Fast-Rate Counters as Indicators of Signal Quality and Therapy Delivery in Subcutaneous Implantable Cardioverter-Defibrillators

David Montilla[1,2], Beatriz Giraldo[2,3], Stefano Accinelli[4], Steven Donnelley[5], LeAnne Eberle[5], Claudia Perez[1], Nicolas Charlier[6]

[1] Boston Scientific Iberica Ribera del Loira 46, Edificio 2 28042 Madrid,
[2]Universitat Politécnica de Catalunya (UPC), [3] Institute for Bioengineering of Catalonia (IBEC) and CIBER de Bioingeniería, Biomateriales y Nanomedicina. Barcelona, Spain, [4] Boston Scientific Viale Enrico Forlanini 23 20134 Milan, Italy, [5] Boston Scientific 4100 Hamline Ave, Mailstop 10-207, Arden Hills, MN 55112, United States of America, [6] Boston Scientific Green Square – Lambroekstraat 5D, Diegem, Belgium

Abstract

Subcutaneous implantable cardioverter-defibrillators (S-ICDs) prevent sudden cardiac death (SCD) without intravascular leads, reducing complications and infection risk. Reduction of inappropriate therapy remains an important opportunity, typically caused by impaired sensing associated with low signal quality, including reduced R-wave amplitude and diminished R:T ratio which increase oversensing and erroneous rhythm classification. This study investigates whether fast-rate counter dynamics derived from remote monitoring can serve as a surrogate marker of sensing quality to support to true spontaneous ventricular tachyarrhythmias from sensing abnormalities. Transitions into the tachycardia therapy profile (TTP), activated when the detected heart rate exceeds the programmed treatment zone threshold, were analyzed. Under adequate sensing conditions, ventricular tachyarrhythmias typically produce sustained and organized fast-rate counter behaviour, whereas impaired sensing results in irregular and intermittent counter patterns. To account for variability in remote monitoring transmission intervals, TTP values were temporally smoothed using an exponential smoothing filter. The approach was evaluated in 318 device records from the UNTOUCHED dataset. Signal quality was classified according to predefined criteria, with independent expert adjudication serving as the reference standard. On a per-record basis, the method achieved a sensitivity of 84.38%, a specificity of 73.78%, and a negative predictive value of 97.69% for detecting low signal quality. Mean smoothed TTP values also differed significantly between records with and without adjudicated sensing abnormalities ($p < 0.01$). These findings suggest that fast-rate counter dynamics may provide a useful indicator of S-ICD sensing quality. In its present form, this algorithm may be better suited to triage, by identifying changes in sensing performance. Remote monitoring of data dynamics could support earlier identification of sensing degradation, facilitating timely clinical assessment and potentially reducing inappropriate S-ICD therapies.

1. Introduction

Implantable cardioverter-defibrillators (ICDs) are effective for preventing sudden cardiac death (SCD) in patients at high risk of life-threatening ventricular arrhythmias. Sudden cardiac death accounts for approximately 50% of cardiac deaths and nearly 15% of overall mortality worldwide [2]. By rapidly detecting and terminating malignant ventricular tachyarrhythmias, ICDs have significantly improved long-term survival. Continued advances in device technology have further enhanced their safety, reliability, and therapeutic performance.

The subcutaneous implantable cardioverter-defibrillator (S-ICD) represents a major advancement in ICD therapy because it eliminates the need for transvenous leads. Unlike conventional ICDs, which require intracardiac lead placement, the S-ICD employs a fully subcutaneous electrode system, thereby reducing lead-related complications and the risk of systemic infection while maintaining effective defibrillation therapy [3]. Despite these advantages, reducing inappropriate therapy remains an important clinical opportunity in S-ICD management.

The sensing electrodes and device can are used to acquire subcutaneous electrocardiographic signals. The cardiac signal is detected through two sensing electrodes (the sense A and sense B nodes below the manubriosternal junction and proximal to the xiphoid respectively) in combination with the device can, depending on the programmed sensing vector. Patients undergo noninvasive preoperative screening to confirm that the cardiac signal is suitable for accurate heart-rate estimation [4]. Improved discrimination among cardiac, noncardiac, and nonphysiological signals is essential for reducing inappropriate detections and unnecessary therapy.

The objective of this study was to evaluate whether TTP dynamics derived from S-ICD remote monitoring can indicate sensing quality. Specifically, we investigated whether fast-rate counter behaviour can distinguish true

spontaneous ventricular tachyarrhythmias from episodes associated with impaired sensing, thereby providing a novel approach for continuous assessment of signal quality and early identification of sensing abnormalities.

2. Material and Methods

2.1. Study population

The data analyzed in this study were provided by Boston Scientific International S.A through its proprietary internal database. The UNTOUCHED study was a large, multicentre, prospective trial designed to evaluate the performance of S-ICD in primary prevention patients with reduced left ventricular ejection fraction (LVEF) and New York Heart Association (NYHA) functional class II or III, or coronary artery disease. A total of 1116 patients were enrolled in the trial [1].

For the present analysis, a representative subset comprising 329 S-ICD devices was selected from the overall UNTOUCHED cohort. The selected records predominantly reflected normal device operation and were used to evaluate the proposed signal-quality assessment method based on device-derived diagnostic data. Specifically, the analysis focused on fast-rate counter behaviour associated with heart-rate detection to characterize sensing quality over time and establish quantitative thresholds for identifying low-quality sensing characteristics. Table 1 summarizes the baseline characteristics of the UNTOUCHED study population.

2.2. Data acquisition

This study analyzed device-derived heart-rate calculations and associated diagnostic counters recorded by the S-ICD. Heart rate is calculated from the average of four consecutive valid R–R intervals (the time between successive R-wave detections) [4]. Prior to heart-rate estimation, each sensed event is processed by proprietary sensing algorithms designed to reject noise, T-wave oversensing, and other nonphysiological detections. Only events classified as valid ventricular depolarizations are included in the heart-rate calculation.

In addition to rhythm and therapy information, the S-ICD stores internal diagnostic counters that reflect the evolution of the sensing process. Among these, the transition to the tachycardia therapy profile (TTP) indicates that the detected heart rate has entered a programmed therapy zone and satisfies the device criteria for tachyarrhythmia evaluation. Depending on device programming, therapy assessment is performed using one or two detection zones: a conditional shock zone, in which both heart-rate and morphology discrimination algorithms are applied, and a shock zone, in which therapy decisions are based exclusively on heart-rate criteria.

Table 1. Baseline Patient Characteristics of the UNTOUCHED study [5]

Variable	Mean ± SD or n/N (%)
Patients, N	1116
Age (y)	55.8±12.4
Women, N (%)	286/1116 (25.6)
Black, N (%)	239/1020 (23.4)
Height, in	(N=1095) 67.9±4.3
BMI, kg/m^2	(N=1093) 30.2±7.3
Previous MI, N (%)	453/1099 (41.2)
Previous valve surgery	36/1114 (3.2)
History of AF, N (%)	142/1116 (12.7)
Ischemic cause, N (%)	570/1065 (53.5)
LVEF, %	26.4±5.8
NYHA class II/III, N (%)	888/1013 (87.7)
High Blood Pressure, N (%)	787/1116 (70.5)
Diabetes, N (%)	364/1116 (32.6)
Kidney disease, N (%)	160/1116 (14.3)

SD: standard deviation; BMI: body mass index; MI: myocardial infarction; AF: atrial fibrillation; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association.

Device data can be retrieved either during in-clinic programmer interrogation or through the remote monitoring system, which securely transmits diagnostic information to a central server for clinician review. The diagnostic counter analyzed in this study is an internal device parameter stored in device memory and accessible through the manufacturer's technical services.

2.3. Analysis of signal quality through TTP via Smoothed Average

During normal sinus rhythm, transitions to the TTP are not expected. In contrast, spontaneous ventricular tachyarrhythmias typically produce a limited number of sustained TTP transitions preceding therapy delivery. However, impaired sensing caused by low signal quality, such as a reduced R-wave-to-T-wave ratio, myopotential oversensing [5], or mechanical artifacts associated with the sensing system [6], may result in irregular and intermittent TTP transitions, increasing the risk of inappropriate therapy.

Because TTP values are acquired at irregular intervals determined by the remote monitoring follow-up schedule, an exponential smoothing filter was applied to reduce short-term variability and emphasize longer-term trends. The smoothed TTP (TTP_{SM}) is defined by

$$TTP_{SM}(i) = \propto \cdot TTP(i) + (1-\propto) \cdot TTP_{SM}(i-1) \quad (1)$$

where α (0 < α <1) determines the degree of temporal smoothing (α set to 0.25 for this study analysis). The performance of the proposed method for detecting low signal quality was evaluated using predefined thresholds. All episodes exceeding the established thresholds were independently reviewed by an experienced technical specialist and compared with expert adjudication to identify sensing abnormalities. The threshold was established as 3.5 TTP based on internal data analysis from the development of the algorithm and not modified during this study.

3. Results and Discussion

A total of 329 device records were reviewed, of which 318 (96.66%) met the inclusion criteria. Mean device follow-up was 1554 ± 102 days (approximately 4.25 years), providing a representative longitudinal assessment of sensing performance.

The proposed method classified device records into four categories: true positive (TP), true negative (TN), false positive (FP), and false negative (FN). Table 2 summarizes the distribution of analyzed records and the corresponding mean smoothed transition-to-tachycardia profile (TTP_{SM}). Records classified as TP or FP had substantially higher TTP_{SM} values than TN records, indicating that increased fast-rate counter activity is associated with impaired sensing conditions.

Pairwise comparisons showed significant differences between the TP and TN groups ($p < 0.01$), as well as between the TN group and both the FP and FN groups ($p < 0.01$). No statistically significant differences were observed between TP and FP, TP and FN, or FP and FN. These findings suggest that episodes associated with impaired sensing exhibit similar fast-rate counter dynamics regardless of their final classification, whereas normal sensing behaviour is clearly distinguishable.

Table 2. Distribution of analysed device records and mean TTP_{SM}.

Group	N (%)	Mean TTP_{SM}
True Positive (TP)	27 (8.49%)	10.51
True Negative (TN)	211 (66.35%)	0.23
False Positive (FP)	75 (23.58%)	12.50
False Negative (FN)	5 (1.57%)	2.46

To further characterize signal behaviour, higher-order statistical descriptors, including kurtosis, were evaluated. Figure 1 illustrates representative examples of TTP distributions under normal sensing conditions and during oversensing caused by T-wave detection. Normal sensing was characterized by stable TTP behaviour with low variability, whereas low signal quality produced broader distributions and increased dispersion, reflecting unstable sensing performance. These observations support the hypothesis that the temporal dynamics of TTP provide additional information beyond simple event counts for identifying sensing abnormalities.

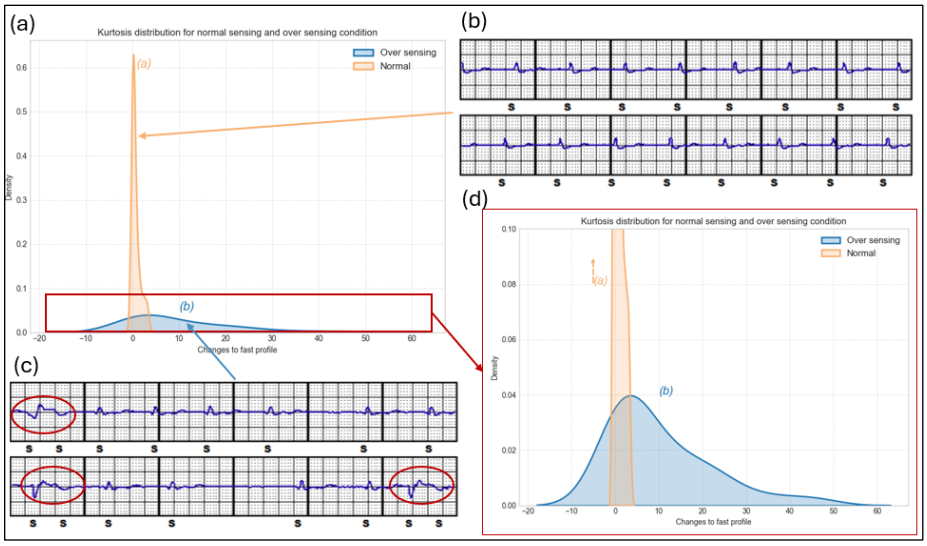

Figure 1 – Example of distribution of TTP kurtosis throughout device follow-up: (a) comparison of two representative devices; (b) device with normal sensing; (c) device with oversensing (red circles indicate T-wave oversensing); and (d) enlarged view of the oversensing distribution.

The proposed method achieved a sensitivity of 84.38%, a specificity of 73.78%, and a negative predictive value of 97.69% for detecting low signal quality. Although 75 records (23.58%) were classified as false positives, the high negative predictive value suggests that the method reliably identifies devices without evidence of sensing degradation.

Analysis of the false-positive cases identified prolonged intervals between successive remote monitoring transmissions as an important source of error. Because TTP values accumulate between device interrogations, long transmission gaps may artificially increase the smoothed counter despite the absence of clinically relevant sensing abnormalities. Additional false-positive cases were associated with atrial tachyarrhythmias, particularly atrial fibrillation, which may increase fast-rate counter activity without reflecting reduced sensing quality. Additionally, future research will evaluate transmission frequency and incorporate device reprogramming interventions into the analysis.

Future work will focus on normalizing TTP values by the elapsed time between consecutive interrogations or implementing adaptive counter-reset strategies to compensate for prolonged transmission intervals. Incorporating clinical variables, including atrial arrhythmia burden, may further improve specificity while preserving sensitivity for detecting sensing degradation. Inclusion of additional data may enhance the ability to identify and characterize potential system integrity issues.

4. Conclusions

This study suggests that device-derived fast-rate counter data obtained through remote monitoring can be used to characterize S-ICD sensing performance without requiring storage of electrogram signals. Significant differences in TTP dynamics were observed between records with normal sensing and those associated with low signal quality, supporting the use of this parameter as a surrogate marker of sensing integrity. The high negative predictive value indicates potential utility as a tool for monitoring signal quality and identifying patients unlikely to have sensing abnormalities.

Early identification of sensing degradation may facilitate timely device assessment and optimization before inappropriate therapies occur, potentially improving patient management and reducing unnecessary interventions. Although the method was evaluated in a cohort composed predominantly of devices with normal sensing performance, the results support its feasibility as a remote monitoring tool. Future work will focus on validating the approach in larger and more diverse patient populations, incorporating normalization for prolonged intervals between device interrogations, implementing adaptive counter-reset strategies, and integrating clinical variables, such as atrial arrhythmia burden, to further improve specificity while maintaining high sensitivity for detecting sensing degradation.

Acknowledgments

This study was supported by Boston Scientific as a provider of the data reviewed.

Research supported in part by the Secretaria d'Universitats i Recerca de la Generalitat de Catalunya GRC 2021 SGR 01390, and in part by the Spanish Ministry of Science and Innovation (PID2021-126455OB-I00 MCIN/AEI/FEDER).

References

[1] M. Gold *et al*., "Primary results from the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) trial," *Circulation*, vol. 143, no. 1, pp 7-17, 2021, doi:10.1161/CIRCULATIONAHA.120.048728.

[2] M. J. Juntilla, L. T. A. Holmström, and H.V. Huikuri, "Sudden cardiac death – Progress in epidemiology limited by time", *Heart Rhythm*, vol.20, no. 11, pp. 1510-1511, doi:10.1016/j.hrthm.2023.08.024.

[3] R. Weiss, B. P. Knight, M. R. Gold, A. R. Leon, J. M. Herre, M. Hood, M. Rashtian, M. Kremers, I. Crozier, K. L. Lee, W. Smith, and M. C. Burke, "Safety and efficacy of a totally subcutaneous implantable cardioverter-defibrillator," *Circulation*, vol. 128, no. 9, pp. 944–953, Aug. 2013, doi: 10.1161/CIRCULATIONAHA.113.003042.

[4] A. Brisben, "How the S-ICD (Subcutaneous implantadble cardioverter-defibrillator) sense cardiac signals to minimize cardiac over-sensing and maximize rhythm discrimination", *J. Electrocardio.*, vol.51, no.6. pp. S38-S43, doi: 10.1016/j.electrocard.2018.08.022.

[5] A. Corzani, M. Ziacchi, M. Biffi, I. Diemberger, C. Martignani, and G. Boriani, "Inappropriate shock for myopotential oversensing in a patient with a subcutaneous implantable cardioverter-defibrillator," *Indian Heart J.*, vol. 67, no. 2, pp. 197–199, Mar.–Apr. 2015, doi: 10.1016/j.ihj.2015.01.001.

[6] L. O'Neill, K. Gillis, J.-Y. Wielandts, G. Hilfiker, S. Knecht, M. Duytschaever, R. Tavernier, and J.-B. Le Polain De Waroux, "Flatline on the alternate vector: Is this subcutaneous implantable cardiac defibrillator lead fractured?," HeartRhythm Case Rep., vol. 7, no. 11, pp. 758–761, 2021, doi: 10.1016/j.hrcr.2021.08.008

Address for correspondence:

David Montilla Garcia
Boston Scientific Ibérica S.A., Calle Ribera del Loira 46, Edificio 2 planta baja, 28042 Madrid (Spain).
david.montillagarcia@bsci.com