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Benefit of Pulmonary Vein Isolation Guided by Loss of Pace Capture on the Ablation Line

Results From a Prospective 2-Center Randomized Trial

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Objectives This study was conducted to determine if an additional procedural endpoint of unexcitability (UE) to pacing along the ablation line reduces recurrence of atrial fibrillation (AF) or atrial tachycardia (AT) after radiofrequency catheter ablation.

Background AF/AT recurrence is common after pulmonary vein isolation (PVI).

Methods We included 102 patients from 2 centers (age 63 ± 10 years; 33 women; left atrium 38 ± 7 mm; left ventricular ejection fraction 61 ± 6%) with symptomatic paroxysmal AF. A 3-dimensional mapping system and circumferential mapping catheter were used in all patients for PVI. In group 1 (n = 50), the procedural endpoint was bidirectional block across the ablation line. In group 2 (n = 52), additional UE to bipolar pacing at an output of 10 mA and 2-ms pulse width was required. The primary endpoint was freedom from any AF/AT (>30 s) after discontinuation of antiarrhythmic drugs.

Results Procedural endpoints were successfully achieved in all patients. Procedure duration was significantly longer in group 2 (185 ± 58 min vs. 139 ± 57 min; $p < 0.001$); however, fluoroscopy times were not different (23 ± 9 min vs. 23 ± 9 min; $p = 0.49$). After a follow-up of 12 months in all patients, 26 patients (52%) in group 1 versus 43 (82.7%) in group 2 were free from any AF/AT ($p = 0.001$) after a single procedure. No major complications occurred.

Conclusions The use of pacing to ensure UE along the PVI line markedly improved near-term single-procedure success, compared with demonstration of bidirectional block alone. This additional endpoint significantly improved patient outcomes after PVI. (Unexcitability Along the Ablation as an Endpoint for Atrial Fibrillation Ablation; NCT01724437) (J Am Coll Cardiol 2013;62:44–50) © 2013 by the American College of Cardiology Foundation

Because ectopy from the pulmonary veins is primarily responsible for initiation and maintenance of paroxysmal atrial fibrillation (PAF), pulmonary vein isolation (PVI) has become the standard treatment of this arrhythmia (1–3). Arrhythmia recurrence is high, however, especially during longer follow-up (4). Data suggest that dormant conduction gaps on the ablation line are the most common reasons for arrhythmia recurrence (5,6). To date, no successful strategy to decrease the likelihood of conduction gaps using point-by-point catheter ablation technology has been reported in a prospective, randomized trial. Previously published results suggest that additional radiofrequency (RF) application guided by atrial tissue excitability may be helpful to identify potential conduction gaps in atrial myocardium (7,8). The present prospective, randomized 2-center trial was conducted to evaluate whether the endpoint of unexcitability along the ablation line is as safe and more effective in preventing arrhythmia recurrence than electrical PVI alone.

The aim of the study was to assess the near-term (12 months) efficacy of PVI using a standard approach compared with application of an additional acute procedural endpoint of unexcitability along the ablation line.

Methods

Study population. A total of 103 patients (age 63 ± 10 years; 34 women; left atrium [LA] 38 ± 7 mm; left ventricular ejection fraction 61 ± 6%) referred for catheter ablation for

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symptomatic PAF who had failed at least 1 type I or III antiarrhythmic drug were included in our study. One patient withdrew written informed consent. Ablation was performed in one of 2 participating centers (University Hospital, Hamburg, Germany, or Brigham and Women's Hospital, Boston, Massachusetts) by 1 of 3 surgeons during sinus rhythm in all patients. Randomization to either study arm was conducted before the procedure based on a previously generated computer algorithm (Fig. 1). No patients had evidence of significant structural heart disease (see next section) as assessed by at least 1 imaging study such as echocardiography, computed tomography scan, or magnetic resonance imaging. Baseline parameters are shown in Table 1. There were no statistically significant differences between groups.

Study inclusion/exclusion criteria. Patients were eligible for the study if they: 1) were able and willing to give written, informed consent; 2) had a history of symptomatic PAF (episode duration <48 h; 3) had no prior electrical cardioversion in the year before study inclusion; 4) at least 1 class I or III antiarrhythmic drug had failed; and 5) presented in sinus rhythm. Exclusion criteria consisted of: 1) age <18 years; 2) structural heart disease (hypertrophic cardiomyopathy [septal thickness >13mm], left ventricular ejection fraction ≤35%, significant valvular heart disease, LA size >50 mm); 3) reversible causes of AF; 4) intracardiac thrombus; and 5) inability to take warfarin.

Electrophysiological study and ablation procedure. The patients underwent electrophysiological study and catheter ablation after providing written informed consent. Study protocols were approved by the Brigham and Women's Hospital Human Subject Protection Committee and the Ethical Board Committee of the Ethical Committee of the Medical Association, Hamburg, Germany. All antiarrhythmic drugs except amiodarone were stopped a minimum of 5 half-lives prior to the procedure.

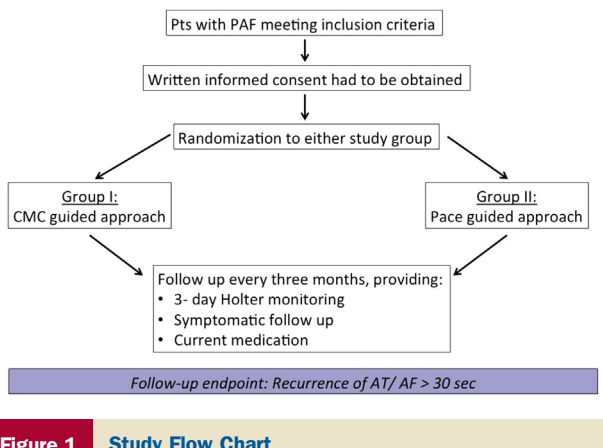

Figure 1 Study Flow Chart

AF = atrial fibrillation; AT = atrial tachycardia; CMC = circumferential mapping catheter; PAF = paroxysmal atrial fibrillation.

Abbreviations and Acronyms

AF = atrial fibrillation
AT = atrial tachycardia
CMC = circumferential mapping catheter
ECG = electrocardiogram
LA = left atrial/atrium
LAA = left atrial appendage
PAF = paroxysmal atrial fibrillation
PVI = pulmonary vein isolation
RF = radiofrequency

Surface and intracardiac electrocardiograms (ECGs) were digitally recorded and stored (Prucka CardioLab EP system, GE Healthcare, Waukesha, Wisconsin; LabSystem Pro EP recording system, BARD Electrophysiology, Lowell, Massachusetts). Nonfluoroscopic 3-dimensional mapping was performed using the Carto (Biosense Webster, Diamond Bar, California) or Ensite NavX (St. Jude Medical, St. Paul, Minnesota) system at the operator's discretion.

A 7-F multipolar (20-pole) catheter (Daig DuoDeca 2-10-2, St. Jude Medical, or Ismus, Biosense Webster) was used with the distal poles (poles 1 to 10) placed within the coronary sinus and the proximal electrodes (poles 11 to 20) located along the tricuspid annulus in the lateral and inferior right atrium. In some cases, the duodecapolar catheter was introduced through a long guiding sheath (Convoy 55° curve, Boston Scientific, Natick, Massachusetts) to facilitate placement and stability. Alternatively, a 6-F decapolar catheter (St. Jude Medical) was placed within the coronary sinus. A 10- or 20-pole circumferential PV mapping catheter (Optima, Irvine Biomedical, Irvine, California, or Lasso, Biosense Webster) was positioned at the ostium of one of the ipsilateral PVs, usually the superior vein, either before or after PVI. To avoid potential bias with respect to conduction breakthrough prior to PV entrance block, the circumferential mapping catheter (CMC) signals were continuously recorded but not displayed to the operators during deployment of the ablation line or until atrial tissue directly on this line was rendered unexcitable to pacing. The electrogram signals from the CMC were then reviewed, and the catheter was positioned to sequentially assess electrical isolation of the ipsilateral PVs. Entrance block into PVs was confirmed by the complete absence of PV potentials and/or by retrospective review of the PV signals after each ablation lesion to determine when entrance block was achieved. If far-field potentials were seen on the CMC, direct pacing of the suspected far-field source was performed for confirmation. Pacing along the ablation line was performed with careful attention to avoid parallel orientation of the ablation catheter tip to the tissue; this prevented inadvertent pace capture from the proximal electrode of the distal bipole. During LA ablation, heparin was administered intravenously to maintain an activated clotting time of >300 s.

Ablation was performed using an open-irrigated 3.5-mm tip mapping and ablation catheter (Thermocool, Biosense Webster) advanced into the LA via a long sheath (SL0, 8-F, St. Jude Medical) to mechanically support the ablation catheter. Ablation lesions were generated in a power-controlled mode applying 10 to 40 W for 30 to 60 s per