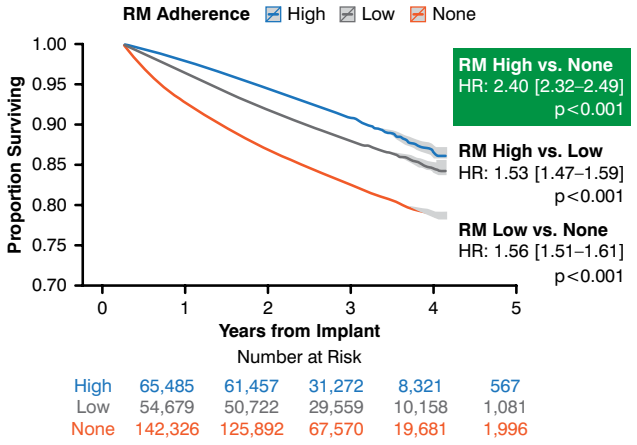
code to race, education level, employment status, health care insurance, median income, use of food stamps, and urban/rural classification.

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.

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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.

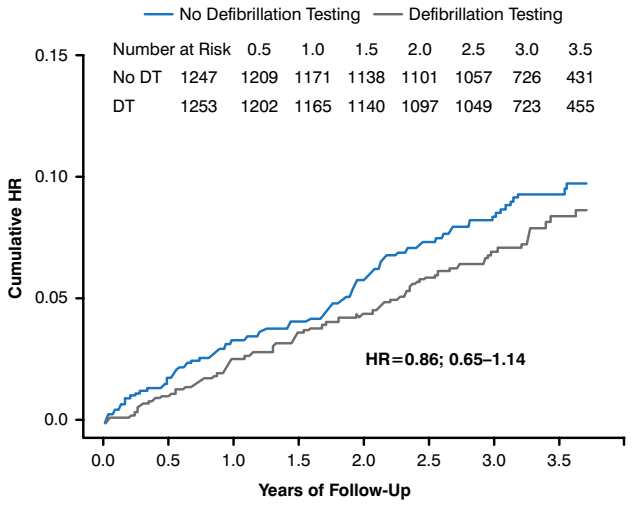
The primary efficacy outcome was a composite of ineffective first appropriate clinical shock or arrhythmic death. Secondary safety outcomes included rate of serious perioperative complications at 30 days and all-cause mortality. For protocol adherence, 4.5% in the

no–defibrillator testing arm and 8.5% in the defibrillator testing arm had clinical shock programming >31 J.

Patients who did not undergo defibrillation testing had similar rates of ineffective first appropriate clinical shock or arrhythmic death when compared to patients treated with defibrillation testing (HR, 0.86; 95% CI, 0.65–1.14; p=0.0001 noninferiority; Figure 1). In addition, the first appropriate ICD shock was likely to be successful in the no–defibrillation testing arm as compared with the defibrillation testing arm (p=0.08). However, there was no significant difference in the first shock success for monomorphic or polymorphic ventricular tachycardia. There was no significant difference in all-cause mortality between the study arms. Similar findings were seen across the other subgroups presented (Figure 2).

As compared with the no–defibrillation therapy arm, significantly more patients in the group treated with defibrillation therapy had death, stroke, non–central nervous system systemic embolism, pulmonary embolism, myocardial infarction, heart failure, intraoperative hypotension, need for chest compression, or nonelective intubation (4.5% vs 3%; p=0.047).

Figure 1. Effect of No Defibrillator Testing During Implantable Cardioverter Defibrillator Implantation on Failed Appropriate Shock or Arrhythmic Death



DT=defibrillator testing.

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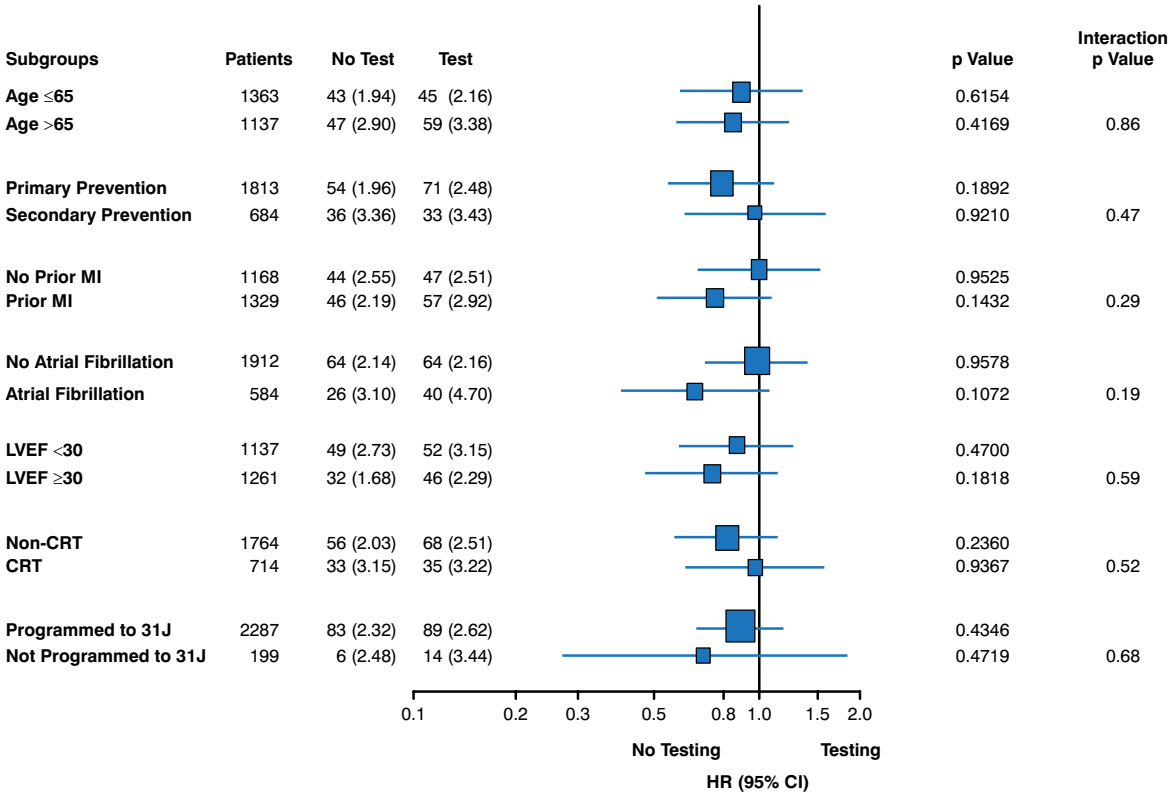
Figure 2. Subgroup Analysis of the Primary Outcome in the SIMPLE Trial



CRT=cardiac resynchronization therapy; LVEF=left ventricular ejection fraction; MI=myocardial infarction.

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Dr. Healey concluded that the SIMPLE trial did not suggest that defibrillation testing improves the outcomes of patients undergoing ICD implantation.

Promising and Feasible: Leadless Cardiac Pacing

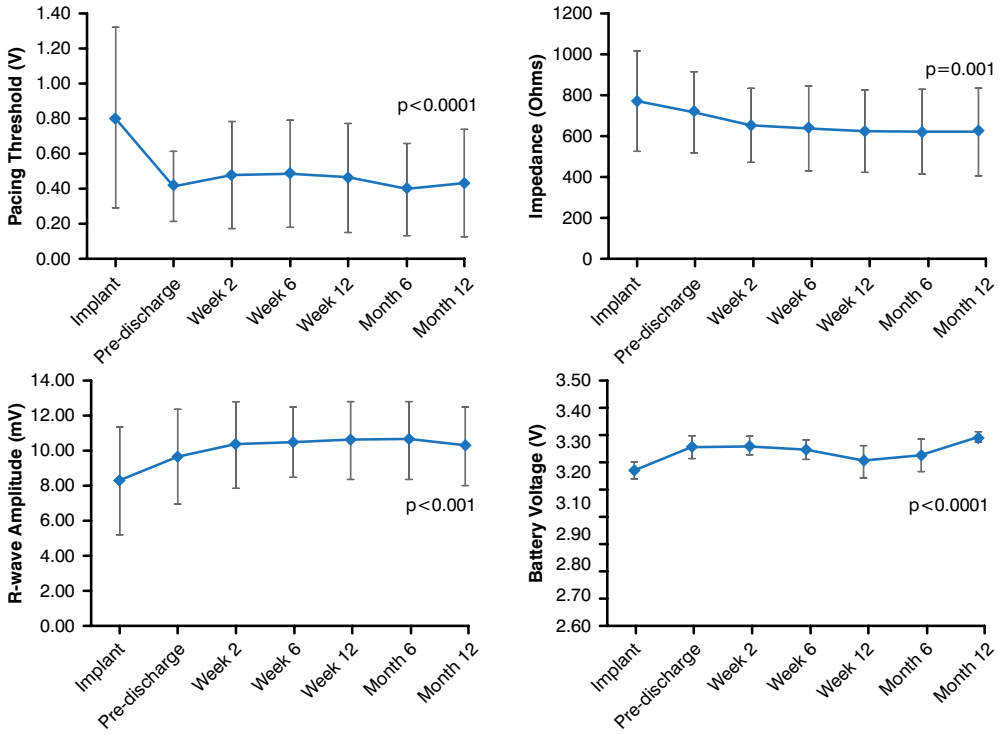
Written by Maria Vinall

Implantation of a leadless cardiac pacemaker (LCP) offers the potential to eliminate the need for the pocket, generator, and connections in most pacemaker systems—the transvenous lead subcutaneous pocket, subcutaneous pulse generator, and intra-system connections. Vivek Y. Reddy, MD, Mount Sinai School of Medicine, New York, New York, USA, reported that permanent leadless cardiac pacing is safe and feasible at 1 year after implantation in patients with an indication for single-chamber (ventricular) pacing. The leadless cardiac pacemaker contains a pulse generator and sensing or pacing electrodes within a single, miniaturized unit.

In this prospective, nonrandomized Evaluation of a New Cardiac Pacemaker study [LEADLESS; Reddy VY et al. *Circulation* 2014], 33 patients received the Nanostim LCP. The device was delivered to the right ventricle using a deflectable delivery catheter and affixed to the myocardium using a distal single-turn (screw-in) steroid-eluting helix. The mean age of the patients was 77±8 years, and 67% were male (n=22). Permanent atrial fibrillation with atrioventricular block was the most common reason for cardiac pacing (n=22; 67%). The mean procedure duration was 28±17 minutes, and the average time to hospital discharge was 31±20 hours. The overall complication-free rate was 94% (n=31). Five patients (15%) required the use of more than 1 leadless cardiac pacemaker during the procedure. One male patient sustained right ventricular perforation and cardiac tamponade during implantation; although this was successfully surgically repaired, he ultimately died approximately 1 week later from an AF-related stroke. The implant success rate was 97% (32/33).

After 1 year, the measures of pacing performance (sensing, impedance, and pacing threshold) either improved or were stable within the accepted range. Pacing threshold was 0.43±0.30 V (p<0.0001), R-wave amplitude was 10.32±2.23 mV (p=0.001), impedance was 627±209 ohms (p=0.001), and battery voltage was 3.29±0.02 V (p<0.0001). The p values were derived from a comparison between that measured at 12 months and at time of implantation (Figure 1).

Figure 1. Pacing and Sensing Parameters



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