# **Comparative outcomes of subcutaneous and transvenous cardioverter-defibrillators**

Jin-Jun Liang<sup>1,2</sup>, Hideo Okamura<sup>2</sup>, Roshini Asirvatham<sup>2</sup>, Andrew Schneider<sup>3</sup>, David O. Hodge<sup>4</sup>, Mei Yang<sup>2</sup>, Xu-Ping Li<sup>2</sup>, Ming-Yan Dai<sup>2</sup>, Ying Tian<sup>2</sup>, Pei Zhang<sup>2</sup>, Bryan C. Cannon<sup>3</sup>, Cong-Xin Huang<sup>1</sup>, Paul A. Friedman<sup>2</sup>, Yong-Mei Cha<sup>2</sup>

<sup>1</sup>Department of Cardiology, Renmin Hospital of Wuhan University, Wuhan, Hubei 430060, China;

<sup>2</sup>Department of Cardiovascular Medicine, Mayo Clinic, Rochester, MN 55905, USA;

<sup>3</sup>Division of Pediatric Cardiology, Mayo Clinic, Rochester, MN 55905, USA;

<sup>4</sup>Biostatistics Unit, Mayo Clinic, Jacksonville, FL 32224, USA.

## Abstract

**Background:** The comparative outcomes of subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous ICD (T-ICD) have not been well studied. The aim of this study was to evaluate the safety and efficacy of currently available S-ICD and T-ICD.

**Methods:** The study included 86 patients who received an S-ICD and 1:1 matched to those who received single-chamber T-ICD by gender, age, diagnosis, left ventricular ejection fraction (LVEF), and implant year. The clinical outcomes and implant complications were compared between the two groups.

**Results:** The mean age of the 172 patients was 45 years, and 129 (75%) were male. The most common cardiac condition was hypertrophic cardiomyopathy (HCM, 37.8%). The mean LVEF was 50%. At a mean follow-up of 23 months, the appropriate and inappropriate ICD therapy rate were 1.2% *vs.* 4.7% ( $\chi^2$ =1.854, *P*=0.368) and 9.3% *vs.* 3.5% ( $\chi^2$ =2.428, *P*=0.211) in S-ICD and T-ICD groups respectively. There were no significant differences in device-related major and minor complications between the two groups (7.0% *vs.* 3.5%,  $\chi^2$ =1.055, *P*=0.496). The S-ICD group had higher T-wave oversensing than T-ICD group (9.3% *vs.* 0%,  $\chi^2$ =8.390, *P*=0.007). Sixty-five patients had HCM (32 in S-ICD and 33 in T-ICD). The incidence of major complications was not significantly different between the two groups.

**Conclusions:** The efficacy of an S-ICD is comparable to that of T-ICD, especially in a dominantly HCM patient population. The S-ICD is associated with fewer major complications demanding reoperation.

Keywords: Hypertrophic cardiomyopathy; Implantable cardioverter-defibrillator; Outcome; Subcutaneous implantable cardioverter-defibrillator

## Introduction

The totally subcutaneous implantable cardioverter-defibrillator (S-ICD) has been designed as an alternative to conventional implantable defibrillators.<sup>[1]</sup> It is safe, effective, and avoids the adverse effects from intravascular leads.<sup>[2]</sup> The best candidates are patients without indications for pacing and those who are at increased risk for complications related to placement of transvenous leads. It is especially attractive for patients who are young, lack of venous access for lead placement, or are susceptible to recurrent lead-related bloodstream infection.<sup>[3,4]</sup> Results of the Investigational Device Exemption (IDE) study and the Evaluation oF FactORs ImpacTing CLinical Outcomes and Cost EffectiveneSS of the S-ICD (EFFORTLESS) Registry showed that the S-ICD had a very high efficacy for treatment

Access this article online			
Quick Response Code:	Website: www.cmj.org		
	DOI: 10.1097/CM9.000000000000133		

of ventricular fibrillation (VF) or ventricular tachycardia (VT). However, the long-term comparative experience with S-ICD and transvenous ICD (T-ICD) has not been well studied. Currently known limitations of the S-ICD include its inability to provide bradycardia pacing and antitachycardia pacing and the concern for inappropriate therapies primarily related to T-wave oversensing.<sup>[5]</sup> The objective of this study was to investigate the comparative efficacy and safety of the S-ICD and the single-chamber T-ICD.<sup>[6]</sup>

## Methods

## Ethical approval

The study was approved by the Mayo Clinic Institutional Review Board. All patients provided informed consent before the procedure.

Correspondence to: Dr. Yong-Mei Cha, Department of Cardiovascular Medicine, Mayo Clinic, Rochester, MN 55905, USA E-Mail: ycha@mayo.edu
Copyright © 2019 The Chinese Medical Association, produced by Wolters Kluwer, Inc. under the CC-BY-NC-ND license. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.
Chinese Medical Journal 2019;132(6)

Received: 30-10-2018 Edited by: Li-Shao Guo

## Study patients and design

In this observational study, patients who received an S-ICD at Mayo Clinic between January 1, 2012, and December 31, 2016, were included. All patients had indications for ICD implantation according to the American College of Cardiology/American Heart Association/European Society of Cardiology guidelines.<sup>[7]</sup> These patients had no indications for pacing or a history of monomorphic ventricular tachycardia requiring antitachycardia pacing. Patient demographics, clinical indications, procedural details, device settings, procedure-related complications, and follow-up assessment were collected.<sup>[8]</sup> The decision to implant an S-ICD was determined from (1) a physician's recommendation based on young age, diagnosis, primary sudden prevention of sudden death, no known history of monomorphic VT; (2) patient preference; and (3) presence of high risks for T-ICD infection or lack of transvenous access.<sup>[8]</sup>

Our ICD database was used for 1:1 matching of patients who received an S-ICD with patients who received a singlechamber T-ICD. The two groups were matched by gender and age ( $\pm$ 5 years), diagnosis of cardiomyopathy, primary *vs.* secondary prevention, and left ventricular ejection fraction.<sup>[5,9]</sup>

## **ICD** implantation

Patients were screened for S-ICD eligibility with the Boston Scientific electrocardiography screening tool.<sup>[1]</sup> After eligibility was confirmed, patients underwent standard S-ICD implantation. The left side of the chest and axillary area were strictly prepared and draped; the left arm was placed in 70° abduction to expose the left axillary area for creation of the subcutaneous pocket. The procedure was performed with the patient under either general anesthesia or deep sedation. We followed the implantation technique suggested by the manufacturer as described in the S-ICD user's manual.<sup>[5]</sup> Three-incision and 2-incision techniques were described in previous studies.<sup>[8,10]</sup> In three-incision technique, after the axillary pocket was made, the second incision was created at the xiphoid process and at the level of fifth intercostal space at the left parasternal area. The lead was tunneled from the axillary pocket to the xiphoid incision and secured with supplied sleeve adaptor to the musculature close to the proximal sensing electrode. The distal end of the electrode was then tunneled subcutaneously and superiorly toward the third incision which was 1 to 2 cm to the left of the sternal midline. The distal electrode was secured to the underlying muscular fascia. The proximal lead was connected to the generator that was placed inside the axillary device pocket.<sup>[8]</sup> The two-incision technique abandoned the superior parasternal incision; rather, it positioned the lead using a standard 11Fr peel-away sheath via which the distal lead was advanced superiorly along the left sternal border. All incisions were closed in 3 layers with absorbable material.<sup>[1,10]</sup>

Defibrillation was performed in each patient. After VF induction and appropriate detection, a 65-J shock energy was delivered using a 50% tilt biphasic waveform. An unsuccessful shock led to immediate external transthoracic

defibrillation to rescue. The next shock energy was increased to 70 or 80 J to achieve success. If first defibrillation was successful, the defibrillation threshold was considered as 65 J. Defibrillation threshold test was not performed in the T-ICD group.<sup>[7]</sup>

After device implantation, chest radiography was done to confirm the lead and generator positions.<sup>[8,9]</sup> Patients were observed overnight. Incisions were inspected on the next day. The device function was interrogated and confirmed to be of satisfactory status before the patients were dismissed.

# ICD programming

In the S-ICD group, devices were programmed in two zones, VT zone ranging from 180 to 200 beats/min and VF zone ranging from 200 to 220 beats/min. Detection of ventricular tachyarrhythmia in the T-ICD was programmed in two zones for primary prevention, including a VT monitor zone (detection rate 170 beats/min) and a VF zone (detection rate 200 beats/min).

## Patient follow-up

Patients underwent 3-month follow-up in person at the device clinic. Thereafter, patients were followed by remote monitoring or as outpatients every 3 months (in the case of lack of remote-monitor capability). All sustained ventricular arrhythmic events detected, including appropriate and inappropriate, were reviewed by device-trained registered nurses and electrophysiologists.<sup>[8]</sup> The device-related complications included any early or late complications deemed to be related to the device.<sup>[11]</sup>

## Statistical analysis

Continuous variables are expressed as mean±standard deviation (SD). Categorical variables are presented with actual numbers and frequencies. Categorical variables are compared between cases and controls using Chi-squared test or Fisher exact test and continuous variables were compared using two sample *t* test or Wilcoxon rank sum test where appropriate. Kaplan-Meier method is used for survival and freedom from shock therapies after ICD implantation. The *P* value <0.05 was considered statistically significant. All analyses were performed with JMP statistical software (version 10.0; JMP, SAS Institute Inc., Cary, NC, USA).<sup>[5]</sup>

#### **Results**

## Patient characteristics

Baseline patient characteristics are shown in Table 1. Of the 172 patients who received ICDs, 86 were in the S-ICD group and 86 in the single-chamber T-ICD group matched to S-ICD group. Male gender was 69.2%. The most common cardiac conditions for receiving ICD were hypertrophic cardiomyopathy (HCM, 37.8%), followed by ischemic cardiomyopathy (ICM, 22.7%), and Dilated cardiomyopathy (DCM, 19.8%). Others included congenital heart disease and cardiac channelopathies.

Variables	Total ( <i>n</i> =172)	S-ICD ( <i>n</i> =86)	T-ICD ( <i>n</i> =86)	Statistics	Р
Male, <i>n</i> (%)	119 (69.2)	59 (68.6)	60 (69.8)	0*	1.000
Age (years)	$45 \pm 18$	$45 \pm 16$	$46 \pm 16$	$-0.433^{\dagger}$	0.666
BMI $(kg/m^2)$	$30\pm7$	$29\pm 6$	$31\pm8$	$-2.078^{\dagger}$	0.039
Follow-up (months)	$23 \pm 15$	$23 \pm 14$	$24 \pm 17$	$-0.486^{\dagger}$	0.625
Cardiac disease				$1.715^{*}$	0.634
ICM, <i>n</i> (%)	39 (22.7)	17 (19.8)	22 (25.6)		
DCM, <i>n</i> (%)	34 (19.8)	17 (19.8)	17 (19.8)		
HCM, <i>n</i> (%)	65 (37.8)	32 (37.2)	33 (38.4)		
Others, $n$ (%)	34 (19.8)	20 (23.3)	14 (16.3)		
Hypertension, $n$ (%)	59 (30.4)	27 (31.4)	32 (37.2)	0.413*	0.521
Atrial fibrillation, $n$ (%)	23 (13.4)	11 (12.8)	12 (14.0)	0*	1.000
Diabetes mellitus, $n$ (%)	20 (11.6)	7 (8.1)	13 (15.1)	$1.414^{*}$	0.234
CKD, <i>n</i> (%)	15 (8.7)	9 (10.5)	6 (6.9)	$0.292^{*}$	0.590
LVEF (%)	$50 \pm 19$	$51 \pm 18$	$49 \pm 20$	$0.785^{+}$	0.434
LVEDD (mm)	$53 \pm 11$	$53 \pm 11$	$54 \pm 11$	$-0.491^{+}$	0.624
Creatinine (mg/dL)	$1.14 \pm 1.00$	$1.28 \pm 1.33$	$1.00 \pm 0.45$	$1.876^{\dagger}$	0.062
Medication					
$\beta$ -blocker, <i>n</i> (%)	131 (76.2)	59 (68.6)	72 (83.7)	4.611*	0.031
ACEI/ARB, $n$ (%)	86 (50.0)	40 (46.5)	46 (53.5)	$0.581^*$	0.446
Aspirin, $n$ (%)	94 (54.7)	40 (46.5)	54 (62.8)	$3.965^{*}$	0.046
Oral anticoagulants, $n$ (%)	32 (18.6)	16 (18.6)	16 (18.6)	$0^{*}$	1.000
Primary prevention, $n$ (%)	136 (79.1)	68 (79.1)	68 (79.1)	0*	1.000

Values are mean  $\pm$  standard deviation or n (%). <sup>\*</sup> $\chi^2$  value. <sup>†</sup>t value. ACEI: angiotensin-converting enzyme inhibitors; ARB: angiotensin receptor blocker; BMI: body mass index; CKD: Chronic kidney disease; DCM: Dilated cardiomyopathy; EP: electrophysiology; HCM: Hypertrophic cardiomyopathy; ICD: implantable cardioverter-defibrillator (E: epicardial; S: subcutaneous); ICM: Ischemic cardiomyopathy; LVEDD: left ventricular end-diastolic dimension; LVEF: left ventricular ejection fraction; OTHER: congenital heart disease and cardiac channelopathies.

# Implantation success

In the S-ICD group, all patients had successful device and lead implantation. Defibrillation threshold (DFT) testing at 65 J was successful in 77 patients (including polarity being reversed in nine patients with failure the first time). Of the nine remaining patients, four did not undergo DFT testing for Eisenmenger syndrome or spontaneous coronary artery dissection, two with paroxysmal atrial fibrillation had DFT testing postponed because of not being well anticoagulated, one had DFT testing deferred because of left ventricular thrombus, one did not have VF sustained after the induction, and one refused to undergo DFT testing.

In the T-ICD group, the mean implant impedance was  $693 \pm 134 \Omega$ , pacing threshold  $0.6 \pm 0.2 V$ , and sensing threshold  $14.0 \pm 7.8 \text{ mV}$ . DFT testing was not routinely performed.

## **Procedure complications**

At a mean follow-up of  $23 \pm 15$  months, there were no significant differences in device-related infection between two groups. Two patients in each group developed pocket hematoma. Infective endocarditis occurred in two patients in the T-ICD group, but in none of those in the S-ICD group [Table 2]. No lead malfunction was found in S-ICD group, but three (3.5%) leads fracture in T-ICD group (P=0.24).

In the S-ICD group, three (3.5%) patients underwent S-ICD removal or revision: pocket infection in one and T-wave oversensing in two. In the T-ICD group, five patients (5.8%) underwent lead removal: infective endocarditis in two and lead malfunction in three. There was no significant difference between two groups in Device and Lead removal or revision (P=0.72).

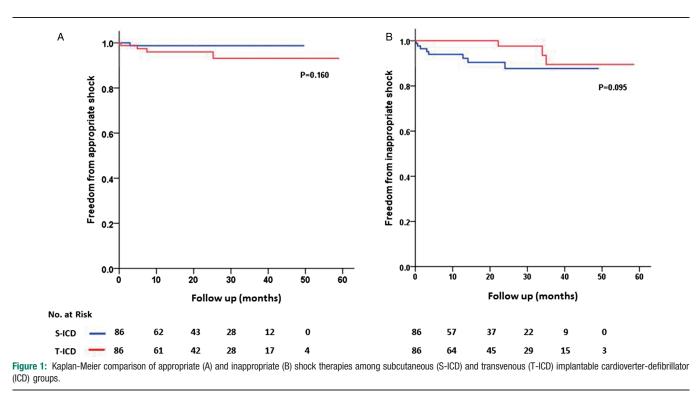
In the S-ICD group, two-incision technique was used in 28 patients and three-incision technique in 58 patients. Lead dislocation occurred in only one patient who had the three-incision technique. There was no significant difference in pocket infection between the two techniques.

# ICD therapies

There was no significant difference in appropriate ICD therapy rate between the two groups (1.2% vs. 4.7%, P =0.211 [Table 2]). In the S-ICD group, one patient received one appropriate shock for monomorphic VT, and sinus rhythm was restored. In the T-ICD group, four patients received appropriate shocks after antitachycardia pacing failed. Overall, the inappropriate ICD therapy rate also was not significantly different between two groups (9.3% vs. 3.5%, P=0.211). However, inappropriate shock occurred in eight (9.3%) patients in the S-ICD group and all were from T-wave oversensing. None of T-ICD group had T-wave oversensing (P=0.007). Six of these eight patients who had T-wave oversensing underwent successful device reprogramming. Two patients had S-ICD removal because T-wave oversensing was unable to be resolved by adjusting the sensing vectors. In the T-ICD group, two patients had inappropriate shock for sinus tachycardia and one patient for atrial fibrillation. Figure 1 shows the Kaplan-Meier comparison of appropriate Table 2: Complication of ICD therapy n (%)

Items	S-ICD ( <i>n</i> =86)	T-ICD ( <i>n</i> =86)	$\chi^2$ value	Р
Procedure-related complications	6 (7.0)	3 (3.5)	1.055	0.496
Device pocket infection	1 (1.2)	0	0	1.000
Pocket hematoma	2 (2.3)	2 (2.3)	0	1.000
Pocket emphysema	1 (1.2)	0	0	1.000
Ecchymosis	1 (1.2)	1 (1.2)	0	1.000
Lead dislodgement	1 (1.2)	0	0	1.000
Complication during follow-up				
Infective endocarditis	0	2 (2.3)	2.024	0.497
Lead malfunction	0	3 (3.5)	3.053	0.246
Device/lead removal/revision	3 (3.5)	5 (5.8)	0.524	0.720
ICD therapy				
Appropriate shock	1 (1.2)	4 (4.7)	1.854	0.368
Inappropriate shock	8 (9.3)	3 (3.5)	2.428	0.211
T wave oversensing	8 (9.3)	0	8.390	0.007
SVT/Atrial fibrillation	0	3 (3.5)	3.503	0.246
Death	5 (5.8)	5 (5.8)	0	1.000

HCM: Hypertrophic cardiomyopathy; ICD: Implantable cardioverter-defibrillator (S: subcutaneous; T: transvenous); SVT: Supraventricular tachycardia.



(A) and inappropriate (B) shocks, the log rank P values were 0.160 and 0.095, respectively.

# Survival

Survival was not significantly different between the two groups (P=1.000). In the S-ICD group, five patients (5.8%) died during follow-up: one died of respiratory failure and four of end-stage heart failure. In the T-ICD group, five patients (5.8%) died of heart failure. None of the study patients required biventricular pacing during follow-up.

## Patients with HCM

Between the two study groups, ICD was given for HCM in 65 patients: 32 in S-ICD group and 33 in T-ICD group. At a mean follow-up of  $21 \pm 15$  months, no patient in the S-ICD group underwent lead revision, two patients in the T-ICD group had device removal for infection and lead malfunction (P=0.492). In the S-ICD group, none had appropriate ICD therapy, and only one patient received inappropriate ICD therapy [Table 3]. Neither appropriate, nor inappropriate ICD therapy occurred in T-ICD group.

# Table 3: Comparison of HCM patients between S-ICD and T-ICD groups.

Characteristics	S-ICD ( <i>n</i> =32)	T-ICD ( <i>n</i> =33)	Statistics	Р
Male, <i>n</i> (%)	27 (84.4)	22 (66.7)	2.745*	0.098
Age (years)	$42 \pm 14$	$39 \pm 13$	$0.670^{\dagger}$	0.544
$BMI (kg/m^2)$	$30\pm4$	$32 \pm 7$	$6.316^{+}$	0.180
Hypertension, $n$ (%)	9 (28.1)	8 (24.2)	$0.127^{*}$	0.722
Atrial fibrillation, $n$ (%)	3 (9.4)	3 (9.4)	$0^{*}$	1.000
Diabetes mellitus, $n$ (%)	1 (3.1)	1 (3.0)	$0^*$	1.000
LVEF (%)	$66 \pm 9$	$66 \pm 7$	$0.009^{\dagger}$	0.804
LVEDD (mm)	$45 \pm 5$	$46 \pm 6$	$1.592^{+}$	0.733
Primary prevention, $n$ (%)	31 (96.9)	32 (96.9)	$0^{*}$	1.000
Procedure-related complications	2 (6.3)	1 (3.0)	$0.383^*$	0.613
Device pocket infection, $n$ (%)	0	1 (3.1)	$0^{*}$	1.000
Pocket hematoma, $n$ (%)	1 (3.1)	1 (3.0)	$0^*$	1.000
Lead dislodgement, $n$ (%)	1 (3.1)	0	$1.047^{*}$	0.492
Complication during follow-up				
Infective endocarditis, $n$ (%)	0	1 (3.0)	$0^*$	1.000
Lead malfunction, $n$ (%)	0	1 (3.0)	0*	1.000
Device/lead removal/revision, $n$ (%)	0	2 (6.1)	$2.001^{*}$	0.492
ICD therapy				
Appropriate shock, $n$ (%)	0	0		
Inappropriate shock, $n$ (%)	1 (3.1)	0	$1.047^{*}$	0.492
T wave oversensing, $n$ (%)	1 (3.1)	0	$1.047^{*}$	0.492
Death, <i>n</i> (%)	1 (3.1)	0	$1.047^{*}$	0.492

Values are mean ± standard deviation or n (%).  $*\chi^2$  value.  $^{\dagger}t$  value. BMI: Body mass index; ICD: Implantable cardioverter-defibrillator (E: epicardial; S: subcutaneous); LVEDD: Left ventricular end-diastolic dimension; LVEF: Left ventricular ejection fraction.

Within the S-ICD group, 32 patients with HCM were compared with those who had ICM (n=17) and DCM (n=17). There were no significant difference in device-related complications or appropriate and inappropriate ICD therapies (P > 0.05). The mortality rate in those with ICM (4/17, 23%) was higher than that in those with DCM (none) and those with HCM (1/32, 3%, P=0.014).

# Discussion

## S-ICD implant success

All patients had successful S-ICD implantation without failure. No lead dislocation occurred in the two-incision technique group. The two-incision technique is simpler, requires less procedure time, and causes less patient discomfort. Similar to previous reports, we favor the two-incision technique over the three-incision approach, given the advantages of fewer procedural steps and equal lead stability.<sup>[5,10,12]</sup> None of the patients in the S-ICD group failed DFT testing at 65 J, confirming that the energy delivery capacity in this technology is sufficient in defibrillation.

# **Device-related complications**

Only patients who received single-chamber T-ICDs were compared with those in the S-ICD group. Previous studies have included dual-chamber ICDs in the T-ICD group with a potential of increased complications compared with single-chamber ICDs.<sup>[13-15]</sup> In our S-ICD group, one patient had device-pocket infection with subsequent device and lead removal. The pocket infection rate was similar to that in the T-ICD group and lower than in the IDE the

EFFORTLESS study.<sup>[16-18]</sup> Most infections may be due to early experience with the implantation technique in the IDE study. The infection rate decreased as experience and attention to technique increased.<sup>[19]</sup> Bloodstream infection or endocarditis occurred in two patients in the T-ICD group but in none in the S-ICD. Avoidance of transvenous lead is the advantage of S-ICD, especially in patients who are at high risk for transvenous lead-related infection. There was no lead malfunction in the S-ICD group, while lead fractures were the main causes of lead malfunction in the T-ICD group.

## Appropriate and inappropriate ICD shocks

There was no significant difference in appropriate ICD therapies between the two groups. The overall event rate was low, less than 5% for a follow-up duration of approximately 2 years in the S-ICD and T-ICD groups, in which 80% of the patients received the devices for primary prevention.

The inappropriate therapy incidence due to T-wave oversensing at rest or during exercise was higher in the S-ICD group. Reprogramming to a different sensing vector was not successful in two patients, and the devices had to be removed. T-wave oversensing remains a major drawback of the S-ICD and the primary cause of inappropriate shock.<sup>[14,15]</sup> In the largest study to date, T-wave oversensing occurred in 5.1% of patients with an S-ICD followed for 3 years,<sup>[16]</sup> and was the major cause of inappropriate shock in the EFFORTLESS study.<sup>[17]</sup> In the IDE trial, the 2-year inappropriate shock rates were 10.3% in the dual-zone programming subgroup and 26.4% in the single-zone programming subgroup.<sup>[20]</sup> Our inappropriate

shock rate is very similar to that reported in the literature. Pre-implant screening is critical to exclude patients who are vulnerable to T-wave oversensing, especially those with long-QT syndrome. The screening ECG should be done at rest and during exercise. The inappropriate shocks in the T-ICD group were for supraventricular tachycardia and atrial fibrillation, which are common causes in these patients. Programming high rate detection, delayed ICD therapy or supraventricular arrhythmia discrimination minimizes related inappropriate shock rates.

## **Survival**

Mortality between two groups was not significantly different during an approximate follow-up of 2 years. Most of the deaths were due to heart failure. This finding was similar to that in previous reports,<sup>[5,17]</sup> in which the 5-year survival was 96.0% in the S-ICD arm and 94.8% in the T-ICD arm.<sup>[5]</sup>

## Benefit of ICD in patients with HCM

As Mayo Clinic HCM clinic is a national referral center, patient with HCM receiving ICD for primary prevention is a unique group in this study. The higher rate of HCM subgroup reflects our practice of favoring S-ICD in this young patient population to avoid transvenous dwelling lead. Patients with HCM did not have increased rates of appropriate and inappropriate ICD shock. S-ICD is a good alternative to T-ICD for patients with HCM to minimize long-term transvenous lead-related complications.<sup>[5]</sup> In the EFFORTLESS registry,<sup>[17]</sup> those patients with HCM or a history of atrial fibrillation experienced higher rates of inappropriate shocks, predominantly due to T-wave oversensing.<sup>[14]</sup> Because these patients may be prone to dynamic T-wave amplitude and QRS morphologic changes, they are vulnerable to the risk of T-wave oversensing and of inappropriate shocks.<sup>[19]</sup> Also, because they are younger than most ICD recipients, often they achieve higher exercise heart rates, a factor disposing their sinus tachycardia to be detected in the VT or VF therapy zone if it is programmed too low.<sup>[20]</sup> In our study, the Twave oversensing only occurred in one HCM patient. Preimplant screening is critical to identify appropriate candidate.

## Limitations

First, this is a retrospective collection of data. All patient events were retrieved from medical records. Physicians' bias for S-ICD selection may impact on the outcomes. We used case-matching T-ICD group with intention to mitigate this weakness. Second, the study sample size is not robust.

# Conclusion

In this study, we compared the outcomes of S-ICD and T-ICD in clinical application. The S-ICD is an effective and safe therapy for treating ventricular arrhythmias compared with the T-ICD. It exposes lower risk of endovascular infection, favorable for young or high-risk infection group. T-wave oversensing remains a challenge for inappropriate VT detection for which pre-implant screening test at rest and during exercise, and programming a high detection rate may mitigate this drawback.

## **Conflicts of interest**

Mayo Clinic does not endorse specific products or services included in this article.

## References

- Bardy GH, Smith WM, Hood MA, Crozier IG, Melton IC, Jordaens L, *et al.* An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010;363:36–44. doi: 10.1056/ NEJMoa0909545.
- Burke MC, Gold MR, Knight BP, Barr CS, Theuns DA, Boersma LV, 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;65:1605–1615. doi: 10.1016/j.jacc.2015.02.047.
- Gold MR, Theuns DA, Knight BP, Sturdivant JL, Sanghera R, Ellenbogen KA, et al. Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous icd arrhythmia detection algorithms: The start study. J Cardiovasc Electrophysiol 2012;23:359–366. doi: 10.1111/j.1540-8167.2011.02199.
- 4. Bordachar P, Marquie C, Pospiech T, Pasquie JL, Jalal Z, Haissaguerre M, *et al.* Subcutaneous implantable cardioverter defibrillators in children, young adults and patients with congenital heart disease. Int J Cardiol 2016;203:251–258. doi: 10.1016/j. ijcard.2015.09.083.
- Brouwer TF, Yilmaz D, Lindeboom R, Buiten MS, Olde Nordkamp LR, Schalij MJ, et al. Long-term clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy. J Am Coll Cardiol 2016;68:2047–2055. doi: 10.1016/j.jacc.2016.08.044.
- 6. Pedersen SS, Mastenbroek MH, Carter N, Barr C, Neuzil P, Scholten M, *et al.* A comparison of the quality of life of patients with an entirely subcutaneous implantable defibrillator system versus a transvenous system (from the effortless s-icd quality of life substudy). Am J Cardiol 2016;118:520–526. doi: 10.1016/j.amj-card.2016.05.047.
- 7. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS, *et al.* Acc/aha/hrs 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: A report of the american college of cardiology/american heart association task force on practice guidelines (writing committee to revise the acc/aha/naspe 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices): Developed in collaboration with the american association for thoracic surgery and society of thoracic surgeons. Circulation 2008;117:e350–e408. doi: 10.1161/CIR-CUALTIONAHA.108.189742.
- Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, Maass AH, de Groot JR, van Oostrom AJ, et al. The entirely subcutaneous implantable cardioverter-defibrillator: Initial clinical experience in a large dutch cohort. J Am Coll Cardiol 2012;60:1933–1939. doi: 10.1016/j.jacc.2012.06.053.
- Kobe J, Reinke F, Meyer C, Shin DI, Martens E, Kaab S, *et al.* Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter casecontrol study. Heart Rhythm 2013;10:29–36. doi: 10.1016/j. hrthm.2012.09.126.
- Knops RE, Olde Nordkamp LR, de Groot JR, Wilde AA. Twoincision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. Heart Rhythm 2013;10:1240–1243. doi: 10.1016/j.hrthm.2013.05.016.
- Honarbakhsh S, Providencia R, Srinivasan N, Ahsan S, Lowe M, Rowland E, *et al.* A propensity matched case-control study comparing efficacy, safety and costs of the subcutaneous vs. Transvenous implantable cardioverter defibrillator. Int J Cardiol 2017;228:280–285. doi: 10.1016/j.ijcard.2016.11.017.
- 12. Migliore F, Allocca G, Calzolari V, Crosato M, Facchin D, Daleffe E, *et al.* Intermuscular two-incision technique for subcutaneous implantable cardioverter defibrillator implantation: Results from a multicenter registry. Pacing Clin Electrophysiol 2017;40:278–285. doi: 10.1111/pace.12987.

- Dewland TA, Pellegrini CN, Wang Y, Marcus GM, Keung E, Varosy PD. Dual-chamber implantable cardioverter-defibrillator selection is associated with increased complication rates and mortality among patients enrolled in the ncdr implantable cardioverter-defibrillator registry. J Am Coll Cardiol 2011;58:1007–1013. doi: 10.1016/j. jacc.2011.04.039.
- El-Chami MF, Harbieh B, Levy M, Leon AR, Merchant FM. Clinical and electrocardiographic predictors of t wave oversensing in patients with subcutaneous icd. J Arrhythm 2016;32:181–185. doi: 10.1016/ j.joa.2016.01.002.
- Aziz S, Leon AR, El-Chami MF. The subcutaneous defibrillator: a review of the literature. J Am Coll Cardiol 2014;63:1473–1479. doi: 10.1016/j.jacc.2014.01.018.
- Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 2013;128:944–953. doi: 10.1161/ CIRCULATIONAHA.113.003042.
- 17. Lambiase PD, Barr C, Theuns DA, Knops R, Neuzil P, Johansen JB, *et al.* Worldwide experience with a totally subcutaneous implantable

defibrillator: early results from the effortless s-icd registry. Eur Heart J 2014;35:1657–1665. doi: 10.1093/eurheartj/ehu112.

- Olde Nordkamp LR, Brouwer TF, Barr C, Theuns DA, Boersma LV, Johansen JB, et al. Inappropriate shocks in the subcutaneous icd: Incidence, predictors and management. Int J Cardiol 2015;195:126– 133. doi: 10.1016/j.ijcard.2015.05.135.
- Patel KH, Lambiase PD. The subcutaneous icd-current evidence and challenges. Cardiovasc Diagn Ther 2014;4:449–459. doi: 10.3978/j. issn.2223-3652.2014.12.02.
- 20. Gold MR, Weiss R, Theuns DA, Smith W, Leon A, Knight BP, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm 2014;11:1352–1358. doi: 10.1016/j.hrthm.2014.04.012.

How to cite this article: Liang JJ, Okamura H, Asirvatham R, Schneider A, Hodge DO, Yang M, Li XP, Dai MY, Tian Y, Zhang P, Cannon BC, Huang CX, Friedman PA, Cha YM. Comparative outcomes of subcutaneous and transvenous cardioverter-defibrillators. Chin Med J 2019;132:631–637. doi: 10.1097/CM9.000000000000133