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DEVICES

Device programing and SMART pass algorithm activation in subcutaneous implantable defibrillator patients: Data from a remote monitoring database

Saverio Iacopino MD[1] | Ezio Santobuono MD[2] | Claudia Amellone MD[3] | Antonio Rapacciuolo MD[4] | Carlo Lavalle MD[5] | Carmelo La Greca MD[6] | Luca Santini MD[7] | Matteo Bertini MD[8] | Giovanni Statuto MD[1] | Mariolina Lovecchio MS[9] | Sergio Valsecchi PhD[9] | Vincenzo Tavoletta MD[10]

[1]Arrhythmology Department, Maria Cecilia Hospital, Ravenna, Italy

[2]Cardiology Unit Polyclinic of Bari, Department of Emergency and Organ Transplantation, University of Bari Aldo Moro, Bari, Italy

[3]Department of Cardiology, Martini-Maria Vittoria Hospital, ASL Città di Torino, Turin, Italy

[4]Department of Advanced Biomedical Sciences, Federico II University of Naples, Naples, Italy

[5]Policlinico Umberto I, University La Sapienza, Rome, Italy

[6]Department of Cardiology, Fondazione Poliambulanza, Brescia, Italy

[7]Department of Cardiology, "G.B. Grassi" Hospital, Rome, Italy

[8]Cardiology Unit, University of Ferrara, S. Anna University Hospital, Ferrara, Italy

[9]Rhythm Management Division, Boston Scientific, Milan, Italy

[10]Unità Operativa di Elettrofisiologia, Studio e Terapia delle Aritmie, Monaldi Hospital, Naples, Italy

Correspondence
Saverio Iacopino, MD, Electrophysiology Unit, GVM Care & Research, Maria Cecilia Hospital, Cotignola, Ravenna, Italy.
Email: siacopino@gvmnet.it

Abstract

Background: The programing of subcutaneous implantable cardioverter-defibrillators (S-ICD) in clinical practice has been little studied, as the activation status of the SMART Pass filter, which was implemented to reduce inappropriate shocks.

Purpose: We assessed device programing during follow-up and the rate of detected arrhythmias in consecutive S-ICD recipients.

Methods: We analyzed data from 670 S-ICD patients followed on the remote network at 17 Italian centers for a median of 31 months (25th–75th percentile: 16–51). The enhanced SMART Pass version, introduced in October 2022, was expected to reduce the unintentional deactivation rate.

Results: At the latest remote data transmission, the median conditional zone cut-off was set to 210 bpm (25th–75th percentile: 200–220), the shock zone cutoff was 250 bpm (25th–75th percentile: 240–250), and the SMART Pass was enabled in 586 (87%) patients. During follow-up, 194 automatic deactivation events were reported in 118 (18%) patients. Shocks were delivered in 129 (19%) patients, and untreated arrhythmias were recorded in 136 (20%) patients. The rate of shocks was lower when SMART Pass was enabled -0.12/patient-year (95% CI: 0.10–0.14) versus 0.20 (95% CI: 0.15–0.26) ($p = .002$), as it was the rate of untreated arrhythmias -0.12/patient-year (95% CI: 0.11–0.14) versus 0.23 (95% CI: 0.18–0.30) ($p = .001$). The enhanced SMART Pass version was associated with a lower rate of deactivations -0.04/patient-year (95% CI: 0.02–0.05) versus 0.14 (95% CI: 0.12–0.16) ($p < .001$), and with a reduction in treated and untreated arrhythmias (Incidence rate ratios: 0.40 (95% CI: 0.28–0.53) and 0.40 (95% CI: 0.30–0.55), respectively ($p < .001$)).

Conclusions: Centers tend to program devices to detect high ventricular rates for arrhythmia detection, to minimize inappropriate shock occurrences. SMART Pass activation is associated with lower rates of detected and treated arrhythmias. The

ABBREVIATIONS: ICD, implantable cardioverter-defibrillator; S-ICD, subcutaneous implantable cardioverter-defibrillator.

enhanced SMART Pass version seems associated with a lower deactivation rate and with a further decrease in treated arrhythmias.

KEYWORDS
implantable defibrillator, inappropriate shock, programing, subcutaneous, sudden cardiac death, ventricular arrhythmia

1 | INTRODUCTION

Randomized trials,[1,2] observational studies,[3,4] and meta-analyses[5] have consistently demonstrated that the subcutaneous implantable cardioverter-defibrillator (S-ICD) is at least as effective and safe as the transvenous ICD in preventing sudden cardiac death over extended periods. The S-ICD's performance has seen improvement over the years, owing to advancements in device programing strategies[6,7] and to the progression of its filtering algorithms. The SMART Pass algorithm, a high-pass filter, aims to diminish cardiac signal oversensing by elevating the R:T ratio. Its effectiveness in reducing inappropriate therapies, while preserving appropriate ones, has been validated through blinded evaluation of remote monitoring system data[8] and prospective study.[7] The algorithm incorporates an automatic disable feature to mitigate ventricular fibrillation undersensing, which requires an in-clinic device interrogation for reactivation. An upgraded version of the SMART Pass, introduced in October 2022 for both new and existing EMBLEM S-ICD device recipients (Boston Scientific Inc., Natick, MA, USA), aims to refine the algorithm's disable function. This version is designed to reduce deactivation incidents. The adoption rate of proposed programing approaches in real-world clinical settings remains underexplored, as does the monitoring of the SMART Pass filter's activation status during follow-up. In this study, we evaluated the programing of S-ICDs and the incidence of detected events among a consecutive cohort of S-ICD recipients. Additionally, we examined the correlation between the status of the SMART Pass filter during follow-up and the frequency of detected arrhythmic events.

2 | METHODS

Data for this study were sourced from implanted S-ICD devices that transmit information via the LATITUDE remote monitoring system. In September 2023, we accessed the LATITUDE database to collect data on all S-ICD devices continuously monitored across 17 Italian centers, with a median period from implantation to the last data transmission of 31 months (25th–75th percentile: 16–51 months). The acquired de-identified patient data encompassed the status of arrhythmia detection, therapy parameters at the last transmission, details of each administered shock, and untreated arrhythmias. An episode is defined as "untreated arrhythmia" when therapy delivery is aborted, due to detection of arrhythmia termination criteria after capacitor charging. Additionally, we collected all instances of SMART Pass deactivation. The disable feature of the algorithm becomes active in the presence of a low-amplitude QRS complex. Previously, the algorithm assessed the amplitude and interval of each set of five consecutive beats. If all five beats exhibited low amplitude and two of the five intervals were long, the algorithm would deactivate SMART Pass. In October 2022, the algorithm underwent modification to necessitate seven contiguous low-amplitude measurements instead of five. As a result, the prolonged intervals resulting from undersensed beats following a premature ventricular contraction or amplitude decrease are essentially disregarded. Consequently, SMART Pass remains enabled, allowing normal sensing to continue. This version is designed to be less responsive to premature ventricular contractions or transient amplitude fluctuations while upholding its sensitivity and specificity to arrhythmias, with the anticipated outcome of reducing deactivation incidents.

Descriptive statistics are presented as medians with the interquartile range (25th–75th percentile), while categorical variables are expressed as percentages. Time-to-event analysis utilized the Kaplan–Meier method, with the log-rank test employed to discern trend differences. Event rates were computed both during SMART Pass-enabled and disabled periods, represented as events per patient-year by calculating the ratio between the event counts during these phases and their respective follow-up durations. We further segmented the data based on the periods before and after the SMART Pass algorithm upgrade in October 2022. A p-value $< .05$ was considered significant for all tests. All statistical analyses were performed by means of R: a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria).

3 | RESULTS

Table 1 presents the S-ICD programing details from the latest remote data transmission. In the 670 devices in analysis, the median programmed conditional zone cut-off was set to 210 bpm (25th–75th percentile: 200–220), and the shock zone cut-off was 250 bpm (25th–75th percentile: 240–250). A standard shock polarity was set for 90% of the patients. Of the total, 586 patients (87%) had SMART Pass enabled. During the follow-up, 194 automatic deactivation events were logged, translating to a rate of 0.10 events/patient-year, affecting 118 patients (18%). Figure 1 showcases the time to the first automatic deactivation. Notably, the SMART Pass was inactive for 13% of the overall observation period. Shocks were administered to 129 patients (19%), leading to an incidence rate of 0.13 events/patient-year, while untreated arrhythmias were observed in 136 patients (20%), with an

TABLE 1 Device programing at last transmission.

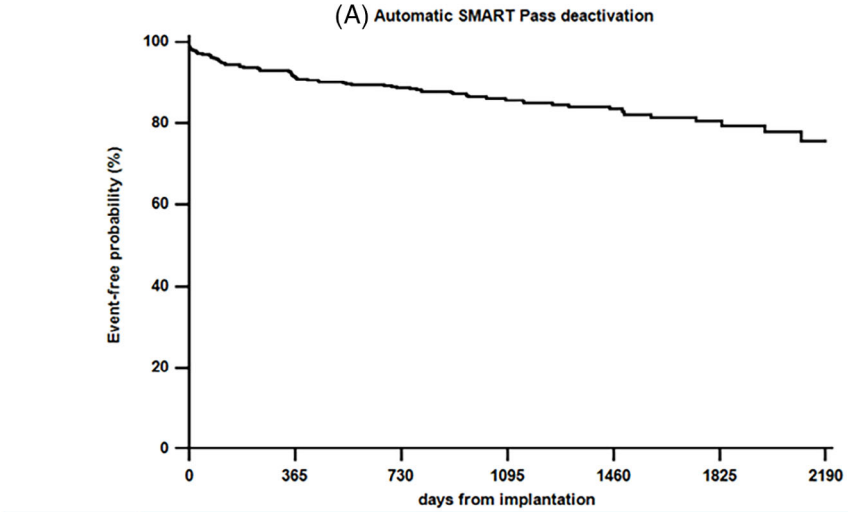
	All patients ($n = 670$)
Conditional zone cut-off rate (beats/min)	210 (200–220)
Shock zone cut-off rate (beats/min)	250 (240–250)
Gain 1 ×, *n* (%)	605 (90)
Sensing vector:	
Primary, *n* (%)	368 (55)
Secondary, *n* (%)	258 (39)
Alternate, *n* (%)	44 (7)
Smart charge delay > 0 s, *n* (%)	156 (23%)
Smart charge delay, s	2.1 ± 1.4
Standard shock polarity, *n* (%)	603 (90)
Post-shock pacing, *n* (%)	656 (98)
SMART Pass ON at last transmission, *n* (%)	586 (87)
Rate of shocks, $p = .002$	
SMART Pass Disabled, events/patient-year	0.20 (95% CI: 0.15–0.26)
SMART Pass Enabled, events/patient-year	0.12 (95% CI: 0.10–0.14)
Rate of untreated arrhythmias, $p = .001$	
SMART Pass Disabled, events/patient-year	0.23 (95% CI: 0.18–0.30)
SMART Pass Enabled, events/patient-year	0.12 (95% CI: 0.11–0.14)
Rate of deactivations, $p < .001$	
Original SMART Pass, events/patient-year	0.14 (95% CI: 0.12–0.16)
Enhanced SMART Pass, events/patient-year	0.04 (95% CI: 0.02–0.05)
Incidence rate ratio (Enhanced versus Original SMART Pass), $p < .001$	
Shocks	0.40 (95% CI: 0.28–0.53)
Untreated arrhythmias	0.40 (95% CI: 0.30–0.55)

Note: Device programming at last transmission. Detected arrhythmias and SMART Pass deactivation recordings during follow-up.

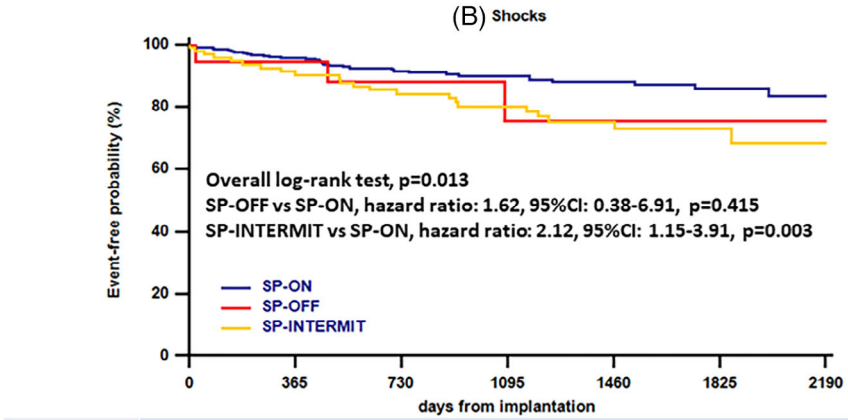
incidence rate of 0.14 events/patient-year. Figure 1 further shows the time to the first treated and untreated arrhythmias, categorizing patients based on their SMART Pass activation status: consistently ON (526 patients, 78%), consistently OFF (26 patients, 4%), and intermittently activated (118 patients, 18%). As detailed in Table 1, both the shock and untreated arrhythmia incidence rates were significantly lower during periods when SMART Pass was active. Additionally, upon comparing the data before and after the enhanced SMART Pass filter's introduction, we observed a marked decrease in deactivation rates and a significant reduction in both shocks and untreated arrhythmias.

4 | DISCUSSION

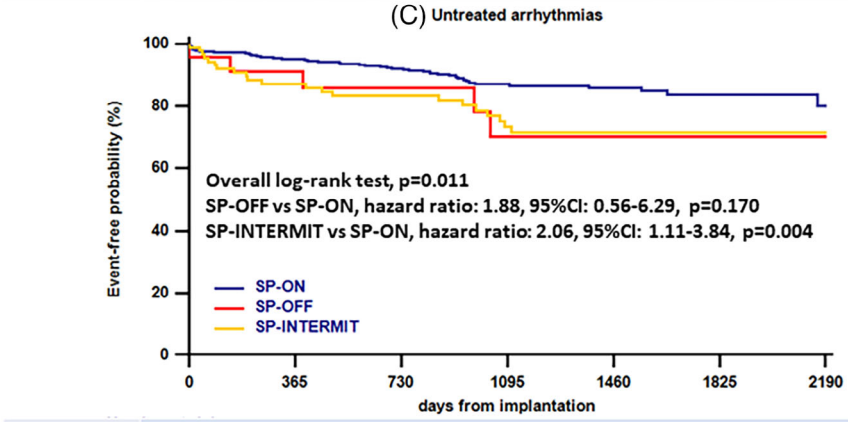
In this analysis of S-ICD patients using a remote monitoring database, we observed that centers tend to program devices to detect high ventricular rates for arrhythmia detection.[7] This approach aims to minimize inappropriate shock occurrences. An analysis from the S-ICD Clinical Investigation (IDE Trial) indicated that adding a second shock zone with an active discrimination algorithm led to a notable reduction in inappropriate shocks.[6] Subsequently, the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) Trial authors advocated for standardized programing, recommending discrimination algorithms be active between 200 and 250 bpm. This approach was shown to decrease the incidence of inappropriate shocks.[7] Recent clinical studies further affirmed the efficacy of the UNTOUCHED programing in curbing inappropriate shocks without compromising therapy effectiveness.[9] Our findings showed that this programing strategy is widely adopted in current clinical practice. We also showed that standard shock polarity was frequently programmed. However, 10% of the patients had the reverse shock polarity set as their primary therapy. This observation, combined with the device's ability to automatically adjust polarity for subsequent shocks upon a conversion failure, underscores the critical nature of this parameter's programmability in ensuring therapy efficacy.[10] In addition, we observed that SMART Pass was activated for the majority (87%) of patients at the latest remote data transmission. Instances of automatic filter deactivation affected 18% of patients at an incidence rate of 0.10 events/patient-year. These deactivation events cumulatively accounted for 13% of the total follow-up duration. It is essential to note that our analysis exclusively relied on data from the remote monitoring system. Consequently, factors contributing to SMART Pass deactivation remain unexplored in this study. However, prior research has linked SMART Pass deactivation primarily to low or inconsistent R-wave amplitude, with a higher prevalence observed in patients with arrhythmogenic right ventricular cardiomyopathy.[11] That single-center study revealed an increased incidence of inappropriate therapies among patients with SMART Pass deactivation during their follow-ups. The authors additionally outlined a management strategy for automatic SMART Pass deactivation. This strategy involves initially reprograming the sensing vector. If the algorithm fails to sustain activation, a lead repositioning procedure is recommended to mitigate inappropriate shocks.[12,13] Our findings further corroborate that SMART Pass deactivation correlates with elevated rates of delivered therapies and arrhythmias detected by the S-ICD. This association is evident both in terms of patient proportions experiencing arrhythmic events and the event incidence rates under different algorithm activation conditions. The evaluation of a possible association between delivered therapies and the patient's clinical outcomes warrants further investigation. Indeed, our analysis lacks data on clinical outcomes and baseline clinical characteristics necessary for correcting any potential biases and for exploring factors contributing to SMART Pass deactivation. An additional limitation of our analysis is the absence of electrogram reviews to validate precise S-ICD rhythm discrimination. Consequently, we could not discern between appropriate and inappropriate therapy occurrences. Nevertheless, prior studies have highlighted SMART Pass's capability to selectively diminish inappropriate therapies while preserving therapeutic efficacy.[7,8,11] Hence, we infer that the lower incidence rate



N. at risk	644	470	345	211	145	71	23



N. at risk							
SP-ON	526	378	268	162	109	52	15
SP-OFF	26	15	13	6	3	3	2
SP-INTERMIT	118	82	65	50	36	18	4



N. at risk							
SP-ON	526	375	270	158	110	55	17
SP-OFF	26	18	16	8	6	4	3
SP-INTERMIT	118	72	57	40	25	12	4

FIGURE 1 Kaplan–Meier estimates of time to first automatic SMART Pass deactivation (A); time to first shock (B); time to first untreated arrhythmia (C). SP-ON: SMART Pass consistently ON, SP-OFF: SMART Pass consistently OFF, SP-INTERMIT: SMART Pass intermittently activated. [Color figure can be viewed at wileyonlinelibrary.com]

observed during SMART Pass-active phases predominantly stems from the reduction of inappropriate therapies. However, this conclusion requires additional evaluations to confirm it. Lastly, our findings highlight a novel insight: the enhanced SMART Pass version significantly reduced deactivation rates in real-world clinical settings, dropping from 0.14 to 0.04 events/patient-year. In our cohort this resulted in a marked decrease in delivered shocks and untreated arrhythmias. Overall, these results signify a further improvement in the performance of current S-ICDs in clinical setting.

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CONFLICT OF INTEREST STATEMENT

M.L. and S.V. are employees of Boston Scientific. The other authors report no conflicts.

DATA AVAILABILITY STATEMENT

The experimental data used to support the findings of this study are available from the corresponding author upon request.

ORCID

Carlo Lavalle MD https://orcid.org/0000-0002-0794-4296
Luca Santini MD https://orcid.org/0000-0001-9048-2039
Matteo Bertini MD https://orcid.org/0000-0002-5285-7140
Giovanni Statuto MD https://orcid.org/0000-0002-6570-6974

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