Study leads to recommendation for use of heart failure treatment nationwide

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A new therapy that reduces the risk of mortality and heart failure in patients with mild cardiac disease received a thumb's up this week from an advisory panel to the U.S. Food and Drug Administration. The panel recommended that the cardiac resynchronization therapy defibrillator (CRT-D), tested extensively nationwide under the leadership of cardiologist Arthur Moss, M.D., professor of Medicine at the University of Rochester Medical Center, be approved for use in patients with mild heart failure in the United States.

The device under review was developed by Boston Scientific and is already approved to treat patients with severe heart failure. With device approval by the FDA, nearly 4 million more Americans could be candidates for treatment with the CRT-D. The recommendations by its panels are often, but not always, followed by the FDA.

In the major study which tested the device - the MADIT-CRT trial - patients who had a cardiac resynchronization device combined with a defibrillator (CRT-D) implanted had a 34 percent reduction in their risk of death or heart failure compared to patients receiving only an implantable cardioverter defibrillator (ICD). Heart failure alone was reduced by 41 percent in all patients, with a remarkable 63 percent reduction of heart failure in women. The study results were published last year in the New England Journal of Medicine.

This week, Moss presented clinical data from the MADIT-CRT study at a meeting of the FDA's Circulatory System Devices panel showing that

the combination of an implanted cardiac defibrillator, which detects irregular and potentially fatal heart rhythms and shocks the heart back into a normal rhythm, with cardiac resynchronization therapy, which improves the mechanical pumping action of the heart, provides preventive benefit to patients with more mild cardiac disease.

"The panel's recommended approval of this therapy is great news for a large population of patients in which it could effectively prevent heart failure progression," said Moss. "The ultimate goal of this new therapy is to not only help patients live longer, but to help them live better."

The new device combines two functions found in current devices: an ICD, which is designed to prevent sudden cardiac death, and cardiac resynchronization therapy, which works to reduce heart failure and associated symptoms.

About 70 percent of the approximately 5.5 million Americans with some form of heart failure, or 3.9 million people, have milder forms of heart failure known as "Class I" or "Class II," the forms considered by the FDA in its decision this week.

The MADIT-CRT study followed 1,820 patients from 110 medical centers in the United States, Canada and Europe for four-and-one-half years. The trial was sponsored by Boston Scientific through a research grant to the University of Rochester. The study is the world's largest randomized trial involving Class I and Class II heart failure patients.

Prior to MADIT-CRT, Moss and his colleagues at the University of Rochester directed MADIT-I and MADIT-II, which evaluated the safety and efficacy of ICDs in high-risk heart failure patients. These trials set the stage for MADIT-CRT and the evaluation of defibrillators with resynchronization therapy in lower-risk patients.

Moss received honoraria from Boston Scientific prior to 2009 for talks at scientific programs. He holds no stock in any device company, has never been a member of any corporate speakers' bureau, and since Dec. 1, 2008, has chosen not to accept honoraria from Boston Scientific for any professional activity.

Provided by University of Rochester Medical Center