

Implantable Cardioverter Defibrillator and Inappropriate Therapy: “Black Box” Examination Yielded Both Human and Technical Causes

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ABSTRACT: We report on a 70-year-old male patient who was recipient of GEM III DR 7275 Cardioverter Defibrillator, and who presented with inappropriate shocks. The patient had a documented slow ventricular tachycardia (VT), and the device was programmed to detect VT at rates >100 bpm, fast VT (FVT, via VT) at rates >150 bpm, and ventricular fibrillation (VF) at rates >188 bpm. After detection of FVT, efficient therapy was delivered; however, this was immediately followed by multiple inappropriate therapies. Inappropriate therapies were discussed, with a focus on programming features.

KEYWORDS: inappropriate shock, implantable defibrillator, black box, technical, human, cause

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Introduction

Inappropriate therapy (IT) remains a significant source of morbidity and mortality in implantable cardioverter defibrillator (ICD) recipients.^{1,2} Moreover, the occurrence of slow ventricular tachycardia (VT) leads physicians to program a detection zone with lower rates, exposing a patient to the risk of IT. The PR Logic™ is the conventional algorithm behind Medtronic ICD devices (Medtronic, Inc, Minneapolis, MN, USA) that allows for the discrimination of supra-VT from ventricular arrhythmias. Its main function is based on analysis of the rate, pattern, regularity, and atrioventricular (AV) dissociation.

Case Presentation

A 70-year-old male patient was the recipient of the Medtronic Gem III DR 7275 ICD (Medtronic, Inc) implanted in 2006. He presented with three repetitive shocks after moderate physical exercise. He had an ischemic cardiomyopathy and was treated with amiodarone and beta-blockers. The patient record showed a previous slow VT (at ~115 bpm), for which

overdrive pacing was efficient; accordingly, programming was “too valiant” and was performed to detect slow VT at rates >100 bpm, fast VT (FVT) >150 bpm (via VT), and ventricular fibrillation (VF) >188 bpm (Fig. 1). Of note, the only therapy in the VT zone was antitachycardia pacing (ATP). Device interrogation showed an initial FVT episode (cycle length of ~380 ms), which was efficiently treated with ATP (burst), followed by five ITs, including three shocks during the redetection phase (Fig. 2). After the last shock, therapy was exhausted and the episode was regarded as persistent for more than 1 hour, until the heart rate slowed down below 100 bpm.

Discussion

The “unfolding” and analysis of the device’s “black box” explained what happened: there was both a technical and a human cause or “error.” Initially, and during moderate exercise, there was a sinus tachycardia (ST) (cycle length ~570 ms), which was well detected by the PR Logic™; then, FVT (TF) was detected and efficiently treated with ATP



Parameter settings

VF	On	320 ms (188 bpm)
FVT	Via VT	400 ms (150 bpm)
VT	On	600 ms (100 bpm)

NID	NID
initial	redetect

VF	18/24	12/16
VT	16	12

Dual chamber SVT criteria

AFib/AFlutter	On
Sinus tach	On
1:1 VT-ST boundary	50%
Other 1:1 SVTs	Off
SVT limit	320 ms

Ventricular SVT criteria

VT stability	40 ms
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Figure 1. Initial ventricular arrhythmia detection parameters, with SVT criteria as shown.

(burst) (Figs. 3A and 3B). Thereafter, the redetection phase was initiated, and the strips showed that the patient was in ST with an average cycle length of 570 ms. Nevertheless, the markers showed that the device detected FVT (TF), and continued to successively deliver therapies (ramp, ramp+) (Figs. 4A and 4B). Then, three successive shocks were administered (Figs. 5A and 5B).

The PR Logic™ algorithm was efficient and could classify the initial rhythm as ST; nevertheless, in the redetection phase, the ST was classified as FVT. This is “normal” behavior for the device during redetection, and it can be explained by two phenomena: 1) the PR Logic™ is not

functional in the redetection phase, and so ST was detected as VT; and 2) ZONE MERGING resulted, whereby VT was considered and treated as FVT. Zone Merging is a feature in Medtronic ICD which is functional during redetection, it allows to merge a VT to a FVT zone (when FVT is programmed via VT) or a FVT to a VF zone (when FVT is programmed via VF); the objective is to compel a more aggressive therapy during re-detection for a maximum safety.

Supra-VT with 1:1 conduction, including ST, accounts for more than 60% of IT in ICD recipient patients.³ The PR Logic™ is efficient for discriminating supra-VT; however,

VT/VF episode #1876 report

ID#	Date/time	Type	V. cycle	Last Rx	Success	Duration
1876	Mar 23 11:18:01	FVT	380 ms	FVT Rx 6	No	>1 hr

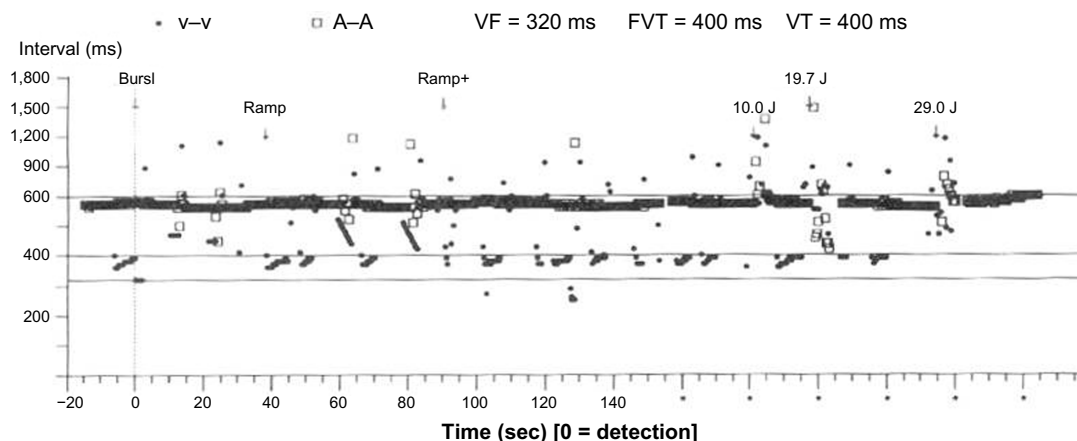


Figure 2. After first efficient therapy for FVT (burst), five inappropriate therapies occurred, including three shocks of 10.0 J, 19.7 J, and 29.9 J.

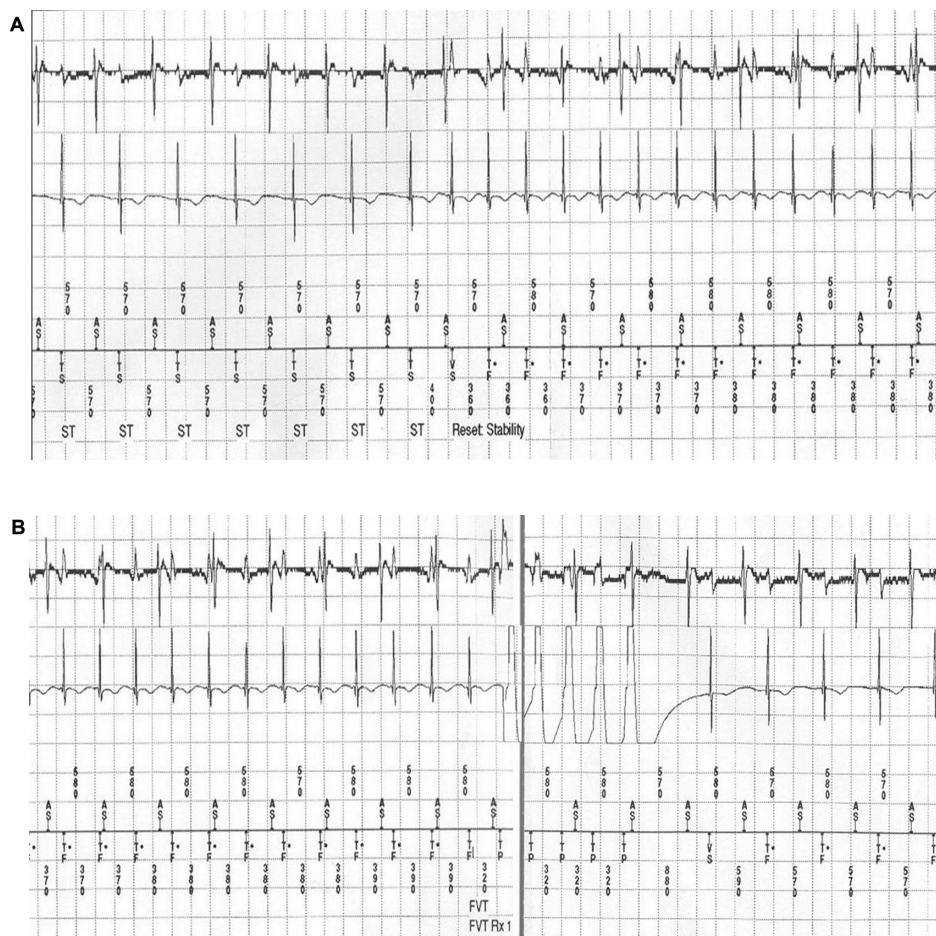


Figure 3. (A) Initial sinus tachycardia (CL 570 ms) was well detected; then, a VFT (CL ~370 ms) occurred. **(B)** ATP (burst) was efficient for FVT therapy; nevertheless, the posttherapy rhythm in sinus tachycardia (CL ~570 ms) is marked as FVT by the markers.

the algorithm is not functional during redetection, and this yielded a “logical” storm. Enhanced PR Logic™ adds wavelet (morphology) discrimination capabilities, and is available in the new generations of Medtronic the ICD devices (ie, Protecta™ DR);⁴ The Wavelet operation aims

to discriminate supra-VT from VT and it is based on initial collection of normal electrograms stored as template, then a matching operation occurs with electrograms collected during an event. However, wavelet operation is only functional during initial detection, supraventricular discrimination

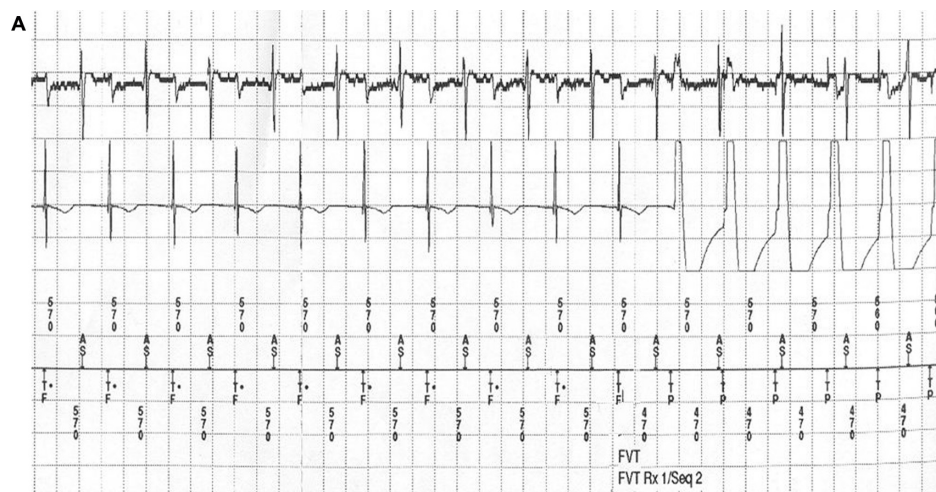


Figure 4 (Continued)

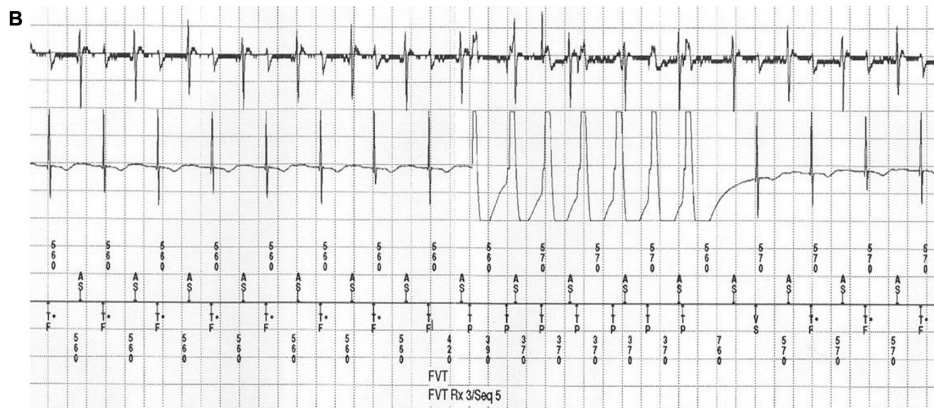


Figure 4. (A) ATP therapy delivered in sinus rhythm (CL ~570 ms). (B) Another sequence of ATP therapy is delivered in sinus rhythm (CL ~560 ms).

criteria in the redetection phase is still not available, and this is a primary concern that electrophysiologists have to deal with in patients with slow VT.

In this patient, avoidance of ST (such as through medical therapy and lifestyle changes) is of utmost importance; one can consider a rate-lowering agent like ivabradine in this context.⁵ Moreover, regular follow up and tailored programming are essential in decreasing the risk of IT (ie, through

programming the VT detection rate above 110 bpm with only ATP therapy in the slow VT zone, while keeping FVT via VT with an increase in the detection rate up to 166 bpm, along with an increase in the number of intervals to redetect ventricular arrhythmia [Re-NID]). However, if slow VT cannot be managed with medications and programming, one should consider VT ablation in this context. Slow VT is usually inducible with programmed ventricular stimulation

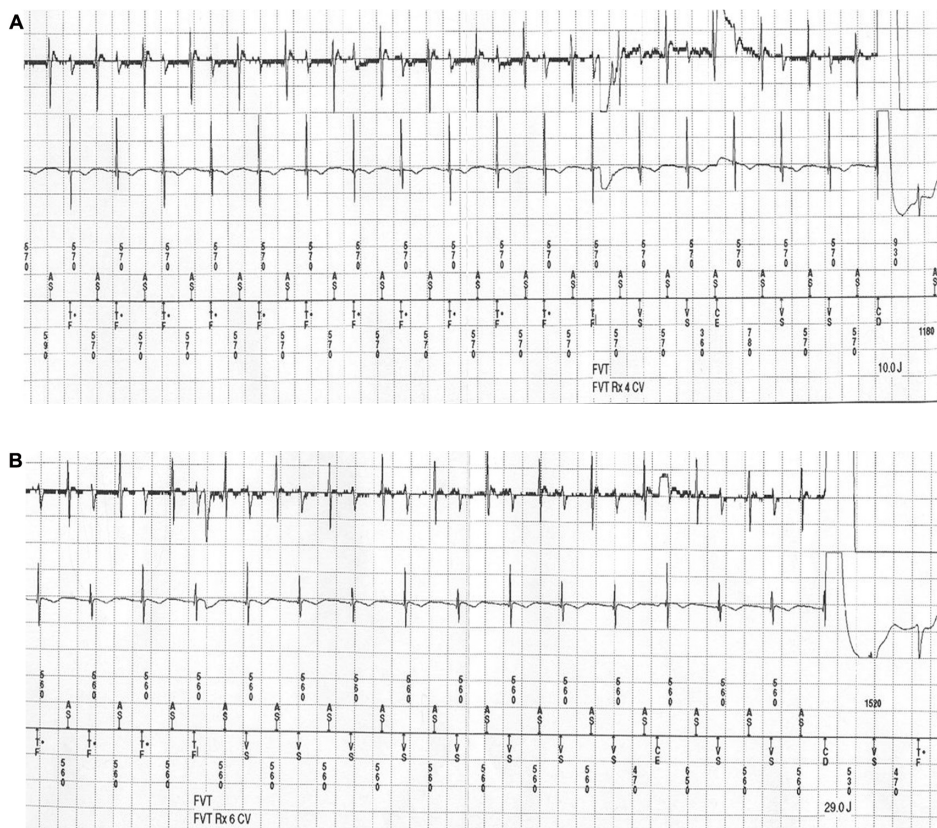


Figure 5. (A) A shock of 10 J is delivered for a sinus tachycardia (CL ~570 ms). (B) Another shock of 29.9 J is delivered for a sinus rhythm (CL ~560 ms).



allowing a satisfactory activation mapping yielding a relatively high success rate during ablation.

Conclusion

Programming very low VT detection rate, together with zone merging and non-functional PR Logic™ during the redetection phase were basically at the origin of the IT; reprogramming higher VT and FVT detection rates, along with longer re-NID, is useful for decreasing the risk of recurrent IT.

Author Contributions

Conceived and designed the experiments: AK. Analyzed the data: AK. Wrote the first draft of the manuscript: AK. Contributed to the writing of the manuscript: AK. Agree with manuscript results and conclusions: AK. Jointly developed the structure and arguments for the paper: AK. Made critical revisions and approved final version: AK. The Author reviewed and approved of the final manuscript.

DISCLOSURES AND ETHICS

As a requirement of publication the author has provided signed confirmation of compliance with ethical and legal obligations including but not limited to compliance with ICMJE authorship and competing interests guidelines, that the article is neither under consideration for publication nor published elsewhere, of their compliance with legal and ethical guidelines concerning human and animal research participants (if applicable), and that permission has been obtained for reproduction of any copyrighted material. This article was subject to blind, independent, expert peer review. The reviewers reported no competing interests.

FOOTNOTE

- A written consent was obtained from the patient to reproduce information or photographs appearing in this work.
- In this paper, we sought to perform a comprehensive analysis and to provide explanations regarding inappropriate shocks that occurred in an ICD recipient-patient. Inappropriate shocks are relatively common incidents occurring post ICD implantation, whatever is the ICD trademark. We concluded that a combination of algorithm configuration together with risky programming yielded such events. The author(s) do not imply -in any way- that inappropriate shocks were caused by a defect or failing function of the ICD; Moreover, and at all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in a particular situation.

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