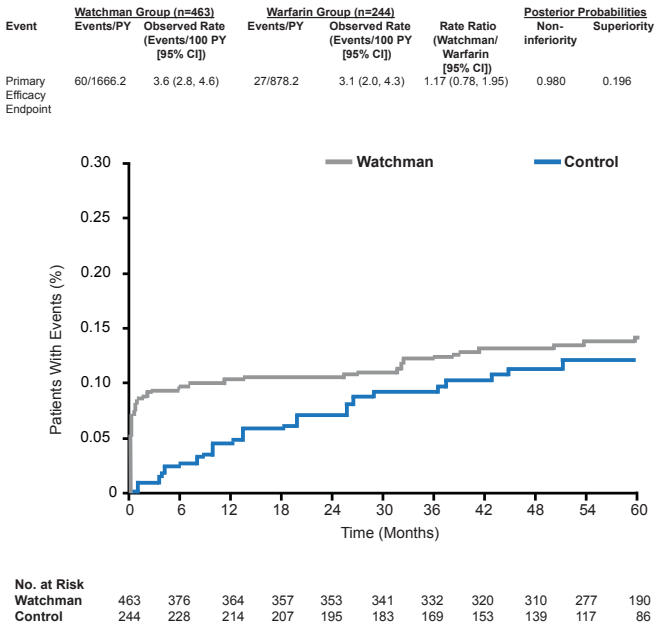
Figure 3. Primary Safety Endpoint

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"Over the course of more follow-up, we see that the amount of benefit hasn't really changed; what has changed is our certainty of this benefit really being true," stated Dr. Reddy.

## First-in-Man Results Show That a Leadless Catheter Pacemaker Is Feasible, Safe, and Effective

Written by **Mary Beth Nierengarten**

Results of a first-in-man study of a novel intracardiac leadless catheter pacemaker (LCP) show its feasibility, safety, and efficacy for right ventricular (RV) pacing, reported study investigators.

Although conventional pacemakers are safe and effective, complications related to lead and generator pocket remain problematic. Each year, it is estimated that chronic lead-related problems affect 65,000 of the over 4.4 million people worldwide with pacemakers.

In an attempt to eliminate the complications related to the lead in conventional pacemakers, a novel percutaneously-delivered LCP was developed for implantation in the right ventricle with a battery life of at least 8 years.

In the prospective, nonrandomized, single-arm LEADLESS study [NCT01700244] conducted at three sites, Vivek Reddy, MD, Mount Sinai School of Medicine, New York, New York, USA, and colleagues evaluated the *in vivo* implantation of the LCP for the first time in 33 patients who required a permanent rate modulated ventricular-based pacemaker. All patients included in the study had documented evidence of chronic atrial fibrillation (AF), normal sinus rhythm with second or third degree atrioventricular block and a low level of physical activity or short expected lifespan, or sinus bradycardia; were aged ≥18 years; had a life expectancy of at least 1 year; and were not pacemaker dependent.

Overall, the mean age of the patients included in the study was 75 years (range, 53 to 91 years), 64% were male, and most had sinus rhythm with low activity or short lifespan (60%) followed by chronic AF and second- or third-degree block (28%) and infrequent pauses or unexplained syncope (24%).

Implantation of the LCP was done by affixing the LCP to the endocardium with a single-turn helix, with a docking feature for repositioning and retrieval capability at the proximal end of the LCP. Implantation was done in the right ventricle by femoral venous access using a deflectable delivery catheter under x-ray guidance. Prior to release, baseline pacing and sensing thresholds were determined and the device was repositioned if these thresholds were suboptimal.

The pacemaker works by increasing the pacing rate with increased metabolic demand by sensing the RV blood temperature.

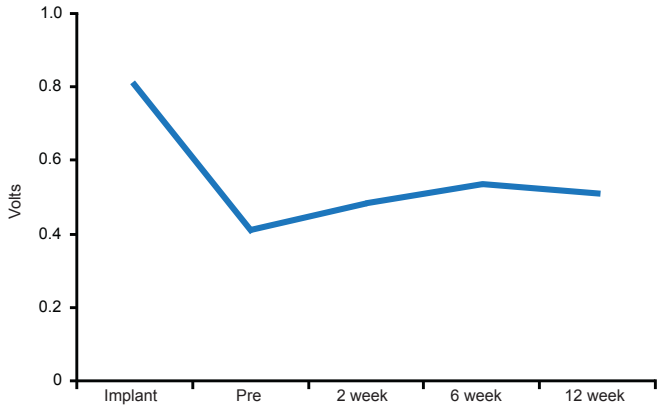
Evaluation of the primary endpoint (ie, safety) and secondary performance endpoints (ie, RV pacing function, battery longevity, rate response, implant success rate, and implant times) were done at 2 days, 2 weeks, 6 weeks, and 3 months after implantation.

Overall, 32 of the 33 (97%) of the patients were implanted successfully with the LCP. The time from procedure to hospital discharge was a mean of 1 day (range, 1 to 4 days).

The study found no major safety complications related to femoral access, with only one minor groin hematoma that did not require treatment. One patient also had a cardiac perforation and tamponade that was surgically repaired, but the patient had a large right-sided stroke 5 days after surgery and died.

The performance of the device was demonstrated in data that showed pacing threshold changes over time (Figure 1), R-Wave amplitude changes over time, and impedance changes over time, that were similar to those expected to be seen in conventional pacemakers. Overall, pacing was achieved in ~40% of patients.

Figure 1. Leadless Catheter Pacemaker Pacing Threshold Changes Over Time

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Based on these results, the investigators concluded that leadless RV cardiac pacing is feasible and raises the possibility of eliminating lead from pacemakers. According to Dr. Reddy, commercial access of the LCP for clinical use is expected in Europe later this year, and a large multicenter study of the LCP in the United States is set to begin by sometime next year. In addition, an atrial LCP to allow for multichamber cardiac pacing is currently in development.

## Reablation Superior to Antiarrhythmic Drug Therapy After a Failed Ablation Procedure

Written by **Maria Vinall**

A second catheter ablation is superior to antiarrhythmic drug (AAD) therapy for reducing the progression and prevalence of atrial fibrillation (AF) after an initial failed pulmonary vein isolation (PVI) ablation for paroxysmal AF. In this randomized comparison of reablation and AAD therapy, reported by Jonathan S. Steinberg, MD, Valley Health System, Columbia University, New York, New York, USA, progression to AF was substantial and progression to persistent AF not uncommon with AAD therapy but much less after redo ablation.

This was a prospective, randomized (1:1), active-controlled, parallel-arm trial in patients with recurrent symptomatic paroxysmal AF after a blanking period of initial PVI ablation procedure. An implantable loop recorder (ILR) was inserted in all patients. In the reablation arm, the endpoint of ablation was complete PVI at which point no additional ablation was undertaken unless an induced sustained atrial tachyarrhythmia (AT) was found. In the AAD arm, patients received either propafenone (450 to 900 mg/day), flecainide (200 to 400 mg/day), or sotalol (160 to 320 mg/day) at the discretion of the investigator instead of a second ablation.

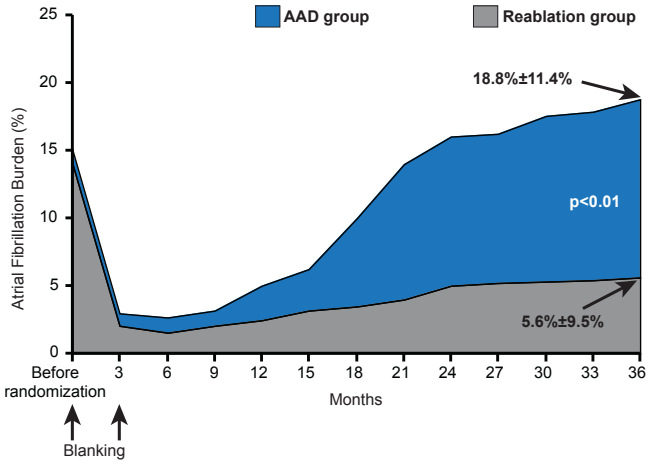
Primary endpoint was the average AF burden on ILR calculated every 3 months. Secondary endpoints included freedom from recurrence of any AT (AF, flutter, etc), progression to persistent AF (≥7 days), progression of symptomatic AF prompting need for another ablation, and procedural complications and AAD adverse events.

Seventy-seven patients were randomized into each treatment arm. There were no baseline characteristic differences. Patient ages ranged between 49 and 64 years, 30% were hypertensive, most had a $CHADS_2$ score of <1 and a left ventricular ejection fraction between 51% and –63%. The mean duration of AF was ~4 years and the mean left atrial diameter was 45 mm. The majority (80%) of patient in the ADD arm received propafenone (mean 579±205 mg/day).

In the reablation group, PVI was accomplished in all 77 patients and no additional ablation was performed other than the repeat PVI. AAD therapy was discontinued in all patients at 6 weeks post ablation.

The baseline AF burden was similar (~15%) for both groups. During the blanking period both groups experienced a dramatic decline in AF burden. After 3 to 6 months, the AF burden began to increase, and reached 18.8%±11.4% in the AAD group and 5.6%±9.5% in reablation group at 36 months. This difference was significant (p<0.01; Figure 1).

Figure 1. Primary Endpoint




AAD=antiarrhythmic drug.

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Freedom from AF/AT was significantly (p<0.0001) greater for the reablation group. At the end of the study only 12% of patients in AAD group were free of AF/AT compared with 60% in the reablation group (Figure 2).