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Reduced Risk for Inappropriate Implantable Cardioverter-Defibrillator Shocks With Dual-Chamber Therapy Compared With Single-Chamber Therapy

Results of the Randomized OPTION Study

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ABSTRACT

OBJECTIVES The OPTION (Optimal Anti-Tachycardia Therapy in Implantable Cardioverter-Defibrillator Patients Without Pacing Indications) trial sought to compare long-term rates of inappropriate shocks, mortality, and morbidity between dual-chamber and single-chamber settings in implantable cardioverter-defibrillators (ICDs) patients.

BACKGROUND The use of dual-chamber ICDs potentially allows better discrimination of supraventricular arrhythmias and thereby reduces inappropriate shocks. However, it may lead to detrimental ventricular pacing.

METHODS This prospective multicenter, single-blinded trial enrolled 462 patients with de novo primary or secondary prevention indications for ICD placement and with left ventricular ejection fractions ≤40% despite optimal tolerated pharmacotherapy. All patients received atrial leads and dual-chamber defibrillators that were randomized to be programmed either with dual-chamber or single-chamber settings. In the dual-chamber setting arm, the PARAD+ algorithm, which differentiates supraventricular from ventricular arrhythmias, and SafeR mode, to minimize ventricular pacing, were activated. In the single-chamber setting arm, the acceleration, stability, and long cycle search discrimination criteria were activated, and pacing was set to VVI 40 beats/min. Ventricular tachycardia detection was required at rates between 170 and 200 beats/min, and ventricular fibrillation detection was activated above 200 beats/min.

RESULTS During a follow-up period of 27 months, the time to the first inappropriate shock was significantly longer in the dual-chamber setting arm ($p = 0.012$, log-rank test), and 4.3% of patients in the dual-chamber setting group compared with 10.3% in the single-chamber setting group experienced inappropriate shocks ($p = 0.015$). Rates of all-cause death or cardiovascular hospitalization were 20% for the dual-chamber setting group and 22.4% for the single-chamber setting group and satisfied the pre-defined margin for equivalence ($p < 0.001$).

CONCLUSIONS Therapy with dual-chamber settings for ICD discrimination combined with algorithms for minimizing ventricular pacing was associated with reduced risk for inappropriate shock compared with single-chamber settings, without increases in mortality and morbidity. (Optimal Anti-Tachycardia Therapy in Implantable Cardioverter-Defibrillator [ICD] Patients Without Pacing Indications [OPTION]; NCT00729703) (J Am Coll Cardiol HF 2014;2:611–9) © 2014 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

ATP = antitachycardia pacing

ICD = implantable cardioverter-defibrillator

SVT = supraventricular tachyarrhythmia

Implantable cardioverter-defibrillator (ICD) therapy prevents sudden cardiac death and prolongs survival in patients who undergo implantation for primary and secondary prevention of sudden cardiac death (1–4). The benefits of the therapy and the expansion of indications for ICDs since their introduction have led to a significant increase in the number of ICD recipients and in lives saved by ICD therapy (5).

However, inappropriate therapies, most commonly caused by supraventricular tachyarrhythmias (SVTs), remain a significant adverse effect of ICD therapy, affecting up to 40% of patients during long-term follow-up (6–10). Besides the pain and discomfort caused by inappropriate shocks, they are also associated with anxiety, depression, impaired quality of life, proarrhythmia, low treatment satisfaction, and possibly mortality (11–13).

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Important efforts have been made in defining optimal programming methods for accurate rhythm detection and minimizing inappropriate ICD interventions. However, so far, there is no consensus on the most appropriate programming methodology (14–17). Likewise, the question of whether dual-chamber ICD therapy with dual-chamber settings can reduce the risk for inappropriate shocks in comparison with single-chamber therapy with single-chamber settings remains unanswered. Several investigators have reported a trend toward fewer inappropriate shocks with dual-chamber setting (18), whereas others have reported no differences between the therapies (19–22). Moreover, additional factors should be considered when choosing single- versus dual-chamber ICD settings, including the risk for complications (23), as well as the detrimental effect of unnecessary ventricular pacing (24). Therefore, the potential superiority of dual-chamber over single-chamber ICD settings in terms of inappropriate shocks can be assessed only in the light of optimal tachyarrhythmia discrimination algorithms combined with optimized bradycardia parameters for minimized ventricular pacing (25).

The OPTION (Optimal Anti-Tachycardia Therapy in Implantable Cardioverter-Defibrillator Patients Without Pacing Indications) trial was designed to compare long-term outcomes in ICD recipients with dual-chamber settings with those in patients with single-chamber settings. All patients received atrial leads and dual-chamber devices, the only difference being the pacing mode setting. The programming in both groups was optimized to minimize ventricular pacing and to reduce inappropriate shocks using discrimination algorithms along with standardized antitachycardia pacing (ATP) therapies.

METHODS

TRIAL DESIGN. The rationale and design of OPTION have been published previously (25). The OPTION trial is a prospective, randomized, multicenter, 2-arm, single-blinded, parallel-group trial. A total of 462 patients were enrolled at 54 centers in Europe and North America between June 2006 and April 2009. Eligible patients were recipients of de novo ICDs for primary or secondary prevention of sudden cardiac death with left ventricular ejection fractions ≤40% despite optimal tolerated heart failure therapy. Major exclusion criteria were an indication for permanent pacemaker or resynchronization therapy; the diagnosis of hypertrophic obstructive cardiomyopathy or acute myocarditis;

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