Incidence of Delayed Conversion in Response to Atrial Therapy in a Multicenter Atrial Conversion Therapy ICD Trial

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Summary

Therapy of atrial tachyarrhythmia with an implantable cardioverter defibrillator (ICD) has been shown to be effective and beneficial for patients that already require implantable cardioverter therapy for ventricular tachyarrhythmias. Similar to ventricular therapy, atrial conversion can result in immediate and delayed conversion. However, it has been noted that the occurrence of delayed conversion after atrial therapy is higher. Data from a dual-chamber ICD study (TACT study) was analyzed to evaluate the incidence of delayed conversion in response to atrial therapy. The study involved 174 patients at 18 U.S. sites. They received the Tachos DR – Atrial Tx ICD in order to detect and convert atrial tachyarrhythmias in patients requiring standard ICD therapy, who also have a history or significant risk of developing atrial tachyarrhythmias. All induced or spontaneous atrial arrhythmia events that received antitachycardia pacing (ATP), high frequency (HF) burst, or atrial shock therapy resulting in cardioversion were reviewed to determine the incidence of immediate conversion (< 1.5 s following atrial therapy) or late termination (> 1.5 s following atrial therapy). From all episodes terminated by ATP, 30% were immediate conversions and 70% were late conversions, with the median time from therapy to late conversion being 8.4 s. Among episodes terminated by HF bursts, 33% were immediate conversions and 67% were late conversions, with a median time from therapy to conversion of 7.0 s. Nearly all (96%) successful atrial shocks were immediate conversions, while in 4% of cases the conversions occurred 1.9 s following the shock. This information must be considered when designing ICD algorithms for redetection and appropriate termination declaration of atrial tachyarrhythmia episodes.

Key Words

Implantable cardioverter/defibrillator (ICD), atrial tachyarrhythmia, delayed conversion

Introduction

Atrial tachyarrhythmias are the most common arrhythmia resulting in hospital admissions in the United States [1]. Although they are not considered immediately life-threatening, these arrhythmias contribute to a patient's morbidity and mortality by impairing cardiac function and increasing the risk of thromboembolic events [2,3]. Additionally, studies suggest that atrial tachyarrhythmias may facilitate the induction or perpetuation of ventricular tachyarrhythmias [4].

Implantable cardioverter defibrillators (ICDs) designed to automatically detect and treat both symptomatic as well as asymptomatic atrial tachyarrhythmias could

potentially benefit patients already requiring standard ICD therapy for ventricular tachyarrhythmias. Benefits include decreased use of those medications for atrial arrhythmia control having poorly-tolerated side effects [5,6]. Patients experiencing asymptomatic atrial tachyarrhythmias may benefit from early automatic intervention, because "electrical remodeling" of the cardiac muscle makes arrhythmia conversion at a later time more difficult [7-10]. Studies have shown that atrial therapies are effective for tachyarrhythmia converson; however, analysis of the termination response has not yet been undertaken [11].

The primary objective of our study was to evaluate the ability of a new dual-chamber, rate-adaptive ICD (Tachos DR – Atrial Tx, Biotronik, Germany) to detect and convert atrial tachyarrhythmias in patients requiring standard ICD therapy who also have a history or significant risk of developing atrial tachyarrhythmias. Additionally, all attempts resulting in atrial cardioversion were analyzed to determine the incidence of either immediate or delayed arrhythmia conversion following delivery of the therapy.

Therapy type	Function
ATP	Atrial burst or ramp delivered at programmable percentage of the AT cycle length. Back-up VOO pacing is available during ATP therapy.
HF Burst	Atrial pulse train at 40 Hz with programmable duration of 1 – 29 s. Back-up VOO pacing is available during HF burst therapy.
Shock	Atrial shock at programmable energies between 1 – 30 J. Atrial shocks are delivered within physician specified times only, using a 24-hour clock. The ICD reconfirms the AT/AF prior to shock delivery. A maximum of two atrial shocks are programmable for each episode.

Table 1. Atrial therapies available in the Tachos DR – Atrial Tx (Biotronik, Germany). AT = atrial tachycardia; AF = atrial fibrillation.

Therapy type	No. of patients	No. of episodes	No. of successful therapies	Success rate
ATP	29	142	63	44.4%
HF Burst	49	408	156	38.2%
Shock	42	108	84	77.1%
Any therapy	66	542	302	55.7%

Table 2. Atrial therapy success rate for spontaneous atrial fibrillation and atrial tachycardia episodes.

Materials and Methods

Device

The Tachos DR-Atrial TX ICD is capable of delivering antitachycardia pacing (ATP) as well as cardioversion and defibrillation shock therapy to convert ventricular tachyarrhythmias. Additionally, the ICD provides an advanced SVT/VT discrimination algorithm and rate-adaptive brady pacing. The device is capable of detecting and converting atrial tachyarrhythmias including atrial fibrillation (AF) and other atrial tachycardias (AT). Atrial tachyarrhythmia therapies include ATP therapy for AT, atrial burst therapy for AF/AT, and shock therapy for AF/AT (see Table 1). The device allows programming of one AF and two AT zones.

Study Population and Implantation Procedure

The Tachos Atrial Conversion Therapy (TACT) study was conducted with 174 patients enrolled at 18 U.S. sites. All patients had a clinical indication for the implantation of a ventricular ICD and a history or significant risk of developing atrial tachyarrhythmias. The average patient was a 68-year-old male with a NYHA class II, a left ventricular ejection fraction of 31%, and a monomorphic ventricular tachycardia as the primary ventricular tachycardia. Patients with atrial tachyarrhythmia refractory to cardioversion shock therapy were excluded from enrollment. The study was conducted under a US Food and Drug Administration (FDA) Investigational Device Exemption. Prior to enrollment, *Institutional Review Board* approval and written informed consent was obtained. The study required implantation of a dual-coil ICD lead. Atrial leads were bipolar and included both passive and active fixation mechanisms. A step-up atrial defibrillation threshold protocol was recommended but not required.

Study Design

The study included evaluation of the AT/AF detection sensitivity, which is the ability of the atrial detection algorithm to appropriately detect AT/AF. Additionally, the overall ability of the device to appropriately convert AT and AF using different therapies was evaluated. The analysis was based on the investigator's review of stored diagnostics from the implanted device. Patients received routine device interrogations at 1, 3, and 6 months after implantation, with additional visits

Therapy type	Arrhythmia cycle length range	Total	Type I	Type II	Median time of therapy to type II conversion (s)
ATP	320 – 165 ms	56	17 (30%)	39 (70%)	8.4 s
HF Burst	328 – 150 ms	141	46 (33%)	95 (67%)	7.0 s
Shock	350 – 125 ms	72	69 (96%)	3 (4%)	1.9 s

Table 3. Conversion type versus atrial therapy type.

as clinically indicated. The patient's quality of life was evaluated using a validated questionnaire at enrollment and at the 3-month follow-up [12]. All induced or spontaneous AT events that received ATP, high frequency (HF) burst, or atrial shock therapy resulting in cardioversion were reviewed to determine the incidence of Type I and Type II terminations. Atrial therapy that results in immediate arrhythmia conversion is classified as Type I conversion. Atrial therapy that results in atrial arrhythmia conversion more than 1.5 s following therapy is classified as a Type II conversion. Stored electrograms reviewed by study investigators were used for this analysis.

Results

Sixty-six patients received a total of 542 atrial therapy episodes. Table 2 provides an overview of the atrial therapy success rate of the different atrial therapies utilized. A total of 269 episodes of AT/AF successfully converted to sinus rhythm were reviewed. Each episode was analyzed with regards to cycle length, immediate (Type I) or delayed (Type II) conversion, and time of therapy to Type II conversion. Table 3 provides an overview of the conversion type occurrence in relation to the type of therapy. Nearly all (96%) successful atrial shocks were Type I conversions, while 70% of ATP conversions and 67% of HF burst conversions were Type II. In Type II conversions the mean time from ATP therapy to conversion was 8.4 s; the mean time from HF burst therapy to conversion was 7.0 s.

Discussion and Conclusion

Although atrial shock therapy is the most effective therapy for atrial tachyarrhythmia conversion, data from the study show that ATP and HF burst are almost 40% effective. Additionally, the data suggests that successful painless termination of AT via ATP and HF burst are predominantly Type II conversions, whereas cardioversion shocks are exclusively Type I. In contrast to conversion of VT/VF, atrial tachyarrhythmias are converted by atrial therapy with a type II response more frequently and with a larger delay (7 – 9 s versus 2 s) [13]. It may be argued that some of these AT/AF episodes may have terminated spontaneously after therapy. However, average conversion times seem very similar for both ATP and HF burst. This suggests a pattern in the conversion mechanism, possibly due to a sufficient disturbance of the tachyarrhythmia to cause termination. Despite this conversion delay, ATP and HF burst should be considered as the primary therapy attempts for conversion of atrial tachyarrhythmias. Additionally, this information must be considered when designing ICD redetection algorithms for atrial tachyarrhythmias, as well as for the appropriate termination declaration of atrial tachyarrhythmia episodes.

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