of dormant PV conduction represents an important intervention to reduce AT and that adenosine should be routinely used to identify and guide the elimination of dormant conduction during PV isolation in patients with paroxysmal AF.

AF Patients With Contraindications to Oral Anticoagulation Therapy Treated Successfully With LAA

Written by Phil Vinall

Randy Lee, MD, PhD, University of California, San Francisco, San Francisco, California, USA, reported follow-up results of the Study of Left Atrial Appendage Closure in Patients With Atrial Fibrillation III [PLACE III; NCT01680757] in patients who underwent left atrial appendage (LAA) ligation with the LARIAT Suture Delivery Device (SentreHEART, Redwood City, California). Dr. Lee believes that the low incidence of access complications and embolic events in this high-risk atrial fibrillation population suggests that LAA ligation may be a treatment option for the prevention of thromboembolic complications in patients with contraindications to oral anticoagulation therapy.

The purpose of this multicenter observational study was to assess the procedural and 30-day periprocedural safety of LAA closure with the LARIAT device. Long-term clinical end points included first event of stroke (ischemic, hemorrhagic, or undefined) or systemic embolism and stroke, systemic embolism, or death of any cause.

The study cohort consisted of 143 consecutive patients with nonvalvular AF, ≥18 years of age, with $CHADS_2$ scores ≥1, and with life expectancies ≥1 year who were not candidates for oral anticoagulation therapy. Patients underwent LAA ligation with the LARIAT device between December 2009 and November 2012. LAA closure was verified by left atrial angiography and transesophageal echocardiography. Patients received aspirin, aspirin with clopidogrel, or no antiplatelet therapy after LAA ligation. No patients were treated with oral anticoagulation therapy following LAA ligation.

The average age of the cohort was 67 years, and the majority of patients were male. Clinical characteristics were as follows: 24% had heart failure, 95% hypertension, and 32% prior stroke or transient ischemic attack; the mean $CHADS_2$ score was 2.4±1.2; the mean $CHADS_2$-VASc score was 3.6±1.8; the mean HAS-BLED score was 2.8±1.2; and the mean follow-up duration was 2.2±1.1 years. Successful closure was obtained in 99.3% of patients (n=138).

Clinical outcomes at follow-up included 4 strokes (2 embolic/ischemic strokes) and 6 deaths (1 procedural). The incidence of stroke, embolism, or death was 3.3% per year. The mean $CHADS_2$ score of the cohort was 2.4; previous studies have suggested that a cohort with this $CHADS_2$ score would be expected to have an incidence of stroke or systemic embolism of approximately 6.2%; however, in the patients treated with LAA ligation in this study, the incidence of stroke or systemic embolism was 1.3% per year [Gage BF et al. *Circulation* 2004; *JAMA* 2001].

Procedure-related adverse events included pericardial effusion (n=1), pulmonary embolus (n=1), periprocedural death (n=1), and cardiac perforation (n=2). Inflammation-related adverse events included pericarditis (most initially; n=8), late hemopericardium (n=1), later pericardial effusion (n=1), and left atrial thrombus (n=2).

These findings suggest the need for prospective, appropriately powered, randomized stroke studies in patients with atrial fibrillation with contraindications or intolerance to oral anticoagulation therapy to assess the efficacy of LAA ligation.

RM of Implantable Cardiac Devices Is Associated With Improved Survival

Written by Emma Hitt, PhD

Use of a remote monitoring (RM) program in patients with an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy–defibrillator (CRT-D) was associated with increased survival, regardless of device type and socioeconomic status. Suneet Mittal, MD, Valley Health System of New York and New Jersey, New York, New York, USA, presented data from a study of adherence to remote monitoring of patients with a pacemaker or defibrillator.

A previous study demonstrated that enrollment in a remote monitoring program was associated with improved survival in patients with an ICD or cardiac CRT-D [Saxon LA et al. *Circulation* 2010]. The purpose of this current study was to examine the association between adherence to remote monitoring and survival and to explore potential mechanisms between remote monitoring and improved outcomes.

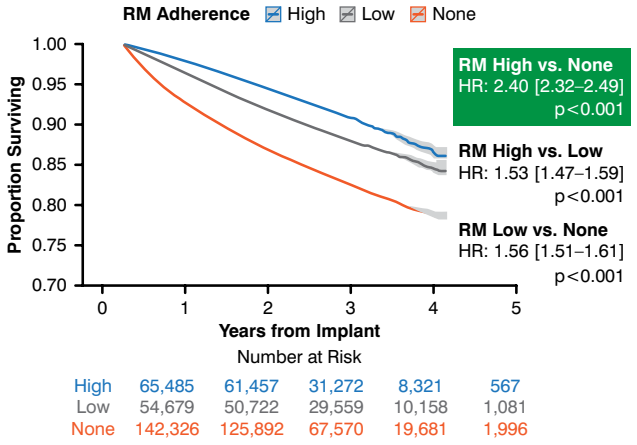
In this prospective observational cohort study, patients (n=262,562) with a wireless pacemaker, CRT-pacemaker, ICD, or CRT-D device capable of remote monitoring with the Merlin.net Patient Care Network were followed from device implantation (between 2009 and 2011) to follow-up (up to November 2012). Device-tracking data included age, sex, implant date, device type, follow-up duration, and postal zip code. US Census data were used to link zip

code to race, education level, employment status, health care insurance, median income, use of food stamps, and urban/rural classification.

The utilization of remote monitoring by patients was assessed weekly with Merlin.net. Adherence was defined as the number of total follow-up weeks that included a status transmission. Remote monitoring adherence was categorized as high (≥75%), low (between 0% and 75%), and none. The primary end point of interest was all-cause mortality.

A larger proportion of patients with high utilization of remote monitoring survived when compared to patients with low utilization of remote monitoring (HR, 1.53; 95% CI, 1.47 to 1.59; p<0.001) or no utilization of remote monitoring (HR, 2.40; 95% CI, 2.32 to 2.49; p<0.001; Figure 1). In addition, patients with low adherence to remote monitoring were more likely to survive than patients who did not utilize remote monitoring (HR, 1.56; 95% CI, 1.51 to 1.61; p<0.001). Remote monitoring adherence was associated with increased survival regardless of device type.

Figure 1. Proportion of Surviving Patients According to RM Adherence



RM=remote monitoring.

Reproduced with permission from S Mittal, MD.

In the United States, adherence rates were highest in the Midwest, South (excluding Florida), and the Pacific Northwest. In contrast, the lowest adherence rates appeared to be in the Northeast, the Chicago area, southern Florida, and California. Socioeconomic factors, such as unemployment, lack of health care insurance, use of food stamps, earnings below the poverty line, education level, and having a telephone, were not associated with adherence to remote monitoring.

In conclusion, Dr. Mittal stated that the data from this study showed that adherence to remote monitoring is associated with improved survival, irrespective of the type of implanted device. He highlighted that patients with high adherence to remote monitoring were associated with improved survival rates when compared with patients with either low or no adherence to remote monitoring. Dr. Mittal indicated that the results of this study suggest that adherence to remote monitoring is important.

No Defibrillation Testing Best for ICD Implantation

Written by Emma Hitt, PhD

Defibrillation testing does not improve the efficacy of first shock after implantable cardioverter defibrillator (ICD) placement, nor does it decrease all-cause mortality. Jeffrey S. Healey, MD, McMaster University, Hamilton, Ontario, Canada, presented data from the Shockless Implant Evaluation trial [SIMPLE; NCT00800384].

Although defibrillation testing is typically performed when an ICD is implanted, it can lead to serious complications (eg, refractory ventricular fibrillation/ventricular tachycardia) or death. In addition, the efficacy and safety of defibrillation testing is controversial, and it has not showed improved outcomes. The SIMPLE trial tested the hypothesis that intraoperative defibrillation testing is noninferior to no defibrillation testing following ICD implantation. In addition, it was expected that no testing would decrease the rate of serious perioperative complications at 30 days and would not increase all-cause mortality.

In this multicenter single-blind trial, 2500 patients undergoing an initial transvenous ICD implantation were randomly assigned to undergo defibrillation testing or no defibrillation testing. Exclusion criteria included a planned right-sided implant, ICD pulse generator replacement, and placement on the active cardiac transplant list. The mean age was 62 years, with 81% male and 64% to 66% with coronary artery disease. Other conditions included dilated cardiomyopathy (31% to 33%), hypertrophic cardiomyopathy (3% to 4%), and long QT, Brugada, or catecholaminergic polymorphic ventricular tachycardia (2%); 50% to 52% had previously undergone percutaneous coronary intervention or coronary artery bypass. In addition, the mean left ventricular ejection fraction was 32%, and 23% of patients had a history of atrial fibrillation. The mean follow-up was 3.1 years.

The primary efficacy outcome was a composite of ineffective first appropriate clinical shock or arrhythmic death. Secondary safety outcomes included rate of serious perioperative complications at 30 days and all-cause mortality. For protocol adherence, 4.5% in the