



## Original Article

# Clinical and electrocardiographic predictors of T wave oversensing in patients with subcutaneous ICD

Mikhael F. El-Chami, MD<sup>a,\*</sup>, Bernard Harbich, MD<sup>b</sup>, Mathew Levy, BS<sup>a</sup>, Angel R. Leon, MD<sup>a</sup>, Faisal M. Merchant, MD<sup>a</sup>

<sup>a</sup> Department of Medicine, Division of Cardiology, Section of Electrophysiology, Emory University School of Medicine, 550 Peachtree Street NE, Atlanta, GA 30308, USA

<sup>b</sup> Department of Medicine, Division of Cardiology, American University of Beirut, AUBMC, Department of Internal Medicine, P.O. Box: 11-0236, Riad El-Solh, Beirut 1107 2020, Lebanon

## ARTICLE INFO

## Article history:

Received 15 October 2015

Received in revised form

18 December 2015

Accepted 7 January 2016

Available online 5 February 2016

## Keywords:

Subcutaneous ICD

T wave oversensing

Inappropriate shocks

## ABSTRACT

**Background:** T wave oversensing (TWOS) is a major drawback of the subcutaneous implantable cardioverter defibrillator (S-ICD). Data on predictors of TWOS in S-ICD recipients are limited.

We sought to investigate predictors of TWOS in a cohort of patients receiving an S-ICD at our institution.

**Methods:** S-ICD recipients at our center were identified retrospectively and stratified based on the presence or absence of TWOS. Clinical and electrocardiographic parameters were collected and compared between the 2 groups.

**Results:** Ninety-two patients underwent an S-ICD implantation at our institution between April 2010 and January 2015. Six (6.5%) patients had TWOS. These patients were younger ( $38.1 \pm 13.7$  vs.  $52.3 \pm 16.1$  years,  $p=0.04$ ) and had higher left ventricle ejection fractions ( $48.5 \pm 14.9\%$  vs.  $28.4 \pm 12.2\%$ ,  $p < 0.01$ ) than patients without a history of TWOS. Baseline 12-lead electrocardiogram (ECG) parameters were not different between the 2 groups. Leads I, II, and aVF (which mimic the sensing vectors of the S-ICD) were further inspected to identify ECG characteristics that could predict TWOS. The QRS amplitude in ECG lead I was significantly smaller in the TWOS group than in the non-TWOS group ( $3.7$  vs.  $7.4$  mV,  $p=0.02$ ).

**Conclusion:** In this study, younger age, higher ejection fraction, and lower QRS amplitude were associated with TWOS. These findings could help identify patients referred for S-ICD at high-risk of TWOS.

© 2016 Japanese Heart Rhythm Society. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## 1. Introduction

The subcutaneous implantable cardioverter defibrillator (S-ICD) is an emerging alternative to the transvenous ICD (T-ICD) for the prevention of sudden cardiac death. The safety and efficacy of this device have been shown in multiple studies [1–3]. The rate of inappropriate shocks, specifically due to T wave oversensing (TWOS), remains an Achilles heel of this therapy. The original S-ICD studies reported 13–15% yearly rates of inappropriate shocks [4,5], with TWOS accounting for the vast majority of cases (estimated as the cause of 64–85% of all inappropriate shocks [1,3,4]). The addition of a conditional tachycardia detection zone (2 zones vs. 1 zone programming) significantly decreased the rate of inappropriate shocks due to supraventricular rhythms and TWOS [6]. In aggregate, increased operator experience with S-ICD programming and routine use of a conditional zone have

resulted in a significant decrease in the rate of inappropriate shocks, which has been reflected in newer studies reporting an annual incidence of 5–7% for inappropriate therapies [2,3]. However, TWOS remains responsible for the majority of these inappropriate shocks.

Limited data are available on the clinical predictors of inappropriate shocks [4,7], and therefore, we sought identify clinical and electrocardiographic predictors of TWOS in a cohort of patients undergoing S-ICD implantation at our institution.

## 2. Materials and methods

The Emory University institutional review board approved the study protocol in 2015 (IRB # 00077019). We retrospectively identified all patients who underwent S-ICD implantation (Cameron health-model number 1010 SQ-RX, with a subcutaneous lead-Cameron health model 3010) at our institution from April 2010 to January 2015. Baseline clinical characteristics and procedural outcomes were

\* Corresponding author. Tel.: +1 404 686 2504; fax: +1 404 686 4826.

E-mail address: [melcham@emory.edu](mailto:melcham@emory.edu) (M.F. El-Chami).

ascertained by medical record review. Data on post-implant clinical events and survival were obtained from review of medical records and device-clinic follow-up. Pre-procedure screening for S-ICD candidacy was performed using body-surface electrocardiograms (ECGs) as recommended by the manufacturer; however, the ultimate decision to implant an S-ICD was at the discretion of the implanting physician. Patients were programmed with 2 tachy-arrhythmia zones (200 and 220 beats/min). All S-ICD shocks were adjudicated by an electrophysiologist and classified as appropriate or inappropriate and further sub-classified based on cause (i.e., appropriate therapies for ventricular tachycardia/fibrillation or inappropriate therapies for TWOS or supra-ventricular rhythms).

Baseline 12-lead ECGs from immediately prior to S-ICD implantation were reviewed for all patients. Baseline intervals (PR, QRS, QT) were obtained from the automated ECG measurements. Leads I, II, and aVF were further used to collect data on QRS and T wave amplitudes, QRS/T amplitude ratio, presence of T wave inversion, and QRS/T discordance. Leads I, II, and aVF were chosen for analysis because they mimic the three sensing vectors of the S-ICD [8]. In each of the three chosen ECG leads, dominant QRS and T wave amplitudes were measured using manual calipers, and the presence of T wave inversion and QRS/T discordance was determined by visual inspection by an electrophysiologist blinded to other clinical variables.

Patients were stratified based on the presence or absence of TWOS during follow-up. Continuous variables are presented as the mean  $\pm$  standard deviation, and categorical data are summarized as frequencies and percentages. Comparisons across groups were performed using the Student's *t*-test, Fisher's exact test, or one-way analysis of variance, as appropriate. For all comparisons, a *p* value  $< 0.05$  was considered to be statistically significant. Analysis was performed using STATISTICA software (Statsoft, Inc., Tulsa, OK).

### 3. Results

#### 3.1. Patient characteristics

Ninety-two patients underwent S-ICD implantation. Baseline characteristics, stratified by the presence of TWOS, are presented in Table 1. During a mean follow-up of  $13.1 \pm 14.3$  months, 6 patients (6.5%) had TWOS resulting in inappropriate shocks. Patients experiencing TWOS were significantly younger ( $38.1 \pm 13.7$  vs.  $52.3 \pm 16.1$  years,  $p=0.04$ ) and had higher left ventricle ejection fractions (LVEF) ( $48.5 \pm 14.9\%$  vs.  $28.4 \pm 12.2\%$ ,  $p < 0.01$ ) than patients without TWOS. There was a trend toward higher prevalence of male gender in the TWOS group. All 6 patients (100%) with inappropriate shocks due to TWOS were male compared to only 51 patients (59.3%) male gender in the group without TWOS ( $p=0.08$ ). Other baseline characteristics were similar between the groups. Approximately half of all S-ICD implants were programmed in the primary sensing vector at implant, with the secondary vector used next most commonly. The S-ICD chooses the optimal vector for sensing based on an automated algorithm that will select the vector with an optimal R to T ratio and minimal beat-to-beat variability.

Only 1 patient in the TWOS group also experienced an appropriate S-ICD shock. In the group without TWOS, 3 patients experienced appropriate shocks, and 2 patients experienced inappropriate shocks for non-TWOS etiologies (1 for supraventricular rhythm and 1 for electromagnetic interference).

Baseline ECG parameters stratified by the presence of TWOS are presented in Table 2. There were no significant differences between the groups in baseline ECG intervals. QRS amplitudes in ECG lead I were significantly smaller in the TWOS group ( $3.7$  vs.

**Table 1**  
Baseline characteristics.

	TWOS ( <i>n</i> =6)	Control ( <i>n</i> =86)	<i>p</i>
Age (years)	38.1 $\pm$ 13.7	52.3 $\pm$ 16.1	0.04
Gender (male)	6 (100)	51 (59.3)	0.08
New York heart association class	2.0 $\pm$ 1.0	2.3 $\pm$ 0.5	0.30
Left ventricular ejection fraction (%)	48.5 $\pm$ 14.9	28.4 $\pm$ 12.2	$< 0.01$
History of atrial fibrillation	1 (16.7)	17 (19.8)	1.00
History of ventricular tachycardia	1 (16.7)	19 (22.1)	1.00
Primary arrhythmia syndrome	2 (33.3)	11 (12.8)	0.20
Hypertrophic cardiomyopathy	1 (16.7)	5 (5.8)	0.34
Coronary artery disease	1 (16.7)	29 (33.7)	0.66
Prior myocardial infarction	1 (16.7)	24 (27.9)	1.00
Prior percutaneous coronary intervention	1 (16.7)	16 (18.6)	1.00
Prior coronary artery bypass grafting	0	20 (23.3)	0.33
History of appropriate defibrillator shocks	1 (16.7)	3 (3.5)	0.24
Chronic lung disease	0	7 (8.1)	1.00
Diabetes mellitus	0	37 (43.0)	0.08
Obstructive sleep apnea	0	12 (13.9)	1.00
Hypertension	3 (50)	68 (79.1)	0.13
End stage renal disease	1 (16.7)	5 (5.8)	0.34
Secondary prevention defibrillator indication	3 (50)	19 (22.1)	0.15
ACE-I/ARB	1 (16.7)	50 (58.1)	0.09
Beta blockers	4 (66.7)	77 (89.5)	0.15
Diuretics	1 (16.7)	50 (58.1)	0.09
Amiodarone	1 (16.7)	6 (7.0)	0.39
Statins	3 (50)	42 (48.8)	1.00
Subcutaneous defibrillator sensing vector			0.86
Primary	3	43	
Secondary	3	30	
Alternate	0	7	

Data are presented as the mean  $\pm$  standard deviation or *n* (%).

ACE-I/ARB=angiotensin converting enzyme inhibitor/angiotensin receptor blocker; TWOS=T wave oversensing.

$7.4$  mV,  $p=0.02$ ). Other markers of QRS and T wave amplitude and morphology were not significantly different between the groups.

Twelve-lead ECGs at the time of TWOS episodes were available on 3 out of 6 patients with TWOS. No significant changes or new conduction delays were noted on these ECGs. The QRS and T wave amplitudes in lead I were similar at the time of implantation and at the time of TWOS. QRS and T wave amplitudes at the time of TWOS as compared to baseline were similar ( $5.3 \pm 0.6$  vs.  $3.7 \pm 1.6$  mV for QRS amplitude and  $1.3 \pm 0.5$  vs.  $1.1 \pm 0.5$  for T wave amplitude).

#### 3.2. Management of TWOS

Six patients presented with inappropriate shocks due to TWOS:

1. A 34-year-old man with hypertrophic cardiomyopathy (HCM) and sudden cardiac death risk factors underwent S-ICD implantation for primary prevention. He experienced an initial inappropriate shock due to TWOS approximately 3 months after implantation. The sensing vector was changed from primary to secondary, and the rate cut-offs for delivery of therapy in both zones were increased. A week later he presented with another inappropriate shock for TWOS. An exercise treadmill test (ETT) was performed with acquisition of a new template during exercise. He currently has had no further inappropriate therapies in the 10 months following this, with activity limitations per guidelines for management of HCM.
2. A 23-year-old male collegiate basketball player experienced cardiac arrest during a game and was rescued with an automated external defibrillator. He was diagnosed with idiopathic ventricular fibrillation after extensive testing. Two months after implantation he experienced an inappropriate shock for TWOS.

**Table 2**  
Electrocardiographic predictors of T wave oversensing.

	TWOS (n=6)	Control (n=86)	p
PR interval (ms)	160.0 ± 22.9	168.4 ± 28.3	0.52
QT interval (ms)	444.3 ± 66.8	409.6 ± 40.4	0.06
QTc (ms)	456.8 ± 39.9	466.4 ± 37.9	0.55
QRS axis (deg)	15.0 ± 121.1	16.9 ± 49.6	0.94
T wave axis (deg)	60.0 ± 37.9	41.6 ± 81.1	0.58
QRS duration (m)	102.0 ± 14.9	101.7 ± 17.8	0.97
ECG lead I			
QRS amplitude (mV)	3.7 ± 1.6	7.4 ± 3.7	0.02
T wave amplitude (mV)	1.1 ± 0.5	1.5 ± 0.7	0.14
QRS/T amplitude	3.5 ± 1.1	5.3 ± 2.8	0.12
Presence of T wave inversion	1 (16.7)	27 (31.4)	0.66
QRS/T discordance	4 (66.7)	31 (36.1)	0.20
ECG lead II			
QRS amplitude (mV)	7.0 ± 4.8	7.6 ± 4.4	0.76
T wave amplitude (mV)	1.8 ± 0.6	1.8 ± 0.9	0.96
QRS/T amplitude	4.0 ± 2.1	4.7 ± 2.5	0.53
Presence of T wave inversion	0	17 (19.8)	0.59
QRS/T discordance	2 (33.3)	26 (30.3)	1.00
ECG lead aVF			
QRS amplitude (mV)	6.3 ± 5.0	6.3 ± 4.2	0.96
T wave amplitude (mV)	1.7 ± 0.5	1.5 ± 0.8	0.51
QRS/T amplitude	3.7 ± 2.3	4.8 ± 3.1	0.38
Presence of T wave inversion	0	14 (16.3)	0.59
QRS/T discordance	1 (16.7)	29 (33.7)	0.66

Data are presented as the mean ± standard deviation or n (%).  
ms=milliseconds; deg=degrees; mV=millivolts; TWOS=T wave oversensing;  
ECG=electrocardiogram.

An ETT was performed with acquisition of a new template, and the sensing vector was changed from primary to secondary for better discrimination of T waves during activity. He has had no further inappropriate therapies in the 27 months since then.

3. A 25-year-old man with Long QT syndrome and a history of aborted cardiac arrest underwent extraction of a T-ICD because of infection attributed to intravenous drug use. He subsequently underwent implantation of an S-ICD and presented with an inappropriate shock for TWOS 1 month later (Fig. 1a, b). An ETT was performed, and the sensing vector was changed from secondary to primary. He has had no further inappropriate therapies in the 10 months since then.
4. A 49-year-old man with ischemic cardiomyopathy underwent S-ICD implantation for primary prevention. Twenty months later he presented with an inappropriate shock for TWOS in the setting of sinus tachycardia during an altercation. The sensing vector was changed from primary to secondary without further TWOS in the following 37 months.
5. A 50-year-old man with non-ischemic cardiomyopathy and end-stage renal disease (ESRD) on dialysis with numerous prior aborted cardiac arrests had previously undergone extraction of T-ICD systems in 2008 and 2012 for endovascular infection attributed to ESRD. Following the second episode of T-ICD infection, he was implanted with an S-ICD and presented 1 month later with two inappropriate shocks for TWOS. Sensing was adequate at that time, and an ETT was not felt to be feasible for clinical reasons. No changes were made to the sensing vectors. Six months later he experienced an appropriate shock for sustained ventricular tachycardia, which was adequately detected and treated. However, due to deterioration in his overall clinical condition, S-ICD therapies were disabled 2 weeks later, and the patient passed away soon thereafter.

6. A 50-year-old man with hypertensive heart disease (LVEF 40%) presented with syncope and sustained ventricular tachycardia, which was easily reproduced with an electrophysiology study and poorly tolerated. Venograms demonstrated bilateral subclavian stenosis, attributed to a history of ESRD, and so he was implanted with an S-ICD. One month after implantation he presented with 5 inappropriate shocks due to TWOS in the setting of light activity. Despite extensive discussions regarding management options, the patient adamantly refused any efforts to minimize the risk of inappropriate shocks and insisted on device explant, which was performed during that hospitalization.

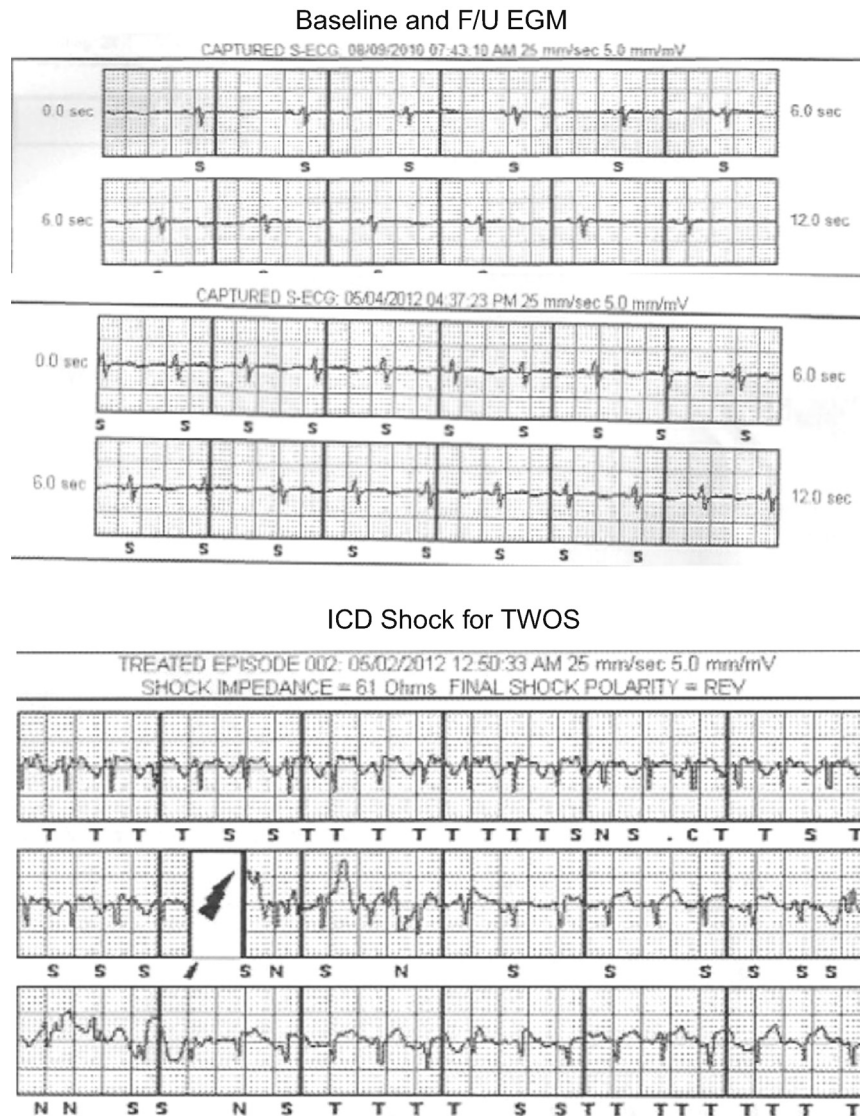
#### 4. Discussion

TWOS remains one of the major drawbacks of the S-ICD [9,10]. Despite the use of a discrimination algorithm (2 zones vs. 1 zone) that reduces the rate of TWOS [6], TWOS is commonly encountered in patients with an S-ICD. In the largest study to date, TWOS occurred in 5.1% of patients with an S-ICD followed for around 3 years [2], accounting for 39% of all inappropriate shocks. An algorithm was developed and tested on stored episodes [11], and this new algorithm reduced the rate of TWOS by around 40% without compromising the detection of ventricular arrhythmias.

In this study, we retrospectively reviewed 92 patients who received an S-ICD at our institution and found that the rate of TWOS was 6.5%, compatible with other contemporary reports of TWOS [1–5]. The major predictors of TWOS in our cohort were younger age, higher LVEF, and low QRS amplitude in ECG lead I. There was also a trend toward increased likelihood of TWOS in male patients. It is conceivable that younger patients are more likely to have channelopathies or HCM as an indication for ICD therapy. These medical conditions are associated with ST-T changes that could predispose patients to developing TWOS. In addition, younger age and normal EF might be associated with a higher likelihood of being physically active, which would therefore result in higher sinus rates. The latter in the presence of TWOS and double counting could lead to inappropriate shocks.

Young age has previously been shown to be a predictor of inappropriate shocks and TWOS in patients with S-ICDs. Jarman et al. reported on their experience with patients implanted with an S-ICD in the United Kingdom [4]. Younger age was a strong predictor of TWOS. In this study, the mean age of patients with TWOS was 24 years, while that in patients without TWOS was 39 years. In addition, most of these patients had an inherited arrhythmia syndrome or HCM, which might explain the higher rate of TWOS in patients with higher LVEF, as also seen in our study. In a more recent study looking at predictors of inappropriate shocks in S-ICD patients enrolled in the EFFORTLESS registry [7], patients with HCM or a history of atrial fibrillation had higher rates of inappropriate shocks, predominantly due to TWOS (73%).

In our study, none of the traditional ECG parameters (QT and PR intervals, QRS duration) predicted inappropriate shocks due to TWOS. However, using the ECG leads (I, II, and aVF) that correspond to the S-ICD sensing vectors (primary, secondary, and alternate, respectively), we were able to identify one baseline ECG finding which was associated with an increased risk of TWOS. In patients with TWOS, the mean QRS amplitude in lead I was roughly half the amplitude of that in patients without TWOS (3.7 vs. 7.4 mV,  $p=0.02$ ). It is conceivable that low QRS amplitude in lead I may result in a higher likelihood of TWOS due to an increased likelihood of detecting T waves when the QRS amplitude is low. The fact that most patients in this cohort were programmed with the primary S-ICD sensing vector, which most closely



**Fig. 1.** (a) EGM at implant and at the day of T wave oversensing (TWOS), (b) implantable cardioverter defibrillator (ICD) shock (lightning arrow) due to TWOS; the latter is seen throughout the EGM. Under-sensing of several beats and occasional T wave sensing rather than QRS sensing is also seen.

corresponds to ECG lead I, may explain why QRS amplitude in other leads (II and aVF) was not a significant predictor of TWOS in our study.

The major limitation of this study is the small number of patients with TWOS. However, to our knowledge, it is the first study to date that has attempted to identify baseline ECG predictors of TWOS. Despite the small size of our TWOS cohort, we were also able to validate clinical predictors of TWOS which have been identified in other studies.

## 5. Conclusion

Despite improvements in device programming strategies, patients implanted with an S-ICD remain at risk of inappropriate therapies due to TWOS. Younger age, higher LVEF, and low QRS amplitude in lead I were significantly associated with a higher risk of TWOS. If validated in a larger study, these findings could help refine the identification of patients who are candidates for an S-ICD but who may be at particularly high risk of TWOS.

## Funding

This research received no funding in the public, commercial or not for profit sectors.

## Conflict of interest

Mikhael F. El-Chami is a consultant for Boston Scientific. All other authors report no conflict of interest.

## Acknowledgments

No acknowledgements to report.

## 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] Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. *Eur Heart J* 2014;35:1657–65.
- [4] Jarman JW, Todd DM. United Kingdom national experience of entirely subcutaneous implantable cardioverter–defibrillator technology: important lessons to learn. *Europace* 2013;15:1158–65.
- [5] Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, et al. The entirely subcutaneous implantable cardioverter–defibrillator: initial clinical experience in a large Dutch cohort. *J Am Coll Cardiol* 2012;60:1933–9.
- [6] Gold MR, Weiss R, Theuns DA, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter–defibrillator. *Heart Rhythm* 2014;11:1352–8.
- [7] Olde Nordkamp LR, Brouwer TF, Barr C, et al. Inappropriate shocks in the subcutaneous ICD: incidence, predictors and management. *Int J Cardiol* 2015;195:126–33.
- [8] 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.
- [9] Aziz S, Leon AR, El-Chami MF. The subcutaneous defibrillator: a review of the literature. *J Am Coll Cardiol* 2014;63:1473–9.
- [10] Patel KH, Lambiase PD. The subcutaneous ICD-current evidence and challenges. *Cardiovasc Diagn Ther* 2014;4:449–59.
- [11] Brisben AJ, Burke MC, Knight BP, et al. A new algorithm to reduce inappropriate therapy in the S-ICD system. *J Cardiovasc Electrophysiol* 2015;26:417–23.