Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results

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BACKGROUND The benefits of implantable cardioverter-defibrillators (ICDs) have been well demonstrated in many clinical trials, and ICD shocks for ventricular tachyarrhythmias save lives. However, inappropriate and unnecessary shock delivery remains a significant clinical issue with considerable consequences for patients and the healthcare system.

OBJECTIVE The purpose of the PainFree SmartShock Technology (SST) study was to investigate new-generation ICDs to reduce inappropriate and unnecessary shocks through novel discrimination algorithms with modern programming strategies.

METHODS This prospective, multicenter clinical trial enrolled 2790 patients with approved indication for ICD implantation (79% male, mean age 65 years; 69% primary prevention indication, 27% single-chamber ICD, 33% replacement or upgrade). Patients were followed for a minimum of 12 months, and mean follow-up was 22 months. The primary end-point of the study was the percentage of patients remaining free of inappropriate shocks at 1 year postimplant, analyzed separately for dual/triple-chamber ICDs (N = 2019) and single-chamber ICDs (N = 751).

RESULTS The inappropriate shock rate at 1 year was 1.5% for patients with dual/triple-chamber ICDs and 2.5% for patients with single-chamber devices. Two years postimplant, the inappropriate shock rate was 2.8% for patients with dual-/triple chamber ICDs and 3.7% for those with single-chamber ICDs. The most common cause of an inappropriate shock in both groups was atrial fibrillation or flutter.

CONCLUSION In a large patient cohort receiving ICDs for primary or secondary prevention, the adoption of novel enhanced detection algorithms in conjunction with routine implementation of modern programming strategies led to a very low inappropriate shock rate.

KEYWORDS Implantable cardioverter-defibrillator; Cardiac resynchronization therapy; Heart failure; Atrial fibrillation; Inappropriate shock

ABBREVIATIONS **AF** = atrial fibrillation; **ATP** = antitachycardia pacing; **CI** = confidence interval; **EGM** = electrogram; **ERC** = episode review committee; **HR** = hazard ratio; **ICD** = implantable cardioverter-defibrillator; **LVEF** = left ventricular ejection fraction; **NID** = number of intervals to detect; **RV** = right ventricle; **SST** = SmartShock Technology; **SVT** = supraventricular tachycardia; **VF** = ventricular fibrillation; **VT** = ventricular tachycardia

(Heart Rhythm 2015;12:926–936)

This study was funded by Medtronic Inc, Minneapolis, Minnesota. Dr. Auricchio is a consultant for Medtronic, Biotronik, Sorin, and Cordis Biologics Delivery Systems; and receives Speaker fees from Medtronic and Sorin. Dr. Schloss is a consultant for Medtronic and Boston Scientific; and receives Speaker fees from Medtronic. Dr. Kurita is a consultant for Medtronic, St. Jude Medical, and Boston Scientific; and receives Speaker fees from Medtronic and St. Jude Medical. Dr. Meijer receives fellowship support from, and is a consultant for, Medtronic. Mr. Gerritse is a Medtronic employee. Dr. Zweibel receives research grants from, and is a consultant for, Medtronic. Dr. Sterns is a consultant for Medtronic, Boston Scientific, and St. Jude Medical; and receives Speaker fees from Medtronic. This study is registered at www.clinicaltrials.gov No. NCT00982397. The full list of investigators and their institutions is given in Appendix A. **Address reprint requests and correspondence:** Dr. Angelo Auricchio, Fondazione Cardiocentro Ticino, Via Tesserete, 48CH-6900 Lugano, Switzerland. E-mail address: angelo.auricchio@cardiocentro.org.

Introduction

Implantable cardioverter-defibrillator (ICD) therapy is the standard of care for secondary prevention of sudden cardiac death and for primary prevention of cardiac arrest in appropriately selected patients with established risk.[1] Although ICD shocks are lifesaving in the case of sustained ventricular tachyarrhythmias, shocks can also be delivered unnecessarily for nonsustained episodes or inappropriately for supraventricular arrhythmias, nonarrhythmic noise, or artifacts.[2,3] These avoidable ICD shocks result in unnecessary hospital admissions and may have a negative impact on patient quality of life[4–6] as well as on morbidity and mortality.[7,8]

Although the reported frequency of ICD shocks varies according to patient population, device type, and specific ICD programming, a substantial proportion of patients consistently receive inappropriate shocks after ICD implantation. Recent studies have reported inappropriate shocks rates of up to 10%, but have largely excluded single-chamber devices that have been associated with inappropriate therapy rates between 14% and 27%.[9–12] Shock reduction strategies have included selective implantation of atrial leads for improved supraventricular tachycardia (SVT) diagnosis, widespread use of empiric antitachycardia pacing (ATP) for relatively rapid arrhythmias, strategic programming to delay ICD detection or treatment, and development of improved arrhythmia discrimination algorithms.

A strategy for reducing inappropriate shocks combining improved arrhythmia discrimination algorithms and longer detection times was previously evaluated through the use of archived patient electrograms and "virtual ICD" computer modeling.[13] In the PainFree SST (SmartShock Technology) study, we sought to prospectively validate the prediction that a novel suite of new detection algorithms in conjunction with routine implementation of a proven programming strategy would improve freedom from inappropriate shocks in a large and heterogeneous "real-world" population of ICD patients.

Methods

Study design

The study design of the PainFree SST trial has previously been described.[14] In brief, the PainFree SST study was a prospective, multicenter clinical trial conducted in 2 consecutive phases. All subjects were followed until study closure but not less than 1 year. Total study duration was 4 years, from September 2009 until August 2013. After implantation, subjects were required to have a follow-up visit every 6 months. Data were collected at the time of enrollment, at scheduled and unscheduled follow-up visits, and at study exit.

Study population

Patients were eligible for the study if they had a clinical indication for an ICD for either primary or secondary prevention of sudden cardiac death and intended to receive a single-chamber or, dual/triple-chamber Protecta device (Medtronic Inc, Minneapolis, MN). This included new implants, system upgrades, and generator replacements. Exclusion criteria included, among others, participation in another study that could confound results, life expectancy less than 12 months, or the presence of a mechanical tricuspid heart valve. The study was performed in compliance with the Declaration of Helsinki. The institutional review board of each participating center approved the study protocol, and all patients gave written informed consent.

Study end-points

The primary study end-point was the percentage of patients receiving at least 1 inappropriate shock at 12 months. Secondary end-points included the percentage of patients receiving any inappropriate device therapy (ie, shocks and/or overdrive pacing (ATP)) at 12 months, the causes of inappropriate shocks, the incidence of appropriate device therapy, and evaluation of any undertreatment of ventricular arrhythmias. All-cause mortality also was reported.

Algorithm description

SmartShock Technology consists of 6 discrimination algorithms that are activated by the device when rate-based arrhythmia detection criteria are met in order to distinguish between true ventricular arrhythmias and other rhythms. This technology has demonstrated clinical safety and ventricular fibrillation (VF) detection efficacy and sensitivity.[15] Detailed descriptions of the new and updated algorithms can be found elsewhere.[14] (1) Wavelet morphology algorithms were integrated with atrioventricular timing discrimination (PR Logic) in dual/triple-chamber ICDs to help differentiate ventricular tachycardia (VT) from SVT based on QRS morphology. This discrimination applies to all VT with rates slower than a programmable limiting rate (SVT Limit). (2) The nominal SVT Limit has been changed from 320 to 260 ms to allow SVT discriminators to withhold detection and therapy for atrial rhythms that are faster than the VF detection interval. (3) Confirmation+ improves recognition of VT/VF termination to prevent inappropriate shock by using confirmation intervals based on ventricular cycle length + 60 ms instead of the slowest programmed therapy zone. (4) T-Wave Oversensing algorithm withholds detection and therapy when T-wave oversensing is occurring based on information from the sensing channel and a parallel signal path that attenuates lower-frequency signals such as T-waves while minimally attenuating R waves. (5) Lead Noise Discrimination algorithm discriminates sensed rhythms that are due to lead noise from those due to VT/VF and provides the ability to withhold therapy delivery. (6) RV Lead Integrity Alert provides early indication of potential lead fracture by an audible alert and automatically extends VF number of intervals to detect (NID) to 30/40 (if it was less).

Device programming

VF zones were programmed with a detection interval of 320 ms, and programming of a VT therapy zone was left up to the