

# Right Ventricular Pacing Triggers Heart Failure

*Pacemaker users had 44% higher rate of HF death, hospitalization.*

BY MITCHEL L. ZOLER  
Philadelphia Bureau

PHILADELPHIA — Single-chamber right ventricular pacing may be producing many new cases of heart failure by causing ventricular dyssynchrony.

New evidence for this hypothesis came from a study with more than 23,000 paced patients and controls, showing that patients with pacemakers were 44% more likely to have heart failure (HF) death or hospitalization than matched patients without pacemakers, Ronald Freudenberger, M.D., reported at the annual meeting of the International Society for Heart and Lung Transplantation.

"This is the first population-based study to show that right ventricular pacing in patients without heart failure is bad," said Dr. Freudenberger, director of the heart failure and transplant cardiology program at Robert Wood Johnson Medical School in New Brunswick, N.J. A link between single-chamber pacing and HF also has been noted in several recent intervention studies.

"The way we've practiced cardiac pacing for the last 3 decades must be abandoned," said Michael O. Sweeney, M.D., director of cardiac pacing and implantable-device therapies at Brigham and Women's Hospital, Boston.

Although Dr. Freudenberger stressed that his findings

do not prove that single-chamber pacing causes HF, the results are suggestive enough that physicians should immediately minimize their use of single-chamber right ventricular pacing as much as possible. One way is to set pacing rates so that patients are paced only when their heart rates make pacing necessary, he told this newspaper.

It's also possible that right-atrial pacing may avoid producing the dyssynchrony and QRS-interval widening that is probably causing HF in patients who have right ventricular pacing. But superior safety of right-atrial pacing must still be proven in prospective studies.

One such study, led by Dr. Sweeney, is testing "the first new mode of cardiac pacing in 35 years," using a device that provides "managed ventricular pacing." This device can produce dual- or single-chamber pacing, depending on conduction activity. When normal conduction is present, it automatically switches to pacing the right atrium only, minimizing right ventricular pacing. The study, being done at about 100 centers in the United States, Canada, and Europe, is on track to finish enrollment this year and produce results in 2007, Dr. Sweeney told this newspaper.

The case-control study involved more than 3 million patients discharged alive from 85 acute-care hospitals in New Jersey during 1997-1999. Records for these patients were in the Myocardial Infarction Data Acquisition System. There were 11,426 patients who had received pacemakers for the first time and had no record of HF either at the time of pacemaker implantation or in the prior year. A group of 11,656 control patients without pacemakers or HF were

selected from the same database. The two groups were matched by demographic and clinical measures including age, sex, and history of MI, hypertension, and diabetes.

Subsequent records for these patients were reviewed at a median follow-up of 33 months to determine the incidence of HF death and hospitalization.

In a multivariate analysis controlling for known variables, patients with a pacemaker had a 44% increased risk of subsequent HF hospitalization or HF death, compared with controls. Patients with a single-chamber pacemaker had a 59% increased risk of HF hospitalization or HF death. Patients with a dual-chamber pacemaker had a 36% increased risk of these outcomes, suggesting that pacing both the right atrium and ventricle may be less hazardous than pacing the right ventricle alone.

Another possible interpretation is that the findings simply show that patients who require pacing have worse outcomes than patients who don't, with no causal link between pacing and the subsequent development of heart failure, said Mariell Jessup, M.D., medical director of the heart failure and cardiac transplantation program at the University of Pennsylvania, Philadelphia.

This probably does not explain the findings, because control patients were carefully matched for other HF risk factors, such as coronary artery disease, hypertension, and diabetes, Dr. Freudenberger said. The main difference between the two study groups was the use of pacing. This, plus the long follow-up and the large number of patients, makes it more likely that the association is real, he said. ■

## Add Sudden Cardiac Death to List Of Poverty-Related Health Risks

BY BRUCE JANCIN  
Denver Bureau

NEW ORLEANS — The incidence of sudden cardiac death is markedly greater in low-income neighborhoods, according to new data from the Oregon Sudden Unexplained Death Study.

Socioeconomic status is known to be an important predictor of many aspects of health. But the Oregon Sudden Unexplained Death Study (Ore-SUDS) is the first formal look at its impact on sudden cardiac death (SCD) on a community-wide basis, Kyndaron Reinier, Ph.D., noted at the annual meeting of the Heart Rhythm Society.

Ore-SUDS is an ongoing Centers for Disease Control and Prevention-sponsored, prospective population-based study of SCD in Portland and the surrounding county. Dr. Reinier presented data on the 714 confirmed cases in 2002-2004. The annual incidence was 54 per 100,000 population.

Each case was matched to the appropriate county census tract, of which there are 170, each

containing 3,000-4,000 people. Ore-SUDS investigators ranked the tracts in quartiles of socioeconomic status: median income, percent of the population below the official poverty level, median home value, and percentage of residents with a bachelor's degree.

The investigators also found that the incidence of SCD among people in the lowest quartile for each of the four socioeconomic status indicators was 30%-80% higher than for those in the top quartile. For example, annual SCD incidence among residents of census tracts in the bottom quartile for median home value was 62 per 100,000, compared with 36 per 100,000 in the top quartile. This represented a 70% increase in relative risk, said Dr. Reinier of Oregon Health and Science University, Portland.

The inverse relationship observed between socioeconomic status and SCD was much stronger among individuals who experienced SCD before age 65. (See box.)

The prevalence of coronary artery disease as reflected in medical records and autopsy reports did not differ between SCD victims in the various quartiles. Neither did body mass index or rates of attempted resuscitation.

Median home value and the other measures of socioeconomic status that were used in the study are really just proxies for some as-yet unidentified factor related to poverty that raises SCD risk, Dr. Reinier said. ■

## Totally Subcutaneous ICD Lead System Passes First Clinical Test

NEW ORLEANS — The many problems associated with traditional transvenous-lead implantable cardioverter-defibrillators could evaporate if a novel, totally subcutaneous lead system bears out the early promise displayed in its initial randomized clinical trial, Gust H. Bardy, M.D., said at the annual meeting of the Heart Rhythm Society.

Although inappropriate shocks are the most frequent adverse events associated with ICD therapy, it's the transvenous-lead complications, including lead fractures and infections, that cause electrophysiologists and surgeons to quake. Lead complications often result in surgical revision or device explantation.

And then there is the complex and time-consuming nature of the implantation procedure. "Part of the reason ICDs aren't used more is the referral bottleneck issue. Special skills are required," observed Dr. Bardy of the Seattle Institute for Cardiac Research.

He reported on 51 adults with a standard indication for ICD therapy who participated in a randomized international trial sponsored by Cameron Health Inc., developer of the subcutaneous-only ICD lead system. All patients first received this system, which was inserted without fluoroscopy. Then they got standard transvenous leads. The

study's purpose was to learn whether defibrillation is possible with a totally subcutaneous lead system at energy levels within the range of what's technically feasible.

The answer proved to be yes, although as expected the mean defibrillation threshold was 3.5-fold greater with the subcutaneous lead system: 36.1 J, compared with 10.9 J with the transvenous system.

"It's quite amazing, really, that without an electrode in the heart the defibrillation threshold can be as low as 5 J—and perhaps even lower," said Dr. Bardy, who is a consultant to and holds an equity position in Cameron Health. The average insertion time for the subcutaneous-only lead system was 6 minutes.

Dwight W. Reynolds, M.D., chief of cardiology at the University of Oklahoma Health Sciences Center, Oklahoma City, called the new lead system "a revolutionary technology" that electrophysiologists will be watching closely.

Andrew E. Epstein, M.D., offered a more guarded assessment. "We have no outcome data for this system. Furthermore, there was no information presented about sensing. So we have a long way to go," said Dr. Epstein, professor of medicine at the University of Alabama, Birmingham.

—Bruce Jancin

