Pacemaker Therapy for Vasovagal Syncope Does Not Prevent Recurrent Syncopal Events


Study Overview

Objective. To determine if pacemaker therapy reduces the risk of recurrent syncope in patients with vasovagal syncope.

Design. A randomized, double-blind, placebo-controlled trial with intention-to-treat analysis.

Setting and participants. Patients were recruited from 15 centers from September 1998 to April 2002. Eligible patients were older than 19 years; had a history of vasovagal syncope with at least 6 episodes of syncope ever, or at least 3 episodes in the 2 years prior to enrollment; and had a positive head-up tilt-table test. Exclusion criteria included any etiology for syncope that was not vasovagal; important valvular, coronary artery, or myocardial disease; any electrocardiographic abnormality; or any major noncardiovascular disease.

Intervention. All patients underwent implantation of a dual-chamber pacemaker (Medtronic Kappa, Medtronic Inc., Minneapolis, MN). After implantation, patients were randomized to either dual-chamber pacing (DDD) or sensing without pacing (ODO). While the health care provider who programmed the device was not blinded to the allocation, the patient, patient’s physician, and all other study personnel remained blinded to actual intervention. The patients’ providers were strongly encouraged not to perform any routine electrocardiograms.

Main outcome measures. The primary outcome was syncope, which was defined as a transient loss of consciousness with prompt spontaneous recovery. Syncope episodes were self-reported by the study participants. A blinded committee of investigators judged whether syncope had or had not occurred based on the syncope reports as well as any confirmatory evidence of the event (eg, signs of injury, eyewitness accounts). Each individual participant was followed for either 6 months or up to their first episode of syncope.

Main results. 137 patients met the eligibility criteria. 100 patients were randomized, 52 patients to the ODO group and 48 patients to the DDD group. 2 patients were excluded and 35 patients refused to participate. No patients in this study were lost to follow-up over the 6-month study period, but 1 patient in the intervention group (DDD) required the removal of their pacemaker and 2 patients had their pacemaker reprogrammed to ventricular pacing. There were fewer males in the treatment group compared with the placebo group (13% versus 27%), but otherwise there were no differences between the 2 study groups. A total of 38 patients experienced a syncopal episode during the study period. In the ODO group, 42% (22/52) of patients had a syncope event as opposed to 33% (16/48) of patients in the DDD group. The cumulative risk of syncope at 6 months was 40% (95% confidence interval [CI], 25%–52%) in the placebo group and 31% (95% CI, 17%–43%) in the intervention group. The relative risk reduction in time to syncope with DDD pacing was 30% (95% CI, −33%–63%; P = 0.14). Two major pacemaker complications were associated with this study: pericardial tamponade (DDD group) and infection requiring reimplantation (ODO group). Minor complications included 7 patients with lead dislodgement or repositioning, 3 patients with infections requiring antibiotics, 1 patient with a vein thrombosis, 2 patients with wound hematomas, and 4 patients with pain associated with the pacemaker generator.

Conclusion. Pacemaker therapy did not reduce the overall risk of recurrent vasovagal syncope when compared to placebo. Both the paced and non-paced groups experienced adverse events associated with the pacemaker device.

Commentary

The differential diagnosis for syncope can be quite broad. Several studies suggest vasovagal or neurocardiogenic
OUTCOMES RESEARCH IN REVIEW

Applications for Clinical Practice

Pacemaker therapy does not appear effective for the reduction of recurrent syncope in patients with severe vasovagal syncope and also is associated with procedural complications. Pacemaker therapy should not be recommended as first-line therapy for vasovagal syncope.

—Review by Harvey J. Murff, MD, MPH

References


Copyright 2003 by Turner White Communications Inc., Wayne, PA. All rights reserved.