Fixed AV Delay Works Well for Most CRT Users

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CHICAGO – The standard, atrioventricular delay built into many cardiac resynchronization devices worked as effectively as did an automated patient-tailored delay or a delay based on a time-consuming echocardiography assessment in a randomized trial that involved nearly 1,000 patients.

"The routine use of AV [atrioventricular] optimization techniques assessed in this trial is not warranted," Dr. Kenneth A. Ellenbogen said at the meeting. But it may help patients who don't initially respond to cardiac resynchronization therapy (CRT), he added, although the results he reported did not assess this possibility.

The findings refuted a recommendation made in 2008 by a panel of the American Society of Echocardiography to routinely use an echo assessment to set the AV delay in patients receiving a CRT device (J. Am. Soc. Echocardiogr. 2008;21:191-213).

"The algorithms [for determining an optimal AV delay] made excellent sense hemodynamically, but you need a clinical trial to look at clinical outcomes," said Dr. Ellenbogen, vice-chairman of cardiology and director of clinical cardiac electrophysiology and pacing at Virginia Commonwealth University in Richmond, Va.

"The bottom line is we can save patients an expensive and time-consuming study that really doesn't benefit the majority of patients. The out-of-the-box settings seem to work in most patients," he added.

A detailed echo study "is about an hour long and uses resources," and was no better than the alternatives, commented Dr. Gordon F. Tomaselli, professor and chief of cardiology at Johns Hopkins University in Baltimore. "The key comparison of the study was do we need to do a detailed echo study on everyone to optimize the hemodynamics, and the answer was no," he said in an interview.

The results also called into question the usefulness of a feature in all CRT devices on the U.S. market that automatically attempts to optimize the AV delay based on what the device detects as the patient's intrinsic AV interval and baseline QRS width. In the Boston Scientific CRT unit used in the new study, this feature is called "SmartDelay." The study results showed no significant benefit from the SmartDelay feature compared with a fixed AV delay of 120 msec for all patients.

"All the companies have their algorithms" for setting the AV delay, said Dr. Tomaselli. He also noted that while the new results showed no significant difference between the fixed delay of 120 msec and the variable delays applied by the device's built-in programming function, several outcomes showed trends toward superiority using the built-in program.

For example, in the study's primary outcome – the median change in left ventricular end systolic volume at 6 months after placement of the CRT device – the results showed a median 21-mL reduction in patients whose delay got set by the device's internal program (which produced an average delay of 48 msec) and a median 15-mL reduction in patients who received a device set to the fixed, 120-msec delay. Patients who underwent an echo-guided procedure to set the delay had a median reduction of 19 mL.

The SmartDelay Determined AV Optimization: A Comparison to Other AV Delay Methods Used in Cardiac Resynchronization Therapy (SMART-AV) trial randomized and implanted 980 patients at 100 centers in the United States and Europe during May 2008–December 2009. The researchers were able to perform follow-up assessments on 86% of the randomized patients. The patients' average age was 66, two-thirds were men, and more than 90% had New York Heart Association class III heart failure.

The study's secondary outcomes analyses also showed no significant differences between the three methods used to set the AV delay for changes in left ventricular end diastolic volume, ejection fraction, 6-minute walk, quality of life, or

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Major Finding: In patients who received a cardiac resynchronization device to treat severe heart failure, three different methods for setting the atrioventricular delay – an echocardiographic assessment, a built-in program of the device, and a fixed, 120-msec delay used for all patients – produced no statistically significant differences in the change in left ventricular end systolic volume at 6 months after device placement.

Data Source: The SMART-AV trial, which randomized and implanted 980 patients at 100 centers in the United States and Europe during May 2008–December 2009.

Disclosures: The study was sponsored by Boston Scientific. Dr. Ellenbogen said that he has served as a consultant or an advisory board member to, lectured on behalf of, and/or received research grants from, Boston Scientific, Biotronik, Medtronic, St. Jude Medical, Sorin Group, Cardionet, Atricare, EBR, Sanofi-Aventis, and Biosense Webster. Dr. Tomaselli said that he had no disclosures.

NYHA heart failure class. A series of post hoc subgroup analyses also generally showed no difference between the three methods. These included patients with ischemic or nonischemic heart failure etiology, patients with either greater or less than 30% atrial pacing, patients with or without bundle branch block, and those with a QRS duration of less than 150 msec and those with a duration of at least 150 msec.

The only subgroup that showed a differential effect was in women, who had a significantly better response to either the device-selected AV delay or an echo-guided delay compared with the fixed, 120-msec delay. In men, the three approaches had identical effects. The implications of this finding for selecting a CRT delay in women will need further study, Dr. Ellenbogen said. He also stressed the need to compare the efficacy of the three delay-setting approaches in the roughly 25% of patients who don't initially respond to their CRT device.

Concurrently with Dr. Ellenbogen's report at the meeting, the results were published online (Circulation 2010 Nov. 15 [doi:10.1161/circulationaha.110.992552]). ■