Effects of enhanced pacing modalities on health care resource utilization and costs in bradycardia patients: An analysis of the randomized MINERVA trial

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BACKGROUND Many patients who suffer from bradycardia and need cardiac pacing also have atrial fibrillation (AF). New pacemaker algorithms, such as atrial preventive pacing and atrial antitachycardia pacing (DDDRP) and managed ventricular pacing (MVP), have been specifically designed to reduce AF occurrence and duration and to minimize the detrimental effects of right ventricular pacing. The randomized MINimizE Right Ventricular pacing to prevent Atrial fibrillation and heart failure trial established that DDDRP + MVP pacing modality reduced permanent AF in bradycardia patients as compared with standard dual-chamber pacing (DDDR).

OBJECTIVE The aim of this study was to estimate the cost savings due to lower AF-related health care utilization events based on health care costs from the United States and the European Union.

METHODS Dual-chamber pacemaker patients with a history of paroxysmal or persistent AF were randomly assigned to receive DDDR (n = 385) or the advanced features (DDDRP + MVP; n = 383). We used published health care costs from the United States and the European Union (Italy, Spain, and the United Kingdom) to estimate the costs associated with AF-related hospitalizations and emergency visits.

RESULTS The rate of AF-related hospitalizations was significantly lower in the DDDRP + MVP group than in the conventional pacemaker group (DDDR group; 42% reduction; incidence rate ratio 0.58). Similarly, a significant reduction of 68% was observed for AF-related emergency department visits (incidence rate ratio 0.32; $P < .001$). As a consequence, DDDRP + MVP could potentially reduce health care costs by 40%–44%. Over a ten-year period, the cost savings per 100 patients ranged from $35,702 in the United Kingdom to $121,831 in the United States.

CONCLUSION New pacing algorithms such as DDDRP + MVP used in the MINimizE Right Ventricular pacing to prevent Atrial fibrillation and heart failure trial successfully reduced AF-related health care utilization, resulting in significant cost savings to payers.

KEYWORDS Atrial fibrillation; Bradycardia; Pacemaker algorithms; Pacing; Health care costs; Hospitalization

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ABBREVIATIONS **AF** = atrial fibrillation; **AV** = atrioventricular; **DDDR** = dual-chamber pacing; **DDDRP** = atrial preventive pacing and atrial antitachycardia pacing; **DRG** = Diagnosis-Related Group; **ED** = emergency department; **HRG** = Healthcare Resource Group; **MINERVA** = MINimizE Right Ventricular pacing to prevent Atrial fibrillation and heart failure; **MVP** = managed ventricular pacing; **NHS** = National Health Service

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Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia encountered in clinical practice. About 2.2 million people in North America and 4.5 million people in the European Union suffer from paroxysmal or persistent AF.[1,2] The prevalence of AF rises with age. Considering the aging population, AF is becoming a global epidemiological problem, which is evident by the rapid increase in the number of patients suffering from AF.[3,4]

AF is a frequent comorbidity in patients who suffer from bradycardia and require a pacemaker. Around one-third of patients have a history of AF at pacemaker implantation or AF is detected during the clinical follow-up.[5–7] Based on a worldwide survey, more than 1 million pacemakers were implanted in 2009, with more than 200,000 pacemakers implanted in the United States alone.[8] This means that more than 333,000 patients with an implanted pacemaker also have AF. As life expectancy of patients with a pacemaker is rising,[9] more patients with a pacemaker will be at risk of AF in the future.[5–7]

AF is associated with adverse clinical outcomes.[5,7,10–12] Treatment of AF imposes significant costs on health care systems. AF accounts for approximately one-third of hospitalizations for cardiac rhythm disturbances, with a clear upward trend worldwide.[13–15] A recent study from the United States reported a 23% increase in hospitalization rates in patients with AF from 2000 to 2010, particularly in patients 65 years and older.[16] Hospitalization is the major driver of AF-related costs.[17] In addition, the cost of managing AF is high and is comparable with other chronic conditions such as diabetes.[17,18] Furthermore, AF increases the risk of stroke and heart failure that represent a high burden for health care systems.[11,12]

In light of the high costs of treating and managing patients with AF, there is a need for medical solutions that reduce AF occurrence and related health care costs. Unnecessary right ventricular pacing has been shown to increase the risk of AF.[19] As a consequence, new pacemaker algorithms, such as managed ventricular pacing (MVP), have been developed to minimize the detrimental effect of right ventricular pacing.[20] The most advanced pacemakers also feature atrial preventive pacing and atrial antitachycardia pacing (DDDRP), which may reduce AF occurrence and duration.

The international MINERVA (MINimizE Right Ventricular pacing to prevent Atrial fibrillation and heart failure) trial has established that DDDRP + MVP pacing modality reduced long-lasting forms of AF. In particular, permanent AF was significantly lower (61% risk reduction) in bradycardia patients with the new pacing algorithm (DDDRP + MVP) than in those with standard dual-chamber pacing (DDDR).[21] As a consequence, AF-related hospitalizations and emergency department (ED) visits were significantly reduced.

This analysis of the MINERVA study estimates the health care cost savings from the reduction in AF-related hospitalizations and ED visits. Four countries are included in the economic evaluation: the United Kingdom, Italy, Spain, and the United States.

Methods

Study design and patient population

The details of the design of the MINERVA trial have been described elsewhere.[21] In brief, the MINERVA trial is a multicenter, randomized, single-blind, controlled trial involving 63 cardiology centers in 15 countries (centers are listed in the Online Supplemental Appendix).

The study was approved by the ethics committee of all participating centers and was conducted in compliance with the Declaration of Helsinki. All patients provided written informed consent. Inclusion criteria were standard indications for permanent DDDR and a history of atrial tachycardia/AF (at least 1 episode of documented AF, atrial flutter, or atrial tachycardia in the last 12 months). The main exclusion criteria were third-degree atrioventricular (AV) block or history of AV node ablation, history of permanent AF, and candidacy for defibrillator or cardiac resynchronization therapy device implantation, uncontrolled hyperthyroidism, anticipated major cardiac surgery, AF ablation, or other cardiac surgery.

Enrolled patients underwent standard implantation of a dual-chamber EnRhythm (Medtronic Inc, Minneapolis, MN) pacemaker, a DDDR pacemaker with specific features for (1) giving priority to intrinsic AV conduction by means of MVP (atrial pacing with ventricular backup pacing if AV conduction fails); (2) detecting atrial tachyarrhythmias with high sensitivity and specificity; (3) preventing the onset of atrial tachyarrhythmias through 3 atrial preventive pacing algorithms; and (4) terminating atrial tachyarrhythmias by means of reactive antitachycardia pacing, with ramp and burst + pacing being delivered at the onset of arrhythmia as well during its dynamic changes toward more organized rhythms.

Eligible patients were randomly assigned in a 1:1:1 manner to (1) standard DDDR (control DDDR group), (2) atrial preventive pacing, reactive antitachycardia pacing and MVP (DDDRP + MVP group), and (3) DDDR with MVP (MVP group).

Economic analysis

The economic analysis focuses on comparing health care costs of 2 groups: DDDRP + MVP and control DDDR. We