Pacemaker implantation for heart failure does not benefit nearly half of the patients

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A new meta-analysis study, led by physician researchers at University Hospitals (UH) Case Medical Center and Case Western Reserve University School of Medicine, and to be published in the *Archives of Internal Medicine*, shows that three-lead cardiac pacemakers implanted in those with heart failure fail to help up to 40 percent of patients with such devices.

"These findings have significant clinical implications and impact tens of thousands of patients in the U.S.," said Ilke Sipahi, MD, Associate Director of Heart Failure and Transplantation at UH Case Medical Center and Assistant Professor at Case Western Reserve University School of Medicine. "In this in-depth analysis, we found that pacemaker patients with less severe electrical disturbance in their hearts did not receive any benefit whatsoever from these expensive and potentially risky implants. Given the abundance of data showing lack of efficacy in this patient population, current treatment guidelines should be changed."

Dr. Sipahi, along with James Fang, MD, Director, Clinical Cardiovascular Services at UH Case Medical Center and Professor at Case Western Reserve University School of Medicine, investigated the treatment method known as cardiac resynchronization therapy (CRT). This highly sophisticated treatment technique involves pacing both ventricles of the heart in an attempt to correct the impaired synchrony during contraction of the heart.

Sometimes also referred to as "biventricular pacing," CRT is a form of therapy for congestive heart failure that utilizes a special pacemaker to re-coordinate the action of the heart chambers.

The study is a combined analysis of clinical trials of nearly 6,000 patients and examines whether the current criteria used by the medical community in selecting patients for the treatment are appropriate.

Treatment guidelines endorsed by various professional societies recommend these pacemakers for patients with heart failure symptoms due to weak heart muscles that have a specific abnormality on the electrocardiogram (EKG) known as QRS prolongation. Current treatment guidelines recommend that heart failure patients with QRS prolongation to greater than 0.12 seconds should get these devices.

However, the new meta-analysis demonstrates that patients do not have a survival benefit or a reduction in hospitalizations from these pacemakers, unless their QRS is prolonged to greater than 0.15 seconds, a threshold much greater than the 0.12 second cutoff advocated in the treatment guidelines. Approximately 40 percent of patients receiving these devices have a QRS prolongation in the range of 0.12 to 0.15 seconds and do not get any benefit from pacemaker therapy according to the results of the new study.

"This study can have profound impact on minimizing unnecessary procedures" added Dr. Sipahi. "Revising the criteria for implantation of these devices will help avoid thousands of unnecessary implants and will also lead to cutting down on unwarranted costs."

In contrast, the tandem's research also confirmed that patients with QRS prolongation greater 0.15 seconds got substantial benefit from their devices, lived longer and were hospitalized less often.

Heart failure, especially at its advanced stages, is a deadly disease affecting approximately 6 million Americans. Annual costs related to heart failure approached $40 billion in 2010. The global CRT devices market is expected to reach at $2.8 billion by 2015 with the North American segment accounting for nearly 40 percent of the global value.

"Our analysis suggests that this important therapy appears to benefit primarily those patients with the greatest prolongation in the QRS duration," said Fang. "This study may help to better select patients who are most likely to benefit from this effective but costly procedure."

Provided by University Hospitals Case Medical Center