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ORIGINAL RESEARCH

Impairment of Quality of Life in Patients with Implanted Subcutaneous Cardioverter Defibrillator (S-ICD) Compared to Implanted Transvenous Cardioverter Defibrillator Therapy

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Background: The subcutaneous cardioverter defibrillator (S-ICD) has been shown to be a viable alternative to transvenous ICDs (TV-ICD) in all patients at risk of sudden cardiac death (SCD) but without pacing indication.

Aim: The aim of this study was to examine the impact of therapy with current S-ICD devices on quality of life (QoL) in comparison to patients with TV-ICD devices.

Methods: In our single-centre study, 52 consecutive patients with S-ICD and 52 matched patients with TV-ICD were analysed. QoL has been assessed by a standardized questionnaire (EQ-5D-3L, modified). Additionally, clinical baseline and follow-up data were evaluated.

Results: Two-thirds of the total study population reported restrictions in daily routine compared to their life before ICD implantation. A total of 27.7% of S-ICD patients stated to expect an improvement of QoL by deactivation or explantation of their defibrillator compared to only 6.4% of patients with TV-ICD (p=0.006), which was mainly caused by discomfort and pain from the S-ICD pocket (relevant discomfort and pain in 32.6% vs 11.5%; p<0.01).

Limitations: Main limitation of the study is that quality of life was assessed for one single time point only and time since implantation differed significantly between S-ICD and TV-ICD. Furthermore our collective is younger, and, due to the high proportion of patients without cardiomyopathy, the mean EF is better than usual ICD collective. The absence of heart failure in about the half of our patients might have relevant impact on our QoL analysis.

Conclusion: A relevant proportion of S-ICD patients expects an improvement of QoL by explantation of the device. Of note, this impression was not driven by the fear of receiving shocks but mainly by discomfort and pain caused by the pulse generator.

Keywords: subcutaneous cardioverter defibrillator, S-ICD, transvenous cardioverter defibrillator, quality of life

Introduction

An implantable cardioverter defibrillator (ICD) enables sufficient protection from sudden cardiac death (SCD) in patients at high risk for sustained ventricular arrhythmia.[1–5] Due to its intravascular lead standard transvenous ICD (TV-ICD) therapy is associated with acute complications such as implantation-related pneumothorax and cardiac perforation as well as long-term issues like lead dysfunction, displacement, and infection.[6–8] To avoid premature defect of leads, TV-ICD implicates restrictions of flexibility of the shoulder, which may cause relevant restrictions of daily activity especially in younger patients.

The subcutaneous cardioverter defibrillator (S-ICD) sought to overcome primarily lead-related complications and has been shown to be a viable alternative to traditional TV-ICDs for all patients in need of an ICD but without pacing

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indications.[9,10] Due to its entirely extra-thoracic system especially younger S-ICD patients might benefit from fewer restrictions in mobility compared to TV-ICDs. On the other hand, the larger pulse generator and its position between M. serratus anterior and M. latissimus dorsi may cause discomfort and pain in particular in slim and female S-ICD patients.[11] The rate of inappropriate shocks has decreased over time,[12] but it is still higher in S-ICD compared to the transvenous systems, which might lead to anxiety and fear of shocks in patients.[13] This may obviously have an impact on patients' mental well-being and their quality of life (QoL), but still the effect of S-ICD therapy with contemporary 2nd- and 3rd-generation S-ICD generators on QoL has not been studied methodically yet. In our current study, we present our experience with a cohort of S-ICD patients with a special focus on the influence on QoL.

Methods

Study Design

The current study reports on a single-centre investigation of consecutive patients with implantation of an S-ICD (Emblem™, Boston Scientific) between June 2015 and November 2020 in our hospital and follow-up in our outpatient department. Longitudinal data were extracted from routine clinical management without additional examinations or treatment beyond routine clinical care in a retrospective manner. Baseline characteristics were collected within the routine follow-up outpatient visit. The study conformed to the 1975 Declaration of Helsinki and was approved by the ethics committee of the Ludwig-Maximilians-University of Munich (accession number: 20–641). All participants gave written informed consent.

Study Population

Patients with S-ICD therapy attending our outpatient department to receive routine follow-up were consecutively recruited to this analysis. S-ICD therapy was prescribed either due to primary or secondary prevention in accordance to current guidelines.[14] Additionally, an age-, sex-, and disease-matched control cohort of patients with conventional TV-ICD was equally recruited in a retrospective manner from our outpatient department.

Quality of Life Assessment

Quality of life was evaluated within the routine follow-up in our outpatient department using a standardized questionnaire (EQ-5D-3L)[15] comprising five dimensions of QoL: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is assessed in three levels: no problems, some problems, and extreme problems. In addition, dichotomous questions (see Supplemental Figure 1) about fear of shock, sense of security, disturbance of sleep, and impairment of usual activities subjectively caused by the ICD were posed in accordance to our previous work.[16]

Statistics

Data are presented as mean ± SEM for continuous variables. Number of cases or percentage were reported for categorical variables. Normality testing was performed using Shapiro–Wilk test, and comparison of continuous variables was done with Student's *t*-test. Categorical variables were compared using a chi-square test. A p-value <0.05 was considered statistically significant. Statistical analysis was conducted using SPSS software, version 28.0, IBM Corp., Armonk, NY, USA.

Results

A total of 52 consecutive patients with S-ICD and a cohort of 52 patients with TV-ICD, matched for age, sex, and underlying disease, were included. Baseline characteristics of the study population are depicted in Table 1. The predominant indication for ICD therapy was secondary prophylactic in patients without structural cardiomyopathy and non-ischemic cardiomyopathy (Figure 1). The mean age was 43.5 years in the S-ICD group compared to 46.0 years in the TV-ICD population (p=0.270). Patients with primary prophylactic indication had symptomatic heart failure with reduced left ventricular ejection fraction. Correspondingly, current medication consisted of pharmacological heart failure therapy.

Device was 2nd- or 3rd-generation S-ICD (Boston Scientific A209 or A219, identical in hardware construction) in 42 patients (81%). Mean time since implantation of the defibrillator was 2.4 years in the S-ICD group and 3.6 years in the TV-ICD group (p=0.05).

Table 1 Baseline Characteristics

Baseline Characteristics	Study Population (*n*=104)	S-ICD (*n*=52)	TV-ICD (*n*=52)	*p*-value
Age	45.2 (± 1.4)	43.5 (± 2.4)	46.0 (± 2.4)	0.27
BMI	26.5 (± 0.6)	25.8 (± 1.0)	27.0 (± 0.8)	0.21
EF	49.2 (± 13.5)	47.64 (± 2.5)	49.46 (± 2.2)	0.60
Timesince implantation (in years)	3.0 (± 2.3)	2.4 (± 0.2)	3.6 (± 0.4)	0.05
Indication for ICD				0.62
- ICM	9 (8.7%)	4 (7.7%)	5 (9.6%)	
- non-ischemic CM	44 (42.3%)	20 (38.5%)	24 (46.2%)	
- sec. prophylactic w/o CM	51 (49.0%)	28 (53.8%)	23 (44.2%)	
Medication				
- Beta-blockers	77 (74.8%)	38 (73.1%)	39 (76.5%)	0.69
- ACE-inhibitor/sartan	44 (42.3%)	22 (42.3%)	22 (43.1%)	0.93
- Diuretics	30 (29.1%)	11 (21.2%)	19 (37.3%)	0.07
- Aldosterone antagonist	32 (31.1%)	15 (28.8%)	17 (33.3%)	0.62
- Amiodarone	5 (4.9%)	0	5 (9.8%)	0.02

Abbreviations: S-ICD, subcutaneous cardioverter defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator; BMI, body mass index; EF, ejection fraction; ICD, implantable cardioverter defibrillator; ICM, ischemic cardiomyopathy; CM, cardiomyopathy; sec, secondary; w/o, without; ACE-inhibitors, angiotensin-converting enzyme inhibitors.

Overall shock was without significant between-group differences (28.8% vs 36.5%; p=0.4). Nevertheless, inappropriate shock (iAS) rate was significantly higher in S-ICD patients (4.8% vs 0.6%/patient year; p<0.01). Although patients in both groups felt equally protected by their defibrillator (86.5% in the S-ICD group, 94.1% in the TV-ICD group; p=0.19), 27.7% of S-ICD patients expected an improvement of quality of life by a deactivation or explantation of the defibrillator compared to only 6.4% of patients with TV-ICD (p<0.01).

This differences could not be explained by fear of receiving shocks (17.3% in S-ICD patients, 13.5% in TV-ICD patients; p=0.15) but rather by discomfort and pain caused by the generator itself (medium or severe pain in 32.6% of S-ICD patients vs 11.5% of TV-ICD patients; p<0.01).

When asked about accomplishing their daily life in general, more than two-thirds of the total study population felt restricted compared to their life before implantation of the defibrillator (73.1% in the S-ICD-group and 63.5% in the ICD group; p=0.32). Patients stated restrictions of physical flexibility in 69.2% without a relevant between-group difference (73.1% in the S-ICD

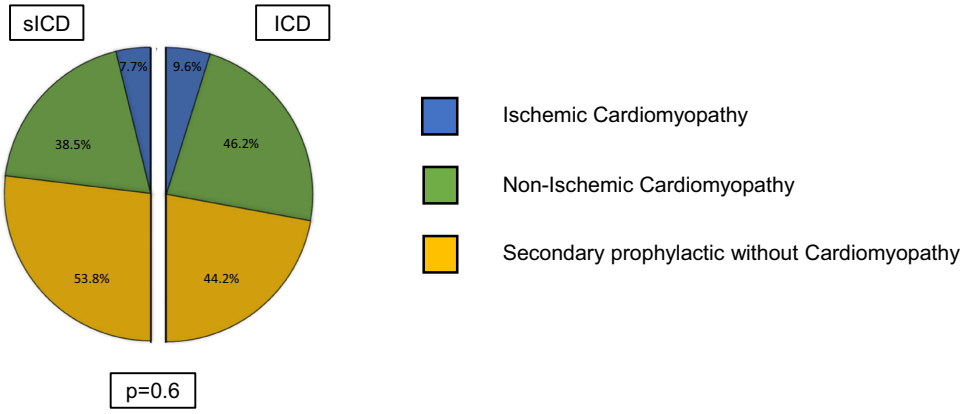

Figure 1 Comparison of the indication for ICD-implantation for implanted subcutaneous ICD and implanted transvenous ICD: This figure demonstrates differences in the indication for ICD therapy.

group vs 65.4% in the TV-ICD group; p=0.69). The ability of self-care (hygiene) was reduced in 73.1% in the S-ICD group and in 63.5% in the TV-ICD group (p=0.29). Numerically more patients with S-ICD reported having restrictions of mental wellbeing (73.1%) compared to TV-ICD patients (63.5%). Nevertheless, this was without statistical significance (p=0.47).

All levels of impairment of daily life asked in the EQ-5D-3L questionnaire are depicted in Table 2 and Figure 2

Table 2 Results

Follow-Up	Study Population (n=104)	S-ICD (n=52)	TV-ICD (n=52)	p-value
History of shocks	34 (32.7%)	15 (28.8%)	19 (36.5%)	0.40
Appropriate shock rate [%] / patient year	9.1	7.2	10.4	0.01
Inappropriate shock rate [%] / patient year	2.4	4.8	0.6	<0.01
- Awake while shocked	26 (25.0%)	12 (23.1%)	14 (26.9%)	0.88
- Pain while shocked	6.3 (± 0.5)	5.9 (± 0.9)	7.1 (± 0.6)	0.79
- Mental stress by shock	6.5 (± 0.50)	7.4 (± 0.5)	5.8 (± 0.8)	0.12
- Fear of shock	16 (15.4%)	9 (17.3%)	7 (13.5%)	0.15
- Grade of fear of shock	4.6 (± 0.5)	4.5 (± 0.8)	4.6 (± 0.8)	0.79
Knowledge about ICD	6.4 (± 0.2)	6.4 (± 0.3)	6.3 (± 0.3)	1.00
General feeling of security	93 (90.3%)	45 (86.5%)	48 (94.1%)	0.19
ICD providing security	101 (98.1%)	50 (98.0%)	51 (98.1%)	0.19
Improvement of quality of life by deactivation or explantation of ICD	16 (17.0%)	13 (27.7%)	3 (6.4%)	<0.01
Sleeping disorder	34 (33.0%)	13 (25.5%)	21 (40.4%)	0.11
Restriction of daily life	71 (68.3%)	38 (73.1%)	33 (63.5%)	0.32
Controls per year				0.09
- <1/year	12 (11.7%)	8 (15.4%)	4 (7.7%)	
- 1/year	3 (2.9%)	2 (3.8%)	1 (1.9%)	
- 2/year	61 (58.7%)	32 (61.5%)	29 (55.8%)	
- 3/year	14 (13.5%)	7 (13.5%)	7 (13.5%)	
- >3/year	13 (12.5%)	2 (3.8%)	11 (21.2%)	
Restriction of daily life				0.48
- none	33 (31.7%)	14 (26.9%)	19 (36.5%)	
- low	35 (33.7%)	21 (40.4%)	14 (26.9%)	
- medium	24 (23.1%)	12 (23.1%)	12 (23.1%)	
- high	12 (11.5%)	5 (9.6%)	7 (13.5%)	
Restriction of career				0.78
- none	35 (33.7%)	16 (30.8%)	19 (36.5%)	
- low	34 (32.7%)	16 (30.8%)	18 (34.6%)	
- medium	23 (22.1%)	13 (25.0%)	10 (19.2%)	
- high	12 (11.5%)	7 (13.5%)	5 (9.6%)	
Restriction of physical flexibility				0.69
- none	32 (30.8%)	14 (26.9%)	18 (34.6%)	
- low	44 (42.3%)	24 (46.2%)	20 (38.5%)	
- medium	18 (17.3%)	8 (15.4%)	10 (19.2%)	
- high	10 (9.6%)	6 (11.5%)	4 (7.7%)	

(*Continued*)

Table 2 (Continued).

Follow-Up	Study Population (*n*=104)	S-ICD (*n*=52)	TV-ICD (*n*=52)	*p*-value
Restriction of hygiene				0.29
- none	33 (31.7%)	14 (26.9%)	19 (36.5%)	
- low	59 (56.7%)	29 (55.8%)	30 (57.7%)	
- medium	8 (7.7%)	6 (11.5%)	2 (3.8%)	
- high	4 (3.8%)	3 (5.8%)	1 (1.9%)	
Restriction of daily routine				0.46
- none	33 (31.7%)	14 (26.9%)	19 (36.5%)	
- low	56 (53.8%)	28 (53.8%)	28 (53.8%)	
- medium	11 (10.6%)	7 (13.5%)	4 (7.7%)	
- high	4 (3.8%)	3 (5.8%)	1 (1.9%)	
Restriction of mental well-being				0.47
- none	33 (31.7%)	14 (26.9%)	19 (36.5%)	
- low	27 (26.0%)	12 (23.1%)	15 (28.8%)	
- medium	29 (27.9%)	17 (32.7%)	12 (23.1%)	
- high	15 (14.4%)	9 (17.3%)	6 (11.5%)	
Restriction caused by pain				0.04
- none	32 (31.7%)	14 (26.9%)	18 (34.6%)	
- low	49 (47.1%)	21 (40.4%)	28 (53.8%)	
- medium	19 (18.3%)	15 (28.8%)	4 (7.7%)	
- high	4 (3.8%)	2 (3.8%)	2 (3.8%)	

Abbreviations: S-ICD, subcutaneous cardioverter defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator; ICD, implantable cardioverter defibrillator.

Discussion

In accordance with current studies, the S-ICD has experienced an expansion of indication for all defibrillator patients without need for additional pacing function, regardless of the underlying cardiac disease.[9,10] However, crucial aspects such as the impact of current 2nd- and 3rd-generation S-ICD on the quality of life remain unstudied yet. Since the initial proof of concept with the 1st-generation S-ICD available since 2002, technical development of hard- and also software of

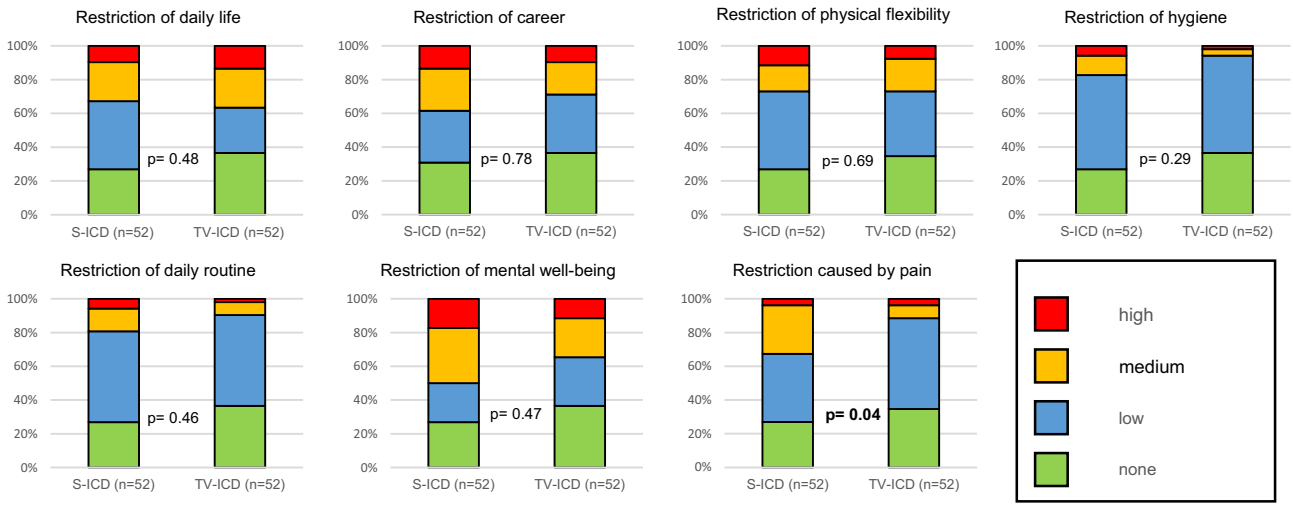

Figure 2 Restriction of QoL: Differences between implanted subcutaneous ICD and implanted transvenous ICD: Patients were asked about restrictions of daily life due to the cardiac implant. They could classify the restriction of different factors of everyday life into four categories: none, low, medium, and high. Only when asked about restrictions caused by pain was there a significant difference (p=0.04, bold lettering) between the two groups, with significantly more patients with S-ICD therapy suffering from restrictions caused by pain.

the S-ICD led to a relevant reduction of generator size with the 2nd-generation generator (about 20% reduction of thickness, launched in 2015) and additionally significant reduction of iAS shock rate as the Smart Pass technology was introduced since 3rd-generation devices in 2016.[9,10] Thus, S-ICD therapy with contemporary generators is not comparable with 1st-generation devices, neither for safety of therapy nor for comfort issues.

To the best of our knowledge, this is the first study analysing the influence of contemporary S-ICD on mental well-being and accomplishment of everyday life in comparison to TV-ICD, as prior data for example from the EFFORTLESS registry refer to 1st-generation devices only.[17,18]

As a major finding, we report that one-third of S-ICD patients experience a serious restriction in quality of life and expect an improvement of their general well-being by removal of the S-ICD. Of note, this impression was not driven by the fear of receiving shocks although a relevant higher rate of iAS in S-ICD compared to TV-ICD patients was documented in our study. In line with this, patients in both groups felt equally protected by their device.

The majority of all patients (S-ICD and TV-ICD) reported restrictions of almost any studied item of QoL without relevant between-group differences.

However, a gain in physical mobility which might have been allowed by the lack of transvenous leads in S-ICD patients could not be depicted in our population.

In fact, device-associated pain and discomfort are so important that many patients think their life will improve with explantation. Contradicting an observation from van der Stuijt et al that especially female S-ICD patients experience daily discomfort mainly caused by their bra, the distribution of men and women was similar in patients complaining about S-ICD-related pain in our cohort.[11]

Correct intraoperative placement and fixation of the generator in the intermuscular space between serratus and latissimus muscle deserves particular attention to satisfy requirements of durable defibrillation threshold as well as comfort issues. Moreover, our findings give a call for technical development enabling further reduction of device size which might increase general well-being of S-ICD patients.

Study Limitations

Our study has several important limitations. First, quality of life was assessed for one single time point only. Therefore, the course of impairment remains unclear. Nevertheless, earlier data indicate stable impairment of QoL a few months after implantation.[17]

Second, time since implantation differed significantly between S-ICD and TV-ICD. Even though a mean time since implantation of 3.0 years represents chronic ICD therapy this might have influenced our findings.

Third, our collective is younger and due to the high proportion of patients without cardiomyopathy, the mean EF is better than usual ICD collective. The absence of heart failure in about the half of our patients might have relevant impact on our QoL analysis.

Conclusion

In our cohort, the majority of S-ICD patients felt well protected by their defibrillator. Impairment of QoL was comparable between S-ICD and TV-ICD patients. Nevertheless, a relevant part expects an improvement of QoL by explantation of the S-ICD. This was not caused by the fear of receiving shocks but mainly by discomfort and pain caused by the pulse generator.

Data Sharing Statement

The data underlying this article will be shared anonymized on reasonable request to the corresponding author.

Ethical Approval and Consent to Participate

The analysis was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of the Ludwig-Maximilian-University of Munich (accession number: 20-641). All participants gave written informed consent.

Consent for Publication

All authors gave consent for publication.

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Disclosure

The authors report no conflicts of interest in this work.

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