Dual Procedures More Effective

A Fib Ablation *from page 1*

bined approach," said Dr. David J. Wilbur, director of the Cardiovascular Institute at Loyola University in Maywood, Ill. The new results "add to the evidence that combination treatment gives the best results [in persistent AF], and is the first report of patients with paroxysmal AF," he said in an interview.

St. Jude Medical, a company that makes devices for transcatheter AF mapping and ablation, sponsored the study. Dr. Verma and Dr. Wilbur reported having financial relationships with St. Jude and with other device and drug companies.

The Substrate Versus Trigger Ablation for Reduction of Atrial Fibrillation (STAR-AF) trial began in August 2006 and enrolled patients at eight medical centers in Canada and Europe. Patients had either persistent AF or a new category called "high-burden" paroxysmal AF, defined as at least four AF episodes in the prior 6 months with at least two episodes lasting more than 6 hours each. Persistent AF had to last at least 7 days but less than 1 year, and required cardioversion to terminate. All patients had to have failed treatment with at least one antiarrhythmic drug.

A third of the enrolled patients had persistent AF, and the average duration of AF for all patients was about 7 years. Three-quarters of the patients were men, and they had failed treatment with an average of 1.4 drugs. Recurrences during the first 3 months after ablation were not counted, and during that time patients could undergo retreatment with whichever treatment(s) they initially received. Treatment with antiarrhythmic drugs also could occur during the first 3 months after ablation.

The study's primary end point was the percentage of patients who remained AF-recurrence free during the first year following ablation. Of the 34 patients who had both procedures, about 75% reached that end point, significantly more than the roughly 45% rate in 32 patients who underwent pulmonary vein isolation alone, and the same 45% rate in the 34 patients who had CFE mapping and ablation.

About 75% of patients who had both procedures remained free of AF episodes in the year following treatment.

DR. VERMA

Similar arrhythmia-free rates were seen in each subgroup in an analysis that tallied the recurrence of AF, atrial flutter, or atrial tachyarrhythmia.

In another analysis that looked at the percentage of patients who remained free from AF the year following the initial treatment with a second treatment if needed, the rates again significantly favored the combined approach, which led to about 90% of patients free from AF. Patients undergoing up to two pulmonary vein isolations had a 70% rate free from AF, and patients undergoing CFE mapping and ablation had 40% of patients free from recurrences.

The percentage of patients who required a repeat procedure was 15% in the combined group, 31% in the pulmonary vein isolation group, and 47% in the CFE mapping group. ■

Real-World Survival With Devices Better Than in Trials

BY MITCHEL L. ZOLER

BOSTON — Patients who received implanted cardiac devices in routine practice in recent years had much better survival than did those who received the same devices in the pivotal trials of the early 2000s, based on data from nearly 86,000 patients.

This first analysis of a huge amount of data from patients with implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapy–defibrillators (CRT-Ds) collected in a device-monitoring network also showed that a substantial number of "inappropriate" shocks that patients received might actually be clinically appropriate, Dr. Leslie A. Saxon said at the Heart Rhythm Society's annual meeting.

"We traditionally program [these devices] to just shock patients for malignant ventricular arrhythmias. But about 20% of the inappropriate shocks were for atrial fibrillation with more than 200 beats/min. The clinical appropriateness of shocks for heart rates of more than 200 bpm is an interesting question," said Dr. Saxon, chief of cardiovascular medicine at the University of Southern California, Los Angeles.

The ALTITUDE clinical science program sponsored by Boston Scientific collected data through the company's LATITUDE patient management system on 47,032 patients who received an ICD and 38,967 who received a CRT-D during 2006-2009. Dr. Saxon, chair of the ALTITUDE physician panel, said she has financial ties with Boston Scientific and several other companies that market cardiac devices.

As of February 2009, the average age of ICD patients in the database was 64 years, with an average implant duration of 40 months. The CRT-D patients were age 69 on average, with implant ages of 32 months.

In the first year of follow-up, the survival rate was 99% in the ICD patients and 96% in those with a CRT-D. These rates compare favorably with the 91%-94% survival rates with ICDs from the two major randomized, clinical trials, the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), and with the 89% survival rate with CRT-D in the major trial for that device, Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION).

The results also confirmed that patients who receive shocks have worse survival than patients who do not (see chart). During follow-up, 19,522 patients received an ICD or CRT-D shock. An adjudication committee reviewed a representative sample of 1,272 shocks. Shocks for an "appropriate" reason—a ventricular arrhythmia—occurred 57% of the time; "inappropriate" shocks made up the remaining 43%. Within that group, 83% were for atrial fib or flutter, 12% were for "noise," and 5% occurred after an appropriate arrhythmia had stopped, Dr. Saxon said. ■

Survival Rates With Cardiac Devices

Device	Number of patients	Survival Year 1	Year 2	Year 3	Year 4	After 5 years
ICD (shock free)	35,530	99%	97%	96%	94%	93%
ICD (with shocks)	11,502	99%	98%	96%	93%	90%
CRT-D (shock free)	30,947	96%	93%	90%	85%	80%
CRT-D (with shocks)	8,020	97%	92%	86%	81%	72%

Note: Based on data from 85,999 patients monitored by Boston Scientific.
Source: Dr. Saxon

ELSEVIER GLOBAL MEDICAL NEWS

Subcutaneous ICD Shows Safety, Efficacy in Early Study

BY MITCHEL L. ZOLER

BOSTON — A subcutaneously placed implantable defibrillator that doesn't use a transvenous lead showed safety and efficacy in initial clinical testing in 55 patients followed for 30 days.

The subcutaneous implantable cardioverter defibrillator (S-ICD) detected 100% of ventricular episodes during the study and had a fibrillation conversion efficacy of more than 98%, comparable to those of conventional ICDs, Dr. Ian G. Crozier said at the Heart Rhythm Society's annual meeting. The S-ICD also involves an easy and low-risk implantation without need for fluoroscopy that may reduce the risk barrier and make ICD therapy a more acceptable option for certain patients and their physicians.

The new device "is innovative and potentially very important," said Dr. Richard L. Page, head of the division of cardiology at the University of Washington in Seattle. "Being able to put in an ICD that does not require fluoroscopy or vascular access has remarkable potential for the future," he said in an interview. Avoiding vascular access means that patients "won't be as prone to intravascular infection as they are with conventional pacemakers and defibrillators."

The S-ICD is made by Cameron Health, and has taken 8 years to develop, said Dr. Crozier, a cardiac electrophysiologist at Christchurch Hospital, New Zealand. Cameron Health sponsored the study. Dr. Crozier said that his financial relationship with the company is limited to research grants and fellow support. Dr. Page said that he had no financial relationships to disclose.

The device is 69 cc in volume, weighs 145 g, and can deliver a shock of up to 80 j. It is believed to have a longevity of 5 years. It is placed through an incision at the sixth rib, over the heart's apex, and is positioned using anatomic landmarks. The three electrodes are drawn through to their locations under the skin with a tunneling tool.

The 55 patients had conventional indications for an ICD. The study excluded patients who also required pacing because the device does not have pacing capability. It also excluded patients with a left ventricular ejection fraction of 30% or less. The patient's average age was 56, 80% were men, and their average LVEF was 34%. The testing protocol was successfully completed in 53 patients, with 52 (98%) passing conversion efficacy testing. The device detected all 137 ventricular fibrillation episodes during testing and emitted a shock an average of 14 seconds after each episode began, Dr. Crozier reported.

'An ICD that does not require fluoroscopy or vascular access has remarkable potential for the future.'

DR. CROZIER

Five adverse events occurred during placement and follow-up, four of which were device related. In two cases, device malfunctions were resolved by reprogramming. The other two cases required repositioning of the leads.

The S-ICD is especially suitable for younger patients who need an ICD because they face the greatest risk from long-term placement of transvenous leads, Dr. Crozier said in an interview. ■