Comparison of quality-of-life measures in patients with transvenous and subcutaneous implantable cardioverter-defibrillators

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Introduction

Sudden cardiac death is one of the leading causes of cardiovascular mortality. Implantable cardioverter-defibrillator systems have improved survival in patients with increased risk of sudden cardiac death and are safe and reliable.[1] Subcutaneous implantable cardioverter-defibrillators (S-ICD) offer potential advantages over transvenous cardioverter-defibrillators (TV-ICD), foremost being no need for venous access. S-ICDs are larger than TV-ICDs, have a shorter battery life, and do not provide consistent pacing. Despite these differences, there is paucity of data regarding quality of life (QoL) in patients with S-ICDs compared with TV-ICDs. The EFFORTLESS study found no difference in physical and mental domains for QoL between the S-ICD and TV-ICD patients up to 12 months after implant but lower anxiety levels and a greater reduction in depression in S-ICD patients.[2,3] However, overall satisfaction with the S-ICD and its unique differences has not been studied.

Study description

We surveyed patients with S-ICD and TV-ICD systems to understand their satisfaction with an ICD, fear of shocks, and overall differences in QoL. A random convenience sample of patients at 2 academic medical centers who had undergone placement of a single-chamber TV-ICD or S-ICD between 2014 and 2019 for primary and secondary prevention, who were 18 years of age or older and English or Span-

ish speaking, were asked to participate. Those with an indication for pacing or ventricular tachycardia amendable to antitachycardia pacing were excluded. We used 3 questionnaires: the Medical Outcomes Survey Short Form-12 (SF-12), to assess overall perceived physical and mental health; the Florida Shock Anxiety Scale (FSAS), to assess anxiety related to ICD shocks; and the Florida Patient Acceptance Survey (FPAS), to assess device acceptance. Patients completed each at baseline and at 3, 6, and 12 months post implantation. Independent samples t test was used for continuous data to compare between S-ICD and TV-ICD. Paired t tests were used to compare outcomes between different follow-up encounters. Fisher exact test and Pearson χ^2 analysis were used for categorical data. Statistical significance was defined by a P value <.05. All analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp, Armonk, NY) software.

Between 2014 and 2019, a total of 52 patients completed the questionnaires: 36 with S-ICD implantation and 16 with TV-ICDs. For major baseline characteristics, including age, sex, education level, indication for prevention (primary vs secondary), underlying cardiac conditions, ejection fraction, racial background, language preference, and marital status, there were no significant differences between the 2 groups. However, patients with S-ICD systems were more likely to have elevated creatinine level (3.18 vs 1.09, P = .023) and were more likely to be on dialysis (27.8% vs 0%) than those with TV-ICD systems (Table 1A).

The overall questionnaire response rate was 48.02%, with 73% at baseline and 38% at 12 months follow-up. There were no significant differences between the 2 groups for shock anxiety (FSAS) at baseline, 3 months, 6 months, and 12 months follow-up. QoL (SF-12) response for physical domain was greater in the TV-ICD group (73.59 ± 7.17) compared to the S-ICD group (43.99 ± 8.17) at baseline. There was a difference for patient acceptance (FPAS), with a higher acceptance rate in the S-ICD group (63.77 ± 10.97) compared to the TV-ICD group (73.50 ± 10.52 P = .001), at baseline. However, there were no other

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Table 1A   Patient characteristics

	S-ICD	TV-ICD	P value
Age, years	51.31	57.31	.117
Male	27 (75%)	12 (75%)	1.000
Low education (<13 y)	20 (55.56%)	8 (50%)	.751
Indication			.307
Primary prevention	25 (69.44%)	14 (87.5%)	
Secondary prevention	8 (22.22%)	2 (12.5%)	
Cardiac disorders			.181
ICM	11 (30.56%)	7 (43.75%)	
NICM	16 (44.44%)	9 (56.25%)	
Channelopathy	8 (22.22%)	0	
LVEF (%)	35.4 ± 15.5	35.6 ± 22.6	.786
Creatinine	3.18 ± 3.51	1.09 ± 0.36	.023*
Hemodialysis	10 (27.78%)	0	.020*
Race			.270
White	10 (27.78%)	9 (56.25%)	
African American	11 (30.56%)	3 (18.75%)	
Hispanic	11 (30.56%)	4 (25%)	
Asian/ Pacific Islanders	2 (5.56%)	0	
Marital status			.832
Married	20 (55.56%)	10 (62.5%)	
Divorced/separated	3 (8.33%)	2 (12.5%)	
Single	11 (30.56%)	4 (25%)	
Questionnaire language			
Spanish	3 (8.33%)	2 (12.5%)	.712

ICM = ischemic cardiomyopathy; LVEF = left ventricular ejection fraction; NICM = nonischemic cardiomyopathy.
*Statistically significant.

Table 1B   Quality-of-life scores

Questionnaire	Type of ICD		
FSAS	S-ICD (n = 36)	TV (n = 16)	P value
Baseline	21.31 ± 9.87	21.44 ± 11.36	.781
3 Months	14.83 ± 11.09	14.60 ± 5.17	1.000
6 Months	16.60 ± 7.56	17.83 ± 6.97	.635
12 Months	26.55 ± 11.29	17.67 ± 9.35	.180
FPAS			
Baseline	63.77 ± 10.99	73.50 ± 10.52	.011*
3 Months	65.83 ± 18.28	58.13 ± 23.83	.414
6 Months	65.00 ± 13.61	63.33 ± 16.33	1.000
12 Months	66.11 ± 27.82	59.00 ± 5.96	.053
SF-12 (Mental)			
Baseline	52.03 ± 7.63	46.75 ± 10.98	.182
3 Months	56.55 ± 5.15	54.20 ± 10.52	.931
6 Months	47.81 ± 9.50	50.67 ± 9.85	.562
12 Months	46.39 ± 12.32	52.37 ± 10.68	.368
SF-12 (Physical)			
Baseline	43.99 ± 8.17	50.47 ± 7.17	.028*
3 Months	43.56 ± 10.92	50.04 ± 4.99	.206
6 Months	48.07 ± 7.03	50.85 ± 8.90	.635
12 Months	45.09 ± 8.05	48.27 ± 8.64	.467

Higher scores denote higher quality of life. All data displayed as mean ± standard deviation.
FPAS = Florida Patient Acceptance Scale; FSAS = Florida Shock Anxiety Scale; SF-12 = Short Form 12 Health Survey.
*Statistically significant.

differences at 3 months, 6 months, and 12 months follow-up (Table 1B).

Conclusion
Although TV-ICD patients had better physical QoL but lower acceptance at baseline, TV-ICD and S-ICD patients had similar results in shock anxiety, device acceptance, and overall mental health QoL at baseline and up to 12 months follow-up. Limitations to this study include a small sample size, a greater number of S-ICD patients, and limited compliance with survey completion. Further research is needed to clarify

differences in patients' psychosocial perceptions of S-ICDs compared to TV-ICDs.

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