Stroke/TIA	4 (4.1)	2 (4.1)	2 (4.1)	1.0
HA	41 (41.8)	23 (46.9)	18 (36.7)	0.31
Type 2 DM	15 (15.3)	11 (22.5)	4 (8.2)	0.049
CKD	14 (14.3)	6 (12.4)	8 (16.3)	0.56
Paroxysmal AF	11 (11.2)	8 (16.3)	3 (6.1)	0.11
Permanent AF	10 (10.2)	6 (12.2)	4 (8.2)	0.50
Procedural course				
Procedure time, min	95 (80–132)	80 (60–95)	120 (100–150)	0.40
Radiation dose, mGy	3.9 (0.9–18)	13.3 (4–26)	1.4 (0.5–4)	<0.001
DAP, mGy×cm^2	57.6 (4.8–398)	352 (37–720)	11.3 (1–59)	<0.001
Hospitalization time, days	3 (2–8)	2 (2–3)	4 (2–12)	0.09
Time from implantation to discharge, days	1 (1–2)	1 (1–2)	1 (1–3)	0.42
Medications at discharge, n (%)				
ACEI	59 (60.2)	33 (67.3)	26 (53.1)	0.15
Aldosterone antagonist	59 (60.2)	34 (69.4)	25 (51.0)	0.06
β-blocker	87 (88.8)	46 (93.9)	41 (83.7)	0.11
Diuretics	46 (46.9)	24 (48.9)	22 (44.9)	0.69

Continuous variables are presented as median (IQR). *P* – for comparison of patients with TV-ICD and S-ICD

Abbreviations: ACEI, angiotensin-converting-enzyme inhibitor; AF, atrial fibrillation; CKD, chronic kidney disease; DAP, dose-area product; DM, diabetes mellitus; HA, hypertension arterial; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; TIA, transient ischemic attack; S-ICD, subcutaneous implantable cardioverter-defibrillator; TV-ICD, transvenous implantable cardioverter-defibrillator

The *P*-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using the software package Statistica version 12.

RESULTS

Study population

Between October 2015 and September 2021, forty-nine patients had S-ICD implantation. During this period, 636 patients were implanted with TV-ICD. Forty-nine TV-ICD recipients were matched with S-ICD subjects by age, sex, indications for the device, and type of prevention in the same time interval. No statistically significant difference in baseline characteristics was found between S-ICD and matched TV-ICD subjects (Table 1).

S-ICD was implanted for primary prevention of SCD in 57.1% of the cases (n = 28). Thirteen S-ICD recipients (26.5%) had had previous conventional TV-ICD and then explantation for the following reasons: 4 patients had revealed cardiac device-related infective endocarditis (CDRIE), 2 patients had had a pocket infection, and there had been 7 cases of lead failure.

TV-ICD was implanted for primary prevention in 61.2% of the patients (n = 30), and ischemic cardiomyopathy occurred in 22 subjects (44.9%).

There were some periprocedural differences between the study groups resulting from the technique of S-ICD and TV-ICD implantation procedures (Table 1). No perioperative complications were observed in S-ICD and TV-ICD patients. There were no ventricular tachycardia/ventricular fibrillation (VT/VF) episodes in either cohort before discharge from the hospital.

Follow-up

During a median follow-up of 736 days (range 190––2325 days), there were two device-related complications observed in the S-ICD group. Two months post-implantation, one patient needed lead revision due to the risk of device externalization, and 3 years after the S-ICD implantation, sudden exhaustion of the battery of the device was observed. One lead revision and one lead exchange due to dysfunction were observed in the TV-ICD group.

Up to 6 months, post-implantation 1 patient (2.04%) had 1 appropriate S-ICD shock due to VF, and 3 patients (6.12%) experienced inappropriate shocks: one of them had 3 inappropriate S-ICD therapies, and 2 others experienced 1 shock. All of them were caused by atrial fibrillation (AF) with a rapid ventricular response. In the group of conventional ICD up to 6 months post-implantation, 1 patient (2.04%) had 1 inappropriate ICD shock (AF with rapid response), up to 1 year, one patient (2.04%) had 1 VT with anti-tachycardia pacing therapy (ATP).

During long-term follow-up, 1 patient in the TV-ICD group had 3 inappropriate ICD shocks due to AF with rap-

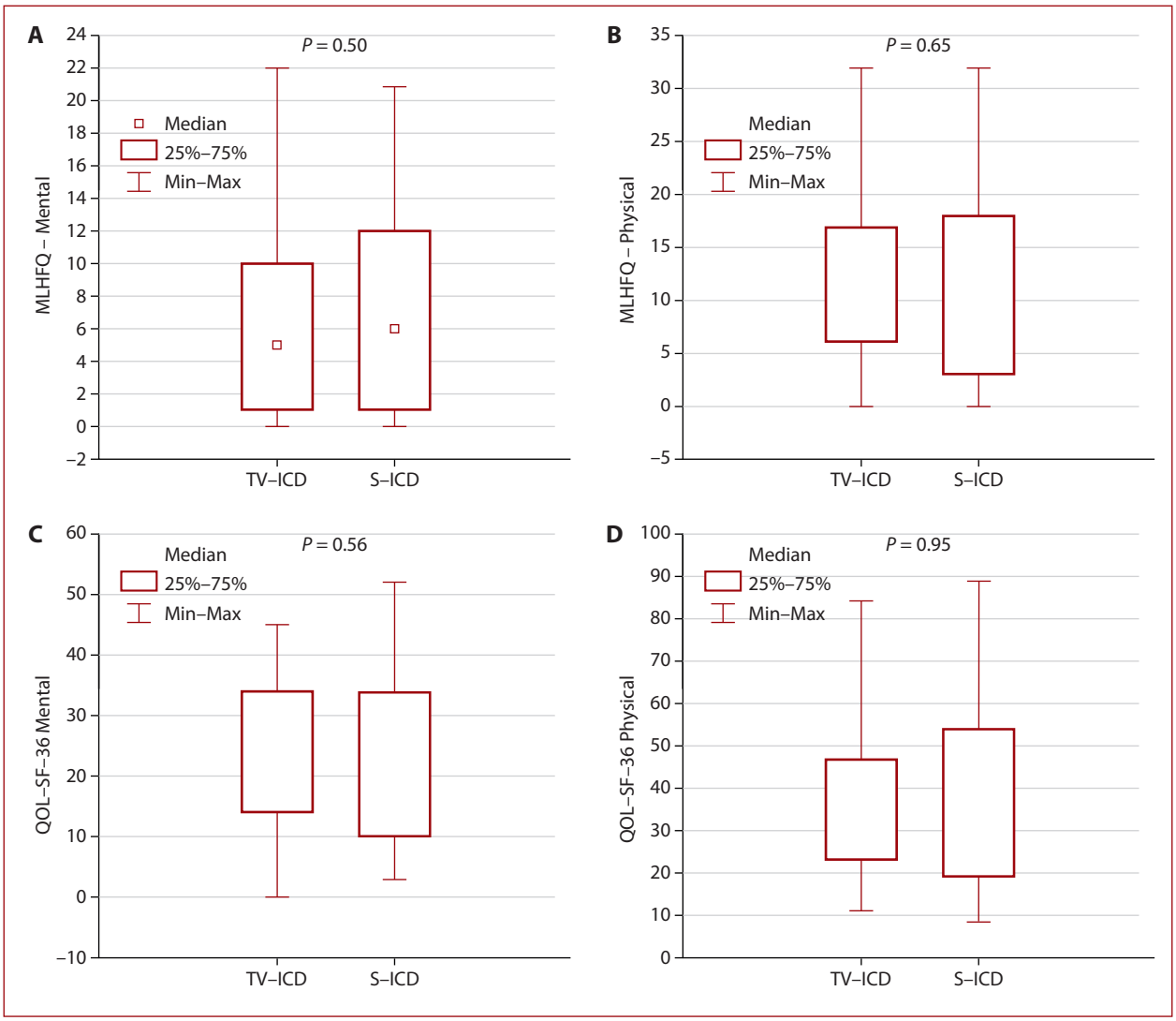

Figure 1. Median scores for MLHFQ and S-36 questionnaires for both cohorts (**A**) MLHFQ mental aspect (**B**) MLHFQ physical aspect (**C**) S-36 mental aspect (**D**) S-36 physical aspect

Abbreviations: MLHFQ, Minnesota Living with Heart Failure Questionnaire; S-36, Medical Outcomes Study 36-Item Short-form General Health Survey; other — see Table 1

id response, and 3 subjects with S-ICD had inappropriate device therapies: one due to sinus tachycardia, one due to AF rapid response, and one due to T-wave oversensing. One patient in the S-ICD group and one with TV-ICD had an electrical storm.

Five patients (10.2%) from the S-ICD group died from non-arrhythmia-related causes and seven (14.3%) from the conventional ICD group during the whole follow-up ($P = 0.54$).

Quality of life

Health-related QoL results did not significantly differ between the two cohorts. The median MLHFQ total score was 24 (9–41) for S-ICD and 28 (14–43) for TV-ICD ($P = 0.83$). For the mental and physical dimensions, the median score was 6 (1–12) and 8.5 (3–18) for S-ICD, respectively, whereas for TV-ICD: 5 (1–10) and 12 (6–17) (S-ICD vs. TV-ICD: $P = 0.50$ and $P = 0.65$).

Patients in the two groups did not vary in terms of the median total score for the SF-36 questionnaire either: it was 62.5 (29–86) vs. 59 (38–77) for S-ICD and TV-ICD, respectively ($P = 0.78$). The median of mental dimension was 21.5 (10–34) for S-ICD and 18.5 (14–34) for TV-ICD ($P = 0.56$), for the physical dimension 41 (19–54) for S-ICD and 36 (23–47) for TV-ICD ($P = 0.95$). A comparison of median scores for MLHFQ and S-36 questionnaires for both cohorts is presented in Figure 1.

DISCUSSION

The main finding of our study is that physical and mental QoL in patients with S-ICD and TV-ICD measured with the use of two kinds of questionaries did not differ 6 months

after device implantation. To the best of our knowledge, only a few studies have compared the quality of life in patients with S-ICD and TV-ICD.

In recent years, apart from hard endpoints such as mortality, the crucial role of QoL in patients with chronic diseases has been emphasized. A high quality of life index indicates that the patient, despite the disease, perceives himself as functioning well physically, mentally, and socially. On the other hand, the low quality of life index shows that the disease limits these functions from the patient's point of view. Patients with ICDs experience limitations in many spheres of activity. Most people are aware of the impact of the disease on life expectancy related to the implanted device, and this knowledge also increases perceived stress. In the case of pacemakers, it has been shown that these devices not only affect prognosis but also improve patients' QoL [6–8]. In the case of the ICD, the issue is a bit more complicated. Numerous randomized trials have shown that these devices extend the life of patients with HF at risk of SCD [9,10]. But how do they affect the QoL?

Pacemakers reduce symptoms associated with atrioventricular block or sick sinus syndrome, so one may expect that they would have a positive effect on QoL [6–8]. ICD does not affect the symptoms of HF, so can QoL in this group of patients improve after device implantation? The improvement of QoL in patients with TV-ICD and S-ICD between baseline and 3 months and between baseline and 6 months was significant, but not between 3 months and 6 months [11].

Our result is consistent with findings of the QoL substudy of the EFFORTLESS S-ICD Registry. [12]. The authors used the 12-Item Short-Form Health Survey (SF-12) at baseline, 3 and 6 months after implantation and applied the Type D Scale (DS14) at baseline to assess the Type D personality in the context of QoL. The result of this study was that both S-ICD and ICD patients were not different in terms of physical and mental QoL. Two other studies showed similar findings — no differences between QoL in patients with S-ICD and TV-ICD were found [11, 13]. Only in one study the physical aspect of QoL was significantly higher in the S-ICD cohort than in the TV-ICD cohort, while the mental aspect of QoL did not differ between the two groups [11].

Data about QoL in patients with TV-ICD compared to S-ICD are important for clinicians and patients, especially in cases of similar indications for S-ICD and TV-ICD implantation. The same QoL in patients with S-ICD and TV-ICD observed in studies indicate that the difference in size and weight between the pulse generator of the S-ICD and the TV-ICD device has a negligible impact on QoL. It seems that other factors, in particular, symptoms of HF and personality, may be more significant determinants of QoL than the type of device itself [14, 15]. It was observed previously that posttraumatic stress disorders occur in almost 15% of ICD patients irrespective of the system [11]. A comparison between TV-ICD and S-ICD showed no statistically significant difference in posttraumatic stress, depression, or anxiety measured by the posttraumatic stress diagnostic scale (PDS) and the Patient Health Questionnaire (PHQ) [11].

One more important aspect is the effect of ICD therapies on QoL. The impact of ICD shocks — both appropriate and inappropriate — on patient wellbeing is widely described in the literature [16, 17]. In the published data, the rates of both appropriate and inappropriate therapies in primary and secondary prevention are nearly equal and steady level during long follow-up [18]. ICD patients represent a high-risk population for the development of panic disorders, and a direct correlation between development of anxiety disorder and frequency of repeated shocks was observed [19]. However, the link between device shocks and patient-centered outcomes is not as unequivocal as described before. The psychological profile and severity of underlying heart disease would be just as significant cause of distress as ICD shocks in this cohort of patients [20]. Some studies in patients with TV-ICD showed that the severity of HF, anxiety, and depression have a more significant impact on QoL than shocks [21, 22]. One study in patients with TV-ICD vs. S-ICD confirmed that personality, HF class, and depression were associated with QoL to a greater extent than the type of device and ICD therapy. [13] What is more, not only do the ICD shocks cause emotional distress but also these negative emotions and stress itself cause malignant arrhythmia that requires ICD therapies. Chronic anxiety may increase vulnerability to arrhythmias by sustained sympathetic stimulation or depressed vagal tone [23]. Therefore, it seems essential to evaluate and control the QoL in those patients to prevent the vicious circle of depression and ICD discharge.

Study limitations

A small number of patients implanted with S-ICD was the basic limitation of this study. Unfortunately, this new technology approved by Food and Drug Administration in 2012 had limited reimbursement by the National Healthcare Fund in Poland before January 2019. The consequent limitation of the study was that we did not evaluate pre-implantation QoL in our patients. The key intention of the present study was to demonstrate the non-inferiority of those two types of devices, and we did not evaluate pre-implantation QoL in our patients thus we have only post-implantation data. The QoL was assessed 6 months after implantation because it was shown that in patients with implanted ICD the QoL improves significantly after the patient gets used to the device, i.e. after about 6 months [24]. We computed the questionnaires using the Polish key that has the opposite calculation from the international data — low scores mean high QoL, while high scores mean impaired QoL.

CONCLUSION

Quality of life 6 months after ICD implantation does not differ significantly between patients with subcutaneous and conventional types of ICD.

Article information

Conflict of interest: EJP, OK, MM, AS, and RL received consultant fees from Medtronic, Biotronik, Abbott, and Boston Scientific. BŚ received consultant fees from Bayer, Boehringer-Ingelheim, Pfizer, Bristol-Myers-Squibb, Medtronic Bakken Research Center (past) and lectures fees from Bayer, Boehringer-Ingelheim, Pfizer, Novartis, MEDICALgorithmics, and ZOLL. ZK received speaker bureaus for Pfizer, Boehringer-Ingelheim, and Abbott.

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