

Survival With Cardiac Devices Up in Recent Trials

BY MITCHEL L. ZOLER

BOSTON — Patients who received implanted cardiac devices in routine practice during recent years had much better survival rates than did patients 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 per minute. The clinical appropriateness of shocks for heart rates of more than 200 bpm is an interesting question, and intriguing data. We’re suddenly looking at data from [many] shocks; it will help us understand this field a lot better,” said Dr. Saxon, chief of cardiovascular medicine at the University of Southern California, Los Angeles. “We will rede-

fine what is an appropriate shock.”

The improved survival rate seen in the new series compared with earlier results in randomized, controlled trials might reflect differences in patient selection, improved contemporary patient management, more frequent patient monitoring, or other factors, Dr. Saxon added.

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 other companies that market cardiac devices.

As of February 2009, the average age of patients with ICDs in the database was 64 years, with an average implant duration of 40 months. The average age of the CRT-D patients was 69 years, with implants in place for an average of 32 months. Three-quarters of patients in both subgroups were men.

During the first year of follow-up, the survival rate was 99% in the ICD patients and 96% among 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) (N. Engl.

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

J. Med. 2002;346:877-83) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) (N. Engl. J. Med. 2005; 352:225-37), and with the 89% survival rate with CRT-D in the major randomized trial for that device, Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) (N. Engl. J. Med. 2004;350:2140-50).

The results also confirmed that patients who receive shocks have worse survival than do patients who remain shock free. (See box.) 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 the inappropriate group, 83% were for atrial fibrillation or flutter, 12% were for “noise,” and 5% occurred after an appropriate arrhythmia had stopped.

A final analysis presented by Dr. Saxon focused on patients who received a device during 2007-2009. Before 2007, some patients received their devices but did not enter monitoring until several months later, possibly skewing the survival findings. By 2007, the delay between device implantation and the start of monitoring was always less than 3 months. Within the most contemporary subgroup, the 1-year survival rate was still higher than in the earlier trials, with a 97% rate for ICD patients and a 94% rate for CRT-D patients, Dr. Saxon said. ■

Panel Backs Catheter Ablation for Ventricular Arrhythmias

BY MITCHEL L. ZOLER

BOSTON — An expert consensus panel that issued recommendations on catheter ablation for ventricular arrhythmias says that catheter ablation should be “considered early” in treating patients with recurrent ventricular tachycardia, with a reduced focus on first trying several antiarrhythmia drugs.

“Many of us see patients [with a ventricular arrhythmia] who are tried on a series of antiarrhythmia drugs that have a negative impact on their quality of life and are referred for ablation relatively late,” said Dr. William G. Stevenson, director of the clinical cardiac electrophysiology program at Brigham and Women’s Hospital, Boston, and cochairman of the expert panel. “We feel that earlier consideration of ablation is warranted,” usually after one antiarrhythmia drug fails, although immediate use of ablation is appropriate for patients with ventricular tachycardia (VT) storms or incessant VT, Dr. Stevenson said during a press briefing at the Heart Rhythm Society’s annual scientific sessions where the consensus recommendations were announced.

“In the past, the first step was drugs. We now know that drugs frequently fail” or are contraindicated in many patients, said Dr. Etienne M. Aliot, an electrophysiologist at Brabois Hospital in Vandoeuvre-les-Nancy, France, and cochairman of the panel. For many patients, catheter ablation is the first-line treatment because it works well.

The expert panel issuing recommendations on the use of catheter ablation for ventricular arrhythmias was organized by the Heart Rhythm Society and by the European Heart Rhythm Association. The guidelines appear in the June issue of *Heart Rhythm* (2009;6:886-933).

The recommendations from the panel represent an expert consensus opinion and don’t rise to the level of formal, evidence-based guidelines, stressed Dr. N.A. Mark Estes, president of the Heart Rhythm Society and professor and director of the cardiac arrhythmia service at Tufts Medical Center, Boston. “In most cases we don’t have good randomized, controlled trials” that clearly document the role for catheter ablation for ventricular arrhythmias and the best way to deliver the treatment, he noted.



“We feel that earlier consideration of ablation is warranted,” said Dr. William G. Stevenson (left, with Dr. Etienne M. Aliot).

In fact, catheter ablation applied to ventricles remains a developing field that until now has not had a comprehensive review of where the treatment stands.

“Over the past several years there has been a great deal of progress in catheter ablation of atrial arrhythmias, with less focus on ventricular arrhythmias, which is a smaller group of patients,” Dr. Stevenson said. “Many of the ablation technologies brought into common use [for atrial arrhythmias] are well applied to ventricular arrhythmias, but we know less about them. A goal of this con-

sensus was to bring together information that is not easily accessed in the literature.”

Demand for catheter ablation of ventricles is growing as the use of implantable cardioverter defibrillators (ICDs) grows. Dr. Stevenson estimated that about 10,000 ICDs are now implanted into U.S. patients every month.

“We know that shocks from ICDs are associated with a reduced quality of life for patients,” he said. While ICDs are seen as a valuable safety net for patients at high risk for VT and other life-threatening arrhythmias, ICD recipients generally

are also treated to reduce their risk for VT episodes and shocks, a process that often involves catheter ablation.

Dr. Stevenson also highlighted the growing availability of catheter ablation for ventricular arrhythmia. The expert document noted that “catheter ablation outcomes derive from single-center studies. In most cases, these studies reflect the experience of large academic centers, the outcomes of which may or may not be replicated by smaller centers.” Despite this, “catheter ablation is increasingly done throughout the world,” with increasing numbers of electrophysiologists trained in the techniques, Dr. Stevenson said.

The expert panel was unable to reach a consensus on what constitutes adequate training for cardiologists performing catheter ablation of ventricular arrhythmias. In part, that was because the panel recognized that in the United States the American Council on Graduate Medical Education has guidelines in place for credentialing physicians in electrophysiology based in part on their experience with catheter ablation, although not specifically for ablation of VT, Dr. Stevenson said in an interview. ■