This was a nonrandomized, prospective, 6-center study in Europe in patients who met current guidelines for CRT but were considered CRT failures due to lead issues or nonresponse to CRT. The primary safety end point was safety during the 24-hour perioperative period, and the primary performance end point was safety and pacing at 1 month. Secondary end points at 6 months were safety, performance, and preliminary efficacy.

A total of 39 patients completed enrollment and screening. Implantation was attempted in 35 participants, 34 (97.1%) of which were successful. All implanted patients completed the 1-month follow-up; 26 patients completed the 6-month follow-up. Participants (88% men) were mean age 65.5 years with a mean ejection fraction (EF) of 26% and mean NYHA class of 2.6. At baseline, the mean intrinsic pre-implant QRS duration was 170 ms. About two-thirds of the patients were on anticoagulants prior to their implant. The most common reason for implantation was the inability to perform coronary sinus pacing.

There were a total of 4 procedure-related events in 4 patients (11.4%) during the <24-hour perioperative period: groin fistula, which was surgically repaired; groin pseudoaneurysm, which required no treatment; ventricular fibrillation during electrode implant; and electrode embolization to the lower leg during catheter/dilator exchange (judged both procedure and device related). Unlike an earlier terminated study that reported a 30% tamponade rate [Auricchio A et al. *Europace.* 2014], this study had no episodes of pericardial tamponade.

During the 1-month follow-up period, there were 8 events in 8 patients (22.9%), including 1 death following prolonged resuscitation. Among these, there were 6 procedure-related events, including pseudoaneurysm, hematoma at transmitter pocket, a suspected infection, and a death following prolonged resuscitation. Furthermore, there was 1 procedure- and device-related event as well as atrial fibrillation (AF) episodes in a patient with AF, although these episodes were unrelated to the procedure or device. During the 6-month follow-up, there were 3 device-related events (premature battery depletion in 3 patients [11.5%]); these events were subsequently resolved. There were also 10 comorbidity events in 5 patients (19.2%), although most were unrelated to the procedure.

At 1 month, the primary end point, consistent CRT, was met in 97.1% of evaluable patients. At 1 month, the mean QRS reductions were 50 and 37 ms, as compared with baseline right ventricular and intrinsic pacing, respectively.

At 1 month, the primary performance end point of biventricular pacing capture on 12-lead electrocardiogram was met in 33 of 34 evaluable patients (97.1%).

Table 1. Improved QRS Duration With Biventricular Pacing

	QRS Duration, ms		
Type of Pacing	**Baseline**	**1 wk**	**1 mo**
Right ventricular pacing	182	—	—
Intrinsic pacing	169	162	157
Biventricular pacing	—	133	132

Furthermore, mean QRS duration with biventricular pacing was 50 ms shorter vs baseline right ventricular pacing and 37 ms shorter than baseline intrinsic pacing (Table 1).

EF increased by ≥5% in 69.5% of patients with a mean 6-month difference from baseline of 6.7%. NYHA decreased from 2.6 at baseline to 1.8 at 6 months (61.5% of patients had a ≥1 class improvement), and 64.7% of patients had ≥15% improvement in LV end-systolic volume.

The results of the SELECT-LV study demonstrated the feasibility of direct, wireless endocardial LV pacing for CRT. Overall CRT efficacy improved with evidence of significant reductions in QRS duration, synchronous LV stimulation, electrical and structural remodeling, and improvement in LVEF. Safety results improved compared with previous studies, but more data are needed.

DECAAF: Balloon Cryoablation Results in More LA Scarring Than Other Ablation Techniques

Written by Maria Vinall

In a cohort study that used late gadolinium enhancement magnetic resonance imaging (LGE-MRI) to evaluate left atrial (LA) scarring, investigators showed that balloon cryoablation resulted in more scarring compared with point-by-point and multipolar radiofrequency (RF) ablation. These data from a cohort of the DECAAF study [Marrouche NF et al. *JAMA*. 2014] were presented in a poster by Nazem W. Akoum, MD, University of Washington, Seattle, Washington, USA.

The DECAAF study showed an independent association between atrial tissue fibrosis estimated by delayed enhancement MRI and the likelihood of recurrent arrhythmia among patients with AF undergoing catheter ablation [Marrouche NF et al. *JAMA*. 2014]. Pulmonary vein isolation (PVI) is commonly used for catheter ablation of atrial fibrillation (AF). The current cohort study used LGE-MRI to evaluate LA scarring resulting from the techniques used for PVI in the DECAAF study.

The study comprised 111 patients with paroxysmal and persistent AF who underwent PVI without additional ablation. Overall scar and pulmonary vein encirclement were compared across 3 different techniques. Point-by-point irrigated RF ablation was used in 91 patients (82.0%), duty-cycled multipolar RF ablation catheter in 8 patients (7.2%), and balloon cryoablation in 12 patients (10.8%). LGE-MRI was obtained 3 months following ablation.

The baseline characteristics of the study participants were not significantly different. The mean age of the mostly male cohort was about 68 years. The most frequent major comorbidities were hypertension, diabetes, and heart failure. Persistent AF was present in 35% of patients, mean left ventricular ejection fraction was 59%, and the mean LA volume was 99 mL. Approximately 20% of patients had evidence of atrial fibrosis.

Overall scarring was highest in the cryoablation group (13.4 ± 6.2%), followed by the point-by-point irrigated RF (10.5 ± 4.3%) and the duty-cycled multipolar RF groups (7.1 ± 2.3%; $P < .01$ for the group comparison).

Scarring completely encircling all 4 pulmonary veins occurred in 1 of 12 patients (8.3%) in the cryoablation group, 7 of 91 patients (7.7%) who received point-by-point ablation, and no patients in the multipolar RF group.

Balloon cryoablation resulted in more LA scarring compared with the other techniques. All techniques were poor in achieving complete pulmonary vein encirclement. In this cohort, neither overall scarring nor complete pulmonary vein encirclement was a significant predictor of arrhythmia recurrence.

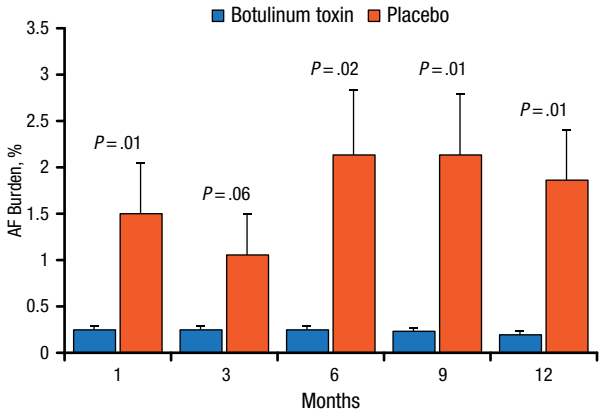
This study suggests that the type of ablation used has an impact on scarring but not necessarily on procedural success. Further, ablation of the pulmonary veins did not predict recurrent arrhythmias, supporting the findings from the DECAAF study, which suggested that rather than targeting the pulmonary veins, procedures that ablate fibrotic tissue might produce better outcomes.

Botulinum Toxin Reduced AF Burden, Heart Rate Variability at 1 Year in Pilot Study

Written by Mary Mosley

Botulinum toxin injected into the epicardial fat pads during coronary artery bypass graft (CABG) surgery significantly reduced the primary end point of atrial fibrillation (AF) events by 10% compared with placebo ($P = .024$) at 30 days in a randomized pilot study [Pokushalov E et al. *J Am Coll Cardiol*. 2014]. New results from a secondary analysis showed this benefit extended to 1 year, along with reduction in heart rate variability (HRV), according to Jonathan S. Steinberg, MD, The University of Rochester, Rochester, New York, and The Valley Health System, New York, New York, USA.

Figure 1. AF Burden With 1-Year Follow-up



AF, atrial fibrillation.

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The prospective, double-blind study was conducted in 2 centers and randomized 30 patients to botulinum toxin (type A; 50 U/1 mL per fat pad) and 30 patients to placebo (normal saline; 1 mL per fat pad). The patients were mostly men (about 80%) who were aged about 62 years and had a history of paroxysmal AF and indication for CABG using the American College of Cardiology/American Heart Association guidelines. An implantable loop recorder was placed on the day of surgery in all patients to capture AF events and burden, and data were collected at 3, 6, 9, and 12 months. Holter recordings were used to obtain serial measurements of HRV to assess the effect of botulinum toxin on the autonomic nervous system, which plays a key role in the initiation and maintenance of AF. This toxin is known to interfere with neurotransmitter release.

In the secondary analysis, there was a marked and significant reduction in AF burden with botulinum toxin vs placebo at all assessments except 3 months (Figure 1). All patients would be considered responders, stated Dr Steinberg, because they did not meet the conventional implantable loop recorder criteria for AF burden of >.5% per month. In the placebo group, 6 patients required additional drug therapy because of clinically frequent AF, and 2 patients required catheter ablation for persistent AF; there were none in the botulinum toxin group. No strokes or other serious clinical events occurred in either group.

HRV, measured as standard deviation of the NN intervals, was reduced substantially in both groups at