

Study Calls for Restraint Using CRT in Heart Failure Patients

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Electrophysiologist and Saint Thomas Hospital researcher Dr. James Baker has recently co-authored a study challenging the hypothesis that cardiac-resynchronization therapy might benefit heart failure patients outside the accepted ranges that signify wide QRS complex.

"The study came from an interest in seeing if there was a larger population of patients who would benefit from an established therapy that has been well proven to be beneficial in improving heart function in patients with congestive heart failure," he explained.

He added that CRT has been effective in those with a prolonged QRS interval equal to or greater than 120 (msec), referred to as "wide QRS complex." However, Baker continued, some small studies indicated that those with a more narrow QRS interval might also benefit from the therapeutic device.

The temptation to push the known boundaries, he added, came from a real desire to see if a therapy could improve the heart function for a wider patient base. Baker said that in patients that fit the current indications for CRT, the device can make a huge difference in their quality of life. He's witnessed patients close to transplantation who had almost no energy improve dramatically with the therapy.

"We use CRT, and they are a well-functioning, active person again; that's wonderful to see," he stated. "When you see that kind of benefit, you want to reach out to others, but in that enthusiasm, you've got to make sure it's proven."

As one of the early research sites for CRT, it was a natural fit for Saint Thomas to participate in the recent study to see if usage indications for the device could be broadened. Baker, who sat on the clinical trial's steering committee and helped develop the research protocol, said the hospital enrolled the second-largest number of patients in the double blind, multi-site, national trial. In total, researchers worked with 172 heart failure patients at 34 locations across the country with a QRS interval of less than 130 (msec) present in all ECG leads. Device manufacturer St. Jude Medical funded the six-month study.

Baker said that patients who were candidates had to have a weakened heart muscle, abnormal dyssynchrony and advanced congestive heart failure symptoms (Class III). All patients were implanted with the device that provided CRT and defibrillator therapy (CRT-D) ... also known as a biventricular pacing defibrillator. The defibrillator function was activated in all patients, but the cardiac-resynchronization therapy was only activated in half the participants.

Participants underwent baseline testing prior to the implant and follow-up testing at the six-month period. Four criteria were used to determine the outcome of activated CRT-D devices.

- Did patients perform any better on their metabolic stress tests?
- Was there an improvement in the quality of life?
- How far could patients walk in six minutes?
- Were there any changes in the assessment of patients' heart failure classification?

"The results were somewhat surprising," Baker said. "The most sophisticated and most objective of the tests — the metabolic stress test — didn't show any real difference in the two groups."



Dr. James
Baker

Researchers set a primary end point of seeing an increase in peak oxygen consumption of at least 1.0 ml per kilogram of body weight per minute during the metabolic stress test after six months of pacing activation. At the follow-up test, 46 percent of those in the CRT group and 41 percent of those in the control group reached the primary end point — a difference not deemed statistically significant.

Baker noted, “There was a little bit of improvement in the congestive heart failure symptoms in those who had the CRT pacing turned on than in those who didn’t, but overall there was really no significant difference, which was not what was expected.”

The takeaway message, Baker said, is that “this therapy should not be applied outside the group of patients we had identified before — those who have wide QRS complex.”

He added that the results surprised many people — including him.

“Even though it’s a ‘negative’ study, it’s extremely important because it begins to set some parameters,” Baker stated. “It’s a good lesson that as a physician you really need to see a therapy proven to be beneficial before you apply it.”

The results of the clinical trial were published in the December 13, 2007, issue of the New England Journal of Medicine (Volume 357:2461-2471). For additional information on the parameters of the trial, go to <http://clinicaltrials.gov/show/NCT00132977>.

February 2008