Implanted Device Shortens HF Hospitalization

BY MITCHEL L. ZOLER
Philadelphia Bureau

DALLAS — Management of heart failure patients with data from an implanted device that continuously monitors hemodynamic pressures led to a 25% reduction in total days spent in the hospital among patients with class III heart failure in a controlled study with more than 200 patients.

"The number of days spent in the hospital for decompensated heart failure is the principal driver of cost for heart failure treatment, and this was significantly decreased," Dr. William T. Abraham said at the annual scientific sessions of the American Heart Association.

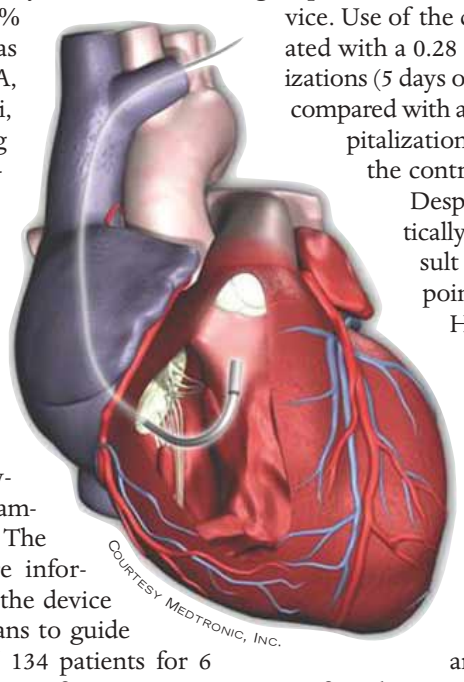
Use of the device in both outpatients and in hospitalized patients with heart failure "may make episodes of decompensation less extreme, and may help get patients out of the hospital more quickly," said Dr. Abraham, professor and director of the division of cardiovascular medicine at Ohio State University in Columbus.

The finding came from new analyses of data collected in the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) trial, which tested the clinical impact of managing patients with intracardiac pressure data collected by the implanted Chronicle device. The device is made by Medtronic, which submitted an application for licensing to the Food and Drug Administration last August that was still pending in January.

The primary end point of the COMPASS-HF was reported last March at the annual meeting of the American College of Cardiology. Although patient management guided by pressure data obtained by the Chronicle device led to a 22% cut in the rate of heart failure–related hospitalizations and emergency department and urgent-care visits, the drop was not statistically significant. However, several secondary analyses also were positive in favor of the device, including a new set of secondary analyses presented by Dr. Abraham, who is a consultant and investigator for Medtronic and has received honoraria from the company for speaking.

He cautioned that the COMPASS-HF study was not designed to provide definitive answers to these secondary analyses, and therefore the findings must be considered exploratory.

In addition, researchers at Medtronic have revised the results presented by Dr. Abraham based on more comprehensive patient follow-up. The revised data showed that use of data from the Chronicle device cut the number of hospitalized days for heart failure by 20% instead of the 25% difference reported by Dr. Abraham. The 20% reduction is what was reported to the FDA, said Dr. David Israeli, director of marketing and business development for Medtronic in Minneapolis.


COURTESY MEDTRONIC, INC.

In the COMPASS-HF study, a total of 274 patients with advanced-stage heart failure underwent surgery to receive the subcutaneously-implanted, hemodynamic monitoring device. The intracardiac pressure information collected by the device was used by physicians to guide the management of 134 patients for 6 months. The pressure information was withheld from the treating physicians in the control group of 140 patients. All patients in the study also received optimal medical care based on clinical findings. The benefits of applying information collected by the Chronicle device were greatest in the 85% of patients who entered the study with New York Heart Association class III disease. Those with class IV disease had much less benefit.

The reduction in hospitalized days using data collected by the implanted device was more marked if the analysis excluded outlier patients with hospitalizations that extended beyond 30 days. With this exclusion, use of the Chronicle data cut the total number of hospitalized days by 42% for all patients in the study, and by 38% in the class III–only patients.

Another secondary analysis examined the impact of using data from the Chronicle device on the rate of prolonged or short hospitalizations for heart failure. Among the class III–only patients, use of Chronicle information was associated with an average rate of 0.19 long hospitalizations (more than 5 days) every 6 months, compared with a rate of 0.31 long hospitalizations every 6 months in the control group, a 40% decrease in favor of the device. Use of the device also was associated with a 0.28 rate of short hospitalizations (5 days or less) every 6 months, compared with a rate of 0.42 short hospitalizations every 6 months in the control group.

Despite the lack of a statistically significant positive result for the primary end point of the COMPASS-HF trial, the researchers who ran the study believe that the results demonstrate the device's efficacy.

"It's a positive study overall," commented Dr. Robert C. Bourge, lead investigator for the study and professor and director of the division of cardiovascular disease at the University of Alabama, Birmingham.

But other experts are concerned about paying for this intensive approach to patient management.

"The implications are profound regarding the cost of care," commented Dr. Harlan M. Krumholz, professor of medicine and epidemiology at Yale University, New Haven, Conn. "How should we decide which patients should get this?"

"We're developing models of how to use it," said Dr. Bourge, who acknowledged that not all physicians would have the expertise or time to review so many pressure measurements for their patients.

Because of this, researchers are working on developing an automated way to review the large number of intracardiac pressure measurements that are made in each patient. ■

Automated Scanning System Tracks Intracardiac Pressures

BY MITCHEL L. ZOLER
Philadelphia Bureau

DALLAS — An automated system may be able to monitor intracardiac pressures and alert physicians when the pattern suggests impending decompensation, based on a pilot analysis of data collected on 95 acute heart failure events.

The system "continuously scans data and can automatically notify the physician when a patient's pressures change meaningfully," Dr. Philip B. Adamson said at the annual scientific sessions of the American Heart Association.

The scanning system developed by Dr. Adamson and his associates monitors changes in intracardiac pressures measured by the implanted Chronicle device, which is made by Medtronic Inc. and is under review by the Food and Drug Administration. Dr. Adamson has served as a consultant to Medtronic.

"The key to using this data is to learn the right pressure for each patient," said Dr. Adamson, director of the Heart Failure Institute at the Oklahoma Heart Hospital in Oklahoma City.

The Chronicle implanted device was tested on 274 patients with advanced heart failure in the Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) trial. Intracardiac pressure data collected by the device was used by physicians to guide their management of 134 patients. The collected data were not used in the management of 140 control patients.

Data collected by the device for 56 of the control patients were used in Dr. Adamson's analysis. These 56 patients had a total of 95 episodes of acute decompensation that resulted in either a hospital admission or treatment in an emergency department or urgent-care clinic.

The automated data monitoring focused on the estimated pulmonary-artery diastolic pressure. A rule about changes in this pressure was devised using pressure information gathered before 42 of the 95 events. The pattern was that events usually occurred about 2 weeks after a significant increase in the pulmonary-artery diastolic pressure, said Dr. Adamson. This criterion was able to identify 35 (83%) of the 42 events.

This criterion was then applied on a test basis to the remaining 53 clinical events used in the analysis. A 7-day average of prior pulmonary-artery diastolic pressures was calculated for each patient every day, and this adaptive reference value was applied to each day's new pressure readings.

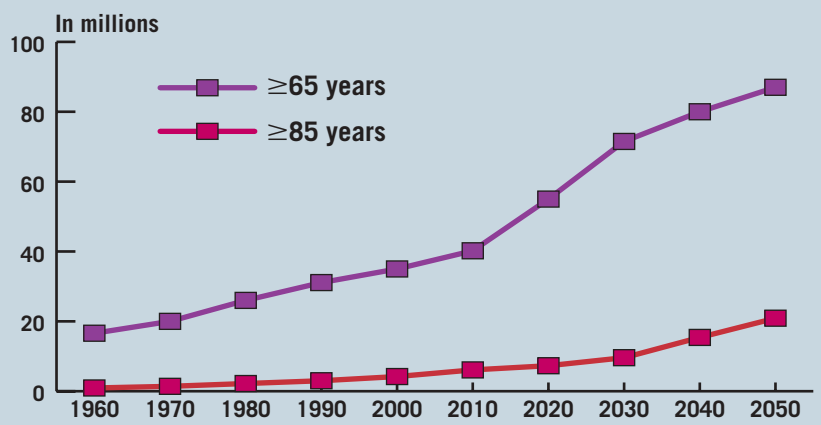
Small changes in pulmonary-artery pressure over a long period of time, or large changes in pressure over a short period of time were both considered flags of an impending event.

This method identified 43 (81%) of the 53 heart failure events included in the test.

The impending events were flagged an average of 26 days before the events actually occurred. ■

DATA WATCH

Elderly Population Expected to Rise Rapidly



Source: U.S. Administration on Aging

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