

Women clear winners with heart failure device

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For women with mild heart failure, device therapy is an extremely attractive option to prevent progression of the disease, according to a study presented today at the Heart Rhythm Society's 31st Annual Scientific Sessions. Women with mild heart disease who had a cardiac resynchronization device combined with a defibrillator (CRT-D) implanted had a 70 percent reduction in heart failure alone and a 72 percent reduction in death from any cause. Men received some benefit from the therapy, but not the out-of-the-park results seen in women.

"This is the first study in which a <u>heart failure</u> therapy has proven more effective in women than in men," said cardiologist Arthur Moss, M.D., professor of Medicine at the University of Rochester Medical Center and lead author of the study.

The study is a sub-analysis of the MADIT-CRT trial, which was published last year in the New England Journal of Medicine. Researchers found that females receiving CRT-D therapy to prevent heart failure progression had significantly better outcomes than males receiving the therapy. Reduction of heart failure in females was twice that of males - 70 percent versus 35 percent. While women saw a significant 72 percent reduction in death from any cause, there was no evident reduction in men.

This gender-based analysis comes less than two months after an advisory panel to the U.S. <u>Food and Drug Administration</u> recommended that the device, which is developed by Boston Scientific, be approved for use in



patients with mild heart failure. The device is already approved to treat patients with severe heart failure. If approved for the new prevention of heart failure indication, nearly 4 million more Americans could be candidates for treatment with the CRT-D.

"Anecdotally, we know that women are offered devices to treat heart failure less often than men," said Wojciech Zareba, M.D., Ph.D., professor of Medicine at the University of Rochester Medical Center and co-author of the study. "We're hopeful that these results will change the mindset of physicians and that they will apply this type of therapy as indicated in women as well as in men."

Currently, 42 million American women are living with heart disease. It is the leading killer of women in the United States, each year claiming more women than men. In 2005, cardiovascular disease claimed the lives of more than 450,000 women, while all forms of cancer claimed the lives of approximately 265,000 women, according to the American Heart Association.

In women with mild heart failure, CRT-D therapy effectively prevented deterioration of the heart, otherwise known as cardiac remodeling. While "remodeling" typically has positive connotations - think new kitchen with updated appliances, sparkling marble countertops and refurbished floors - cardiac remodeling is actually an unwanted consequence of a damaged heart (from a heart attack or an infection) that is marked by enlargement of the heart.

Why did women see such significant preventive benefits from CRT-D therapy compared to their male counterparts? Study authors believe several factors are at play. Women in the study were more likely to have non-ischemic heart disease, which is typically characterized by inflammation of the heart muscle and can lead to reduced pumping strength, abnormal heart rhythms (arrhythmias) and disturbances in the



heart's electrical system. In individuals with non-ischemic disease the entire heart, as opposed to a single region of the heart, is often affected.

Women were also more likely to have left bundle branch block, a condition that results in disorganized electrical activity throughout the heart, including unsynchronized contractions. Because left bundle branch block and non-ischemic disease lead to diffuse, as opposed to localized heart problems, study authors reason women may be more responsive to CRT-D therapy, which strengthens the overall mechanical pumping action of the heart and coordinates the heart's electrical activity.

"Another issue to consider is that women often put their own health lower down on their list of priorities, after taking care of their family, managing their career, and so on," said Zareba. "This may translate into women showing up at the physician's office later than men, with more advanced disease, in which case they might see a greater benefit from CRT-D therapy."

In contrast to women, men were more likely to have ischemic heart disease - otherwise known as coronary artery disease - where narrowed arteries restrict the flow of blood and oxygen to the heart. Ischemic disease often leads to localized problems, for example, when a clogged artery restricts blood flow and causes damage to a particular region of the heart. Moss and his colleagues believe the more localized problems men typically experience may render them somewhat less responsive to CRT-D therapy.

CRT-D therapy combines two functions found in current devices. It combines an implantable cardioverter defibrillator (ICD), which is designed to prevent sudden, rhythm-related cardiac death, with cardiac resynchronization therapy, which works to reduce heart failure and associated symptoms.



In the MADIT-CRT trial researchers followed 1,820 participants from 110 medical centers in the United States, Canada and Europe for four-and-one-half years to compare the effectiveness of ICD versus CRT-D therapy in reducing heart failure and death. Twenty-five percent, or 453 of the study participants, were female. The purpose of the sub-analysis was to explore the factors associated with the more favorable response to CRT-D therapy in women than men.

Moss is leading several follow-up studies that will track participants from the MADIT-CRT trial over longer periods of time to further gauge reductions in heart failure, effects of CRT-D therapy on quality of life, and overall treatment costs.

Provided by University of Rochester Medical Center

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