### CLINICAL TRIAL HIGHLIGHTS

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-bypoint 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  $(13.4 \pm 6.2\%)$ , followed by the point-by-point irrigated RF  $(10.5 \pm 4.3\%)$  and the duty-cycled multipolar RF groups  $(7.1 \pm 2.3\%; P < .01$  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.

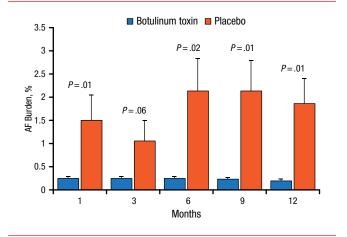
This study suggests that the type of ablation used has an impact on scarring but not necessarily on procedural success. Further, ablation of the pulmonary veins did not predict recurrent arrhythmias, supporting the findings from the DECAAF study, which suggested that rather than targeting the pulmonary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





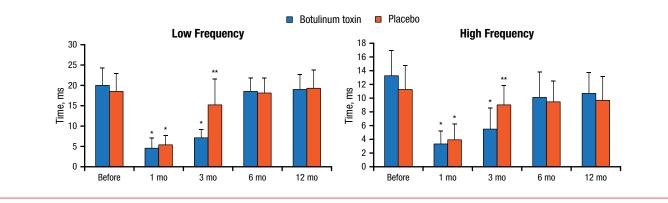
AF, atrial fibrillation. Reprinted with permission from JS Steinberg, MD.

according to Jonathan S. Steinberg, MD, The University of Rochester, Rochester, New York, and The Valley Health System, New York, New York, USA.

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



### Figure 2. Frequency of Heart Rate Variability

\*P < .05 vs baseline; \*\*P < .05 between groups.

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1 month after surgery (P < .05 vs baseline). With botulinum toxin, HRV was significantly lower at 3 months vs baseline (P < .05) and then recovered to near-baseline levels, while HRV recovered to near-baseline levels at 3 months in the placebo group and was maintained. The frequency of HRV in the patients with low and with high frequency was reduced early after surgery with botulinum toxin and placebo, with a similar pattern of rebounding to baseline levels (Figure 2).

According to Dr Steinberg, the alterations in HRV with botulinum toxin suggest there were reductions in parasympathetic and sympathetic activity, but the changes dissipated between 3 and 6 months as expected. Among the limitations of this study are the small number of patients, the lack of data on AF burden prior to surgery, no objective testing to confirm the denervation effect, and no confirmation of functional atrial remodeling or its mechanisms. Although these data suggest botulinum toxin may be a neuromodulator, large-scale trials are required to evaluate its possible value to reduce postoperative AF and in other clinical settings.

# Remote Monitoring of Cardiac Rhythm Management Reduced Hospitalization and Costs

Written by Mary Mosley

A retrospective, observational cohort study showed that remote monitoring (RM) added to clinic visits reduced hospitalization, hospital length of stay (LOS), and healthcare costs in patients implanted with any device for cardiac rhythm management (CRM), according to Jonathan P. Piccini, MD, Duke University Medical Center, Durham, North Carolina, USA. A total of 92566 patients (mean age, 72 years; 63% men) who had a CRM device implanted between April 1, 2008, and March 31, 2013, were included in the study; of these, 34259 were in the RM plus clinic visit arm, and 58307 were in the clinic visit only arm. Patients without any clinic follow-up or whose first clinic or RM follow-up was > 4 months after implant were excluded. Each clinic determined the type of follow-up for each patient. The data source was a commercial and Medicare supplemental health insurance database. All outcomes were adjusted using a boosted logistic regression propensity score that included 22 pre-implant comorbidities and age, sex, and geographic location.

More patients who received an implantable cardioverter defibrillator (ICD; 49%) or cardiac resynchronization therapy defibrillator (CRT-D; 51%) were in the RM arm than the pacemaker (PM; 29%) or CRT pacemaker (CRT-P; 27%) groups. The Charlson Comorbidity Index was 3.1 and 3.2 in the RM and no-RM arms, indicating the patients had a similar degree of comorbidity. In the RM arm vs no-RM arm, more patients had a history of heart failure (49.9% vs 44.9%) and ventricular arrhythmia (24.3% vs 15.7%), and fewer patients had atrial fibrillation (42.7% vs 46.7%) and prior cerebrovascular disease (28.1% vs 33.2%). The first clinic visit was 64 and 63 days after the implant in the RM and no-RM arms. The followup interval was  $\leq$  4 months in > 75% of patients.

The primary outcome of all-cause hospitalization for all device types was significantly lower with RM vs no RM (HR, 0.82; 95% CI, 0.80 to 0.84; P < .001). The mean LOS was 5.3 days with RM and 8.1 days with no RM (P < .001). All-cause hospitalization was lower with all device types in the RM vs no-RM arm, but Dr Piccini noted that the magnitude of this difference was greater with ICD (HR, 0.74; 95% CI, 0.71 to 0.77; P < .001) and CRT-D (HR, 0.72;

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