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Rapid Communication

Initial experience with the subcutaneous implantable cardioverter-defibrillator in a single Japanese center

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ABSTRACT

Background: The subcutaneous implantable cardioverter-defibrillator (S-ICD) is recognized as a viable alternative to the transvenous ICD. The safety and efficacy of this device has been demonstrated in Western countries, but studies with S-ICD implantation in Japanese patients have not been reported.
Methods and results: Twelve patients received an S-ICD implant in our institute between February and September 2016. All S-ICDs were successfully implanted without complications. One appropriate and one inappropriate therapy was identified.
Conclusions: S-ICD implantation appears to provide a viable alternative to transvenous ICD implantation for some Japanese patients. However, we should perform careful follow-up of patients to eliminate inappropriate therapy.

1. Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD) (Boston Scientific, Marlborough, MA), does not require a transvenous lead and has gained recognition as a viable alternative to transvenous ICD for preventing sudden cardiac death [1–3]. The generator is implanted in a left axial position [4], with the lead for both sensing and defibrillation implanted in a left or sometimes right parasternal position [5,6]. The safety and efficacy of the S-ICD has been substantiated in Western countries. In Japan, the S-ICD has been available only since February 2016. In this study, we documented our own experience with S-ICD implantation in Japanese patients. Japanese patients differ from western patients in key characteristics such as stature, underlying heart disease, and ethnicity. We report our early experience with S-ICDs, including the implantation procedure and follow-up methods.

2. Methods

Implantation of an S-ICD was planned for 15 patients at the Okayama University Hospital between February and September 2016. A screening electrocardiogram (ECG) was obtained for all patients before implantation, in accordance with prior studies [7]. Twelve patients passed the screening ECG test and underwent implantation of the S-ICD. The first three implantations were performed with the aid of international proctors who had sufficient experience in the procedure. Subsequent S-ICD implant surgeries were performed solely by doctors from Okayama University Hospital. The pocket for the generator was created between the serratus anterior muscle and the latissimus dorsi muscles in all patients [8]. The lead was implanted in a left or right parasternal position using a two- or three-incision technique [9]. Immediately after implantation, the most suitable sensing vector among three vectors (primary, secondary, and alternate) [5] was chosen by the S-ICD through supine and sitting or standing positions. During the first month post implantation, the patient was tested while exercising, if possible, to determine whether T-wave oversensing occurred. A template ECG was obtained simultaneously. The detection zone was set for two zones (a shock zone and a conditional zone; the latter including the supraventricular tachycardia [SVT] discriminator program) [2] in all patients. One month after discharge, the patients visited the outpatient clinic. The study protocol was approved by the institutional review board at Okayama University Hospital (approval date: March 26, 2016; approval number: 826).

Categorical variables are presented as the number of patients and continuous variables are expressed as the mean ± standard

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Table 1
Patient characteristics.

N	12
Male, *n* (%)	11 (91.7%)
Age, years	43.8 ± 20.2
Height, m	1.68 ± 0.07
Weight, kg	64.2 ± 9.3
Body mass index, kg/m^2	22.8 ± 3.1
Heart disease type, *n* (%)	
Ischemic heart disease	1 (8.3%)
Dilated cardiomyopathy	1 (8.3%)
Hypertrophic cardiomyopathy	2 (16.6%)
Brugada syndrome	2 (16.6%)
Idiopathic ventricular fibrillation	5 (50.0%)
Long QT syndrome	1 (8.3%)
After transvenous lead extraction, *n* (%)	4 (33.3%)
Ejection fraction, %	59.2 ± 9.7
Implantation procedure	
General anesthesia, *n* (%)	10 (83.3%)
Left parasternal implantation, *n* (%)	10 (83.3%)
Three-incision technique, *n* (%)	11 (91.7%)
Procedure time, min	87.30 ± 13.4
Complication, *n* (%)	0 (0%)

deviation. We used SPSS software (IBM SPSS Statistics, Chicago, IL) for all analyses.

3. Results

3.1. Patient characteristics and implantation procedure

Three of the 15 patients were ineligible based on screening ECG. Two patients showed Brugada syndrome, and one patient displayed idiopathic ventricular fibrillation (IVF).

Characteristics of the 12 remaining patients are shown in Table 1, including procedure time and method. No acute complications such as pocket hematoma, device infection, or migration of the generator or lead were encountered.

3.2. Follow-up after S-ICD implantation

During the mean follow-up time of 4.7 months (± 2.4 months) no subacute complications such as device infection, migration of the generator or lead or device erosion were seen.

Appropriate therapy was seen in 1 patient, a 17-year-old boy with IVF. The appropriate therapy was for monomorphic ventricular tachycardia with a cycle length of 260 ms (Fig. 1A), and consciousness was almost lost at the time of S-ICD shock.

Inappropriate therapy was seen in 1 patient, a 27-year-old man with IVF. The selected sensing vector was primary immediately after implantation, based on ECG in only the supine position. However, the next day, the secondary vector was selected based on ECG in both supine and standing positions. Prior to exercise testing, T-wave oversensing appeared while the patient was taking a bath (Fig. 1B). After the sensing vector was changed from secondary to primary, the patient was retested; both while taking a bath and exercising and passed in both cases.

4. Discussion

We have reported our early experience with S-ICD in 12 Japanese patients. No complications associated with the implantation procedure were encountered, despite the relatively low body mass index in Japanese patients compared to Western patients. The tips and tricks provided by the international proctors were very helpful.

One patient experienced appropriate S-ICD therapy. The duration from the detection of ventricular arrhythmia to the appropriate therapy was very short, successfully preventing syncope. However, one patient experienced inappropriate therapy due to T-wave oversensing. Historically, early S-ICDs implant operations demonstrated a high rate of inappropriate therapy, due to T-wave oversensing, lead migration and SVT [3,10]. Use of a suture sleeve should eliminate lead migration. A dual-zone and SVT discriminator could prevent SVT. However, T-wave oversensing leading to inappropriate therapy remains problematic. The incidence of this event has been reduced with the use of pre-implant ECG screening [7], and exercise testing [11]. Patients who experience T-wave oversensing can often be managed noninvasively through device programming [3]. In our patient, T-wave oversensing was successfully resolved by changing the sensing vector even during the exercise test and taking-a-bath test. Then, exercise test seems to be important to identify T-wave oversensing and prevent inappropriate therapy during follow-up.

5. Conclusions

S-ICD implantation appears to provide a safe and viable alternative to transvenous ICD therapy for some Japanese patients, for whom background characteristics differ markedly from populations in Western countries. However, careful follow-up with patients is warranted to avoid inappropriate therapy.

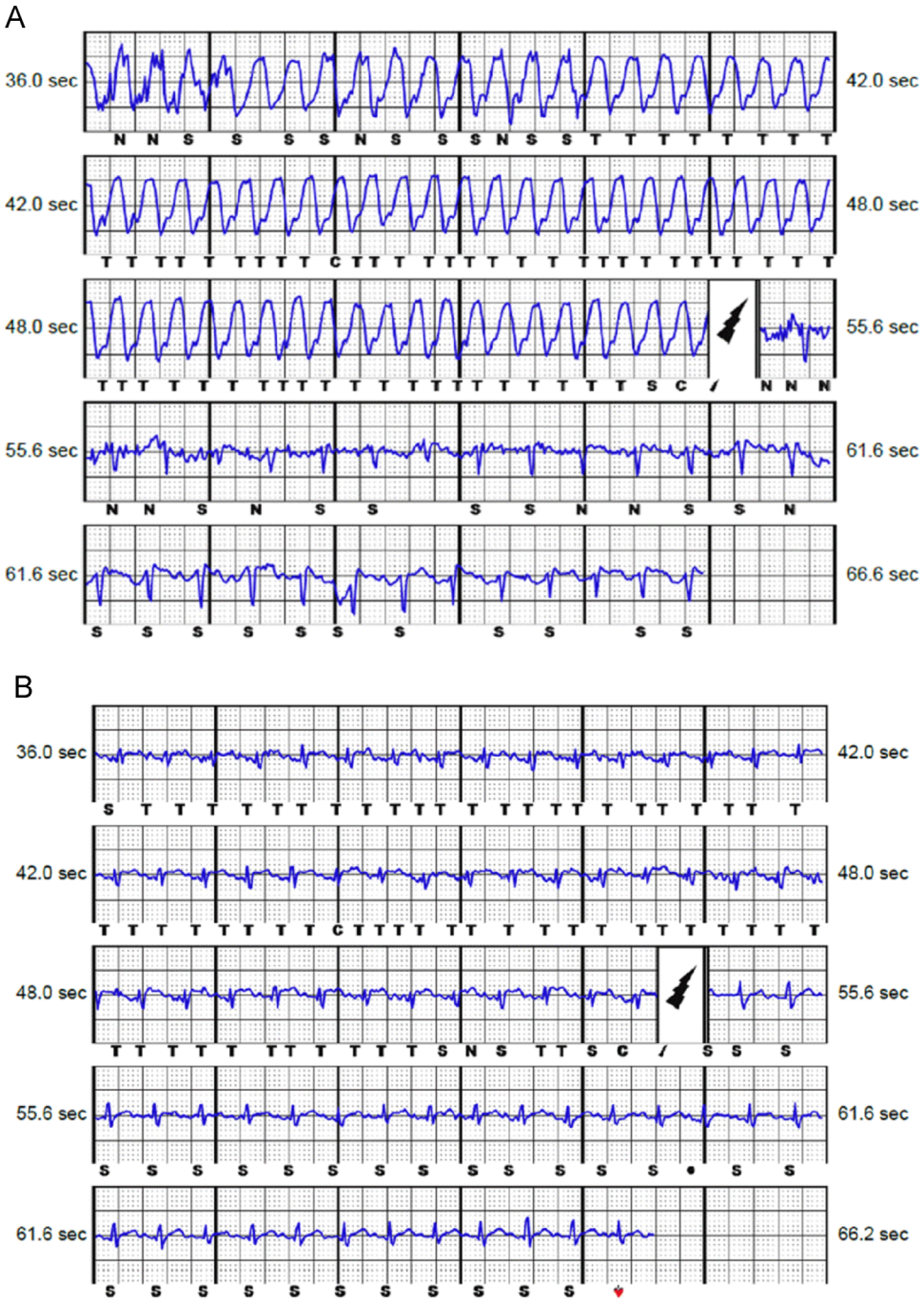

Fig. 1. Episodes of appropriate and inappropriate therapy. A) Electrocardiogram of the appropriate therapy. Sustained monomorphic ventricular tachycardia with a cycle length of 260 ms was successfully detected and was terminated using subcutaneous implantable cardioverter-defibrillator (S-ICD). B) Electrocardiogram of the inappropriate therapy. The cause of the inappropriate therapy was T-wave oversensing.

Conflict of interest

None of the authors has any conflicts of interest in association with this manuscript.

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References

[1] Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 2013;128:944–53.
[2] Burke MC, Gold MR, Knight BP, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry. J Am Coll Cardiol 2015;65:1605–15.
[3] Lewis GF, Gold MR. Safety and efficacy of the subcutaneous implantable defibrillator. J Am Coll Cardiol 2016;67:445–54.
[4] Noro M, Zhu X, Enomoto Y, et al. Decreased defibrillation threshold and minimized myocardial damage with left axilla implantable cardioverter defibrillator implantation. Circ J 2016;80:878–86.
[5] Rowley CP, Gold MR. Subcutaneous implantable cardioverter defibrillator. Circ Arrhythm Electrophysiol 2012;5:587–93.

[6] Okamura H, McLeod CJ, DeSimone CV, et al. Right parasternal lead placement increases eligibility for subcutaneous implantable cardioverter defibrillator therapy in adults with congenital heart disease. Circ J 2016;80:1328–35.
[7] Groh CA, Sharma S, Pelchovitz DJ, et al. Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm 2014;11:1361–6.
[8] Ferrari P, Giofre F, De Filippo P. Intermuscular pocket for subcutaneous implantable cardioverter defibrillator: single-center experience. J Arrhythm 2016;32:223–6.
[9] Knops RE, Olde Nordkamp LR, de Groot JR, et al. Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. Heart Rhythm 2013;10:1240–3.
[10] Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010;363:36–44.
[11] Kooiman KM, Knops RE, Olde Nordkamp L, et al. Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: implications for management. Heart Rhythm 2014;11:426–34.