Multisite Stimulation in Cardiomyopathies Study - MUSTIC

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Description:
The purpose of the MUSTIC trial was to assess the clinical efficacy and safety of cardiac resynchronization therapy (CRT) with transvenous atrio-biventricular (BiV) pacemakers in patients with severe heart failure, left ventricular (LV) systolic dysfunction, and electrical conduction abnormalities.

Hypothesis:
Active BiV pacing will improve exercise capacity and quality of life (QOL) in eligible patients, compared with an inactive pacing mode.

Study Design:
Patients Enrolled: 67 (58 randomized)
NYHA Class: III
Mean Follow Up: 6 months
Mean Patient Age: Mean age 63 ± 10 years
Female: 25
Mean Ejection Fraction: Mean 23 ± 7%

Patient Populations:
1. New York Heart Association (NYHA) class III CHF on stable medical therapy.
2. LV ejection fraction <35%.
3. LV end-diastolic diameter >60 mm.
4. Sinus rhythm with a QRS duration >150 ms.

Exclusions:
Indication for standard pacemaker or cardioverter defibrillator; hypertrophic or restrictive cardiomyopathy; ongoing myocarditis, coronary syndrome, or correctable valvulopathy; recent (three months) or planned revascularization procedure; severe obstructive lung disease; or inability to walk

Primary Endpoints:
Distance walked in six minutes

Secondary Endpoints:
QOL (assessed with the Minnesota Living with Heart Failure questionnaire), peak oxygen consumption, hospitalization for heart failure, patient's preferred pacing mode, and mortality

Drug/Procedures Used:
Each patient underwent implantation of a BiV pacemaker, with leads implanted in standard right atrial and right ventricular locations, and a specially designed lead positioned in a cardiac vein accessed from the coronary sinus in order to pace the LV epicardium. Two weeks after implant, patients were randomized to 12 weeks of active BiV or inactive (VVI at 40 bpm) pacing, and then crossed over to a second 12-week period of the alternative pacing strategy. Patients were blinded to their pacing mode.

Concomitant Medications:
Patients were required to be on stable doses of optimal chronic heart failure (CHF) medications for one month prior to enrollment, including at least angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (96%) and diuretics (94%). Digoxin, beta-blockers, and spironolactone were used in 48%, 28%, and 22% of patients, respectively.

Principal Findings:

LV lead placement was initially successful in 59/64 patients (92%). There were eight early lead dislodgements, five successfully revised. The two crossover phases were completed by 48 subjects.

Average six-minute walk distance was 23% higher for BiV paced versus control periods (399 ± 100 vs. 326 ± 134 m, $p<0.001$). The average QOL score decreased (improved) with BiV pacing versus no pacing (30 vs. 43, $p<0.001$). Peak oxygen consumption was slightly higher with BiV pacing versus control (16.2 vs. 15.0 ml/kg/min, $p=0.03$). When asked, 85% of subjects expressed a preference for the active versus inactive pacing mode.

Interpretation:

In this single-blinded crossover study, BiV pacing with transvenous systems, compared with an inactive pacing mode, was associated with improvements in six-minute walk distance, peak oxygen consumption, and QOL scores in patients with severe heart failure, LV systolic dysfunction, and electrical conduction abnormalities. Transvenous insertion of LV leads was generally successful, with a moderate incidence of early lead dislodgement.

References:

Cazeau S, Leclercq C, Lavergne T, et al., for the Multisite Stimulation in Cardiomyopathies (MUSTIC) Study Investigators. Effects of multisite biventricular pacing in patients with heart failure and intraventricular conduction delay. N Engl J Med 2001;344:873-80.

Clinical Topics: Arrhythmias and Clinical EP, Heart Failure and Cardiomyopathies, Implantable Devices, Acute Heart Failure

Keywords: Cross-Over Studies, Oxygen Consumption, Coronary Sinus, Quality of Life, Heart Failure, Pericardium, Heart Ventricles, Ventricular Dysfunction, Left, Cardiac Resynchronization Therapy

- See more at: http://www.acc.org/latest-in-cardiology/clinical-trials/2010/02/23/19/11/mustic#sthash.OrkaekHY.dpuf