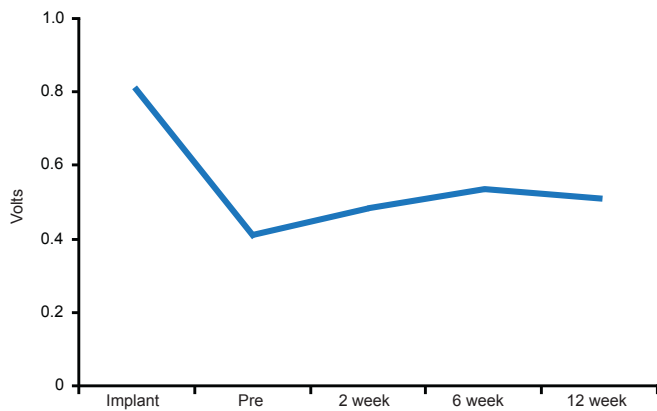




CLINICAL TRIAL HIGHLIGHTS

Figure 1. Leadless Catheter Pacemaker Pacing Threshold Changes Over Time



Reproduced with permission from VY Reddy, MD.

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 Vinal

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 sotalolol (160 to 320 mg/day) at the discretion of the investigator instead of a second ablation.

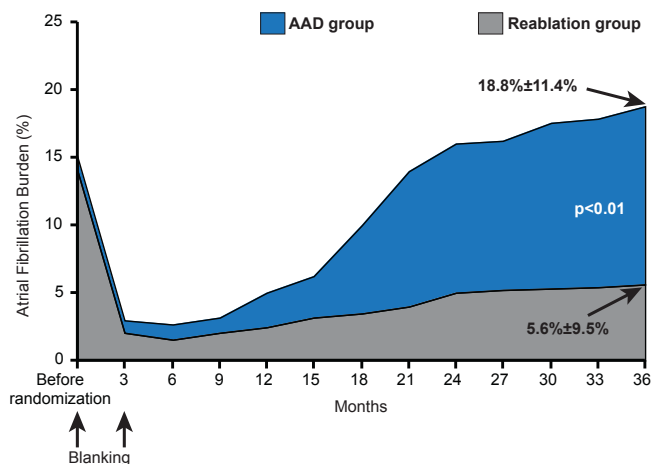
Primary endpoint was the average AF burden on ILR calculated every 3 months. Secondary endpoints included freedom from recurrence of any AT (AF, flutter, etc), progression to persistent AF (≥ 7 days), progression of symptomatic AF prompting need for another ablation, and procedural complications and 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 CHADS₂ score of <1 and a left ventricular ejection fraction between 51% and $\sim 63\%$. 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 ($\sim 15\%$) 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 $18.8\% \pm 11.4\%$ in the AAD group and $5.6\% \pm 9.5\%$ in reablation group at 36 months. This difference was significant ($p < 0.01$; Figure 1).

Figure 1. Primary Endpoint

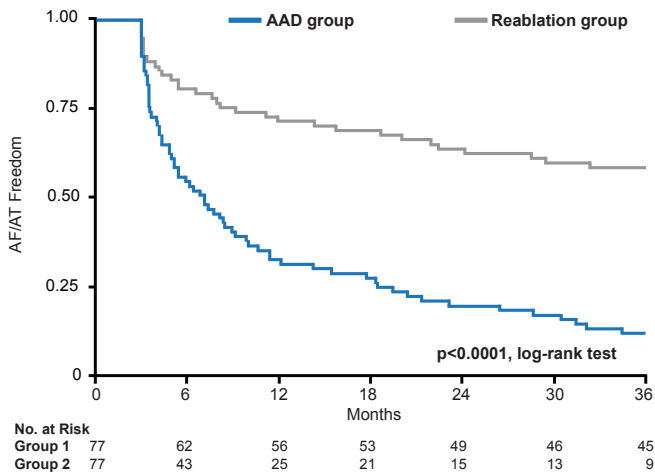


AAD=antiarrhythmic drug.

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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).

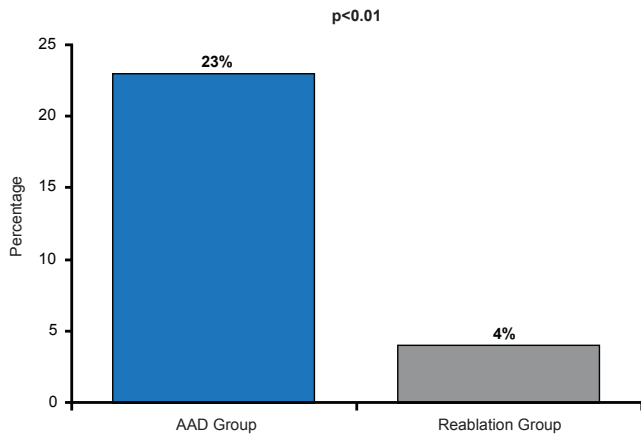
Figure 2. Secondary Endpoint: Freedom From AF/AT



AAD=antiarrhythmic drug; AF=atrial fibrillation; AT=atrial tachyarrhythmia. Reproduced with permission from JS Steinberg, MD.

Progression to persistent AF was also significantly less ($p < 0.01$) in the reablation group (4% of patients) versus 23% in the AAD group (Figure 3).

Figure 3. Secondary Endpoint: Progression to Persistent AF



AAD=antiarrhythmic drug; AF=atrial fibrillation. Reproduced with permission from JS Steinberg, MD.

In the AAD arm, 64% ($n=49$) of patients discontinued therapy because of intolerance and/or inefficacy, while 3% ($n=2$) patients experienced cardiac tamponade in the reablation arm.

Dr. Steinberg concluded by saying, “Reablation targeting restoration of PVI should be strongly considered when patients respond inadequately to the initial ablation.”

Improving Clinician Adherence to Evidence-Based Recommendations Reduces Unnecessary ICD Shocks

Written by Mary Beth Nierengarten

Late-breaking results from the prospective Shock-Less study indicated that providing clinicians with reports about implantable cardioverter defibrillator (ICD) programming improved adherence to shock-reduction guidelines in real-world practice settings, and significantly reduced the risk of unnecessary ICD shocks in patients. Marc T. Silver, MD, WakeMed Physician Practices, Raleigh, North Carolina, USA, presented the findings.

A total of 4131 patients implanted with a single- or dual-chamber ICD or cardiac resynchronization therapy defibrillator system participated in the study from 2009 to 2012 across 118 international sites. Most patients (85%) were treated with ICDs for primary prevention, with a median follow-up of 22 months after enrollment. After a period of 9 to 12 months, clinicians who programmed ICD shock parameters received therapy reports specific to their clinical sites and patient populations. The reports compared clinicians’ programming habits with the targets established in the evidence-based recommendations. These targets included the number of intervals to detect ventricular fibrillation, the longest treatment interval, supraventricular tachycardia discriminators, antitachycardia pacing, and a Lead Integrity Alert (Table 1).

Table 1. Evidence-Based Programming Targets

Programming Parameter	Evidence-Based Target	Source
VF NID (PP)	30/40	PREPARE, RELEVANT
VF NID (SP)	18/24+	PainFREE II
LTI (PP)	329-330 ms	PREPARE, RELEVANT
LTI (SP)	340-360 ms	PainFREE II
Wavelet	ON	WAVE
PR Logic	ON	Wilkoff et al.
SVT Limit	≤300 ms	EMPIRIC, PREPARE
LIA	ON	Swerdlow et al.
ATP	ON to ≤240 ms	PainFREEm ENTRUST, EMPIRIC, PREPARE

ATP=antitachycardia pacing; LIA=lead integrity alert; LTI=longest treatment interval; NID=number of intervals to detect; PP=primary prevention; SP=secondary prevention; SVT=supraventricular tachycardia; VF=ventricular fibrillation.

Clinicians programmed devices at their own discretion; appropriate or inappropriate shock episodes were determined by an independent committee.

The control group (Group 1; $n=2693$) consisted of patients who were implanted before the clinician received