Focal impulse and rotor modulation as a stand-alone procedure for the treatment of paroxysmal atrial fibrillation: A within-patient controlled study with implanted cardiac monitoring

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BACKGROUND Focal impulse and rotor modulation (FIRM) has been proposed as a novel approach for the treatment of atrial fibrillation (AF).

OBJECTIVE This study aimed to investigate the efficacy of FIRM as a stand-alone procedure for the treatment of paroxysmal AF.

METHODS A total of 27 patients with paroxysmal AF underwent sequential biatrial computational mapping. Sites with repetitive centrifugal or spiral reentry-like activity were considered to be AF-sustaining sources and targeted by irrigated radiofrequency (RF) ablation. All patients were seen in the outpatient clinic after 1, 3, and 6 months and thereafter every 6 months. Cardiac monitors were implanted 3 months before ablation in 17 patients (63%).

RESULTS Repetitive activity interpreted as sustained AF sources was found in all patients, with an average of 3.0 ± 1.1 sources located in the left atrium and 0.6 ± 0.6 sources in the right atrium. The majority of sources were rotors (95%). The total source-ablation radiofrequency time was 20.0 ± 9.0 minutes. At 15.2 ± 3.9 months of follow-up, the prespecified end point of <1% AF burden (outside a 3-month blanking period) was achieved in 2 of the 17 continuously monitored patients (12%). Of all the 27 patients who underwent FIRM, AF episodes of ≥30 minutes were recorded in 23 (85%), while AF episodes ≥60 minutes were recorded in 21 patients (78%).

CONCLUSION This study suggest that biatrial ablation of localized patient-specific sources alone, as detected by this method, is not sufficient to reduce paroxysmal AF burden in the majority of patients.

KEYWORDS Atrial fibrillation; Mapping; Rotors; Radiofrequency; Catheter ablation

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Introduction

Pulmonary vein isolation (PVI) is the principal method for catheter ablation of paroxysmal atrial fibrillation (AF)[1–5] and aims to eliminate the trigging mechanism of AF. However, the efficacy is modest, with a single procedure success rate of 40%–70%.[5–8] Important reasons for this are that permanent PVI is difficult to achieve[5,9,10] and that triggers may be located outside the pulmonary veins.[1,11] To improve efficacy, additional lesion sets to eliminate extrapulmonary triggers and to modify the AF sustaining substrate have been used, but with no consistent benefit.[12–14] Recently, ablation of AF sustaining focal impulses and rotors, as defined by biatrial panoramic phase mapping, was introduced as a supplementary or alternative strategy to PVI for the treatment of AF.[15] In a study using this method of focal impulse and rotor modulation (FIRM), Narayan et al[16] showed a significant improvement in efficacy when combined with PVI. In a subsequent trial of FIRM as a stand-alone procedure in patients with paroxysmal AF, they[17] reported a significant reduction in AF burden. In the present study, we wanted to evaluate the independent effect of FIRM on patients with paroxysmal AF using pre- and postprocedural continuous heart rhythm monitoring.

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Methods

Study design and patients

The study included a total of 33 patients referred to our institution for catheter ablation of paroxysmal AF and represents all FIRM procedures performed between December 9, 2013 and October 30, 2014. The first 11 (33%) patients comprised a pilot study sample, of whom 10 underwent FIRM, while 1 patient was excluded because of no inducible AF at the electrophysiology (EP) study. Of the 22 (67%) patients enrolled in the main study, all had a loop recorder (Reveal XT, Medtronic, Minneapolis, MN) implanted 3 months before scheduled ablation. In 5 of these patients,

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FIRM was not performed: in 2 because of minimal AF burden during the preprocedural monitoring period; in 1 because of atrial tachycardia only at the EP study; and the last 2 included patients were reallocated to standard PVI because the study was closed because of the poor accumulated results at that point (Figure 1). In the following, the outcomes of the 27 (82%) patients who underwent FIRM for the treatment of paroxysmal AF are presented. The study was approved by the Regional Board of Research Ethics, and all patients gave written informed consent to participate in the study.

EP study and AF mapping

The EP study was performed after discontinuing antiarrhythmic medications for 5 half-lives and under conscious sedation. Each patient underwent transesophageal echocardiography to rule out left atrial (LA) thrombi. In patients presenting in sinus rhythm, AF was induced by stepwise incremental pacing, and isoproterenol was used if needed, to induce or maintain AF. Induced AF was mapped after a minimum of 10 minutes to allow the formation of stable activation patterns.

Catheters were advanced from the right femoral vein to the right atrium (RA) and coronary sinus and by double transseptal puncture to the LA. Left atriography was performed to aid basket catheter size determination. A 64-polar basket catheter (FIRMap, Topera Medical, Abbot, Abbot Park, IL) was advanced through a steerable sheath (Agilis NxT, St. Jude Medical, St. Paul, MN) for sequential mapping of the RA and LA. The basket catheter was carefully adjusted to optimize electrode contact as judged by fluoroscopy and recorded electrograms. The 64 unipolar electrograms were filtered at 0.05–500 Hz and displayed and examined on an electrophysiological recording system (Bard LabSystem PRO EP Recording system, C. R. Bard, Billerica, MA) before digital export to a mapping system (RhythmView, Topera Medical), which, by the use of a physiologically guided computational method, reconstructed the propagation pattern and displayed it as a movie projected onto a 2-dimensional grid representing the endocardial surface of the atrium studied. In the last 6 patients (22%), a 3-dimensional (3D) electroanatomic mapping system (Carto 3, Biosense Webster, Diamond Bar, CA) with a newly developed feature for displaying the basket catheter was used to simplify the process of localizing the sources, defining the target area, and to increase the precision of the radiofrequency (RF) lesion sets (Figure 2). A skilled FIRM operator was on site for the first 4 pilot study patients, and technical representatives from Topera Medical were present for all cases and helped to determine the presence and location of AF sources to be targeted.

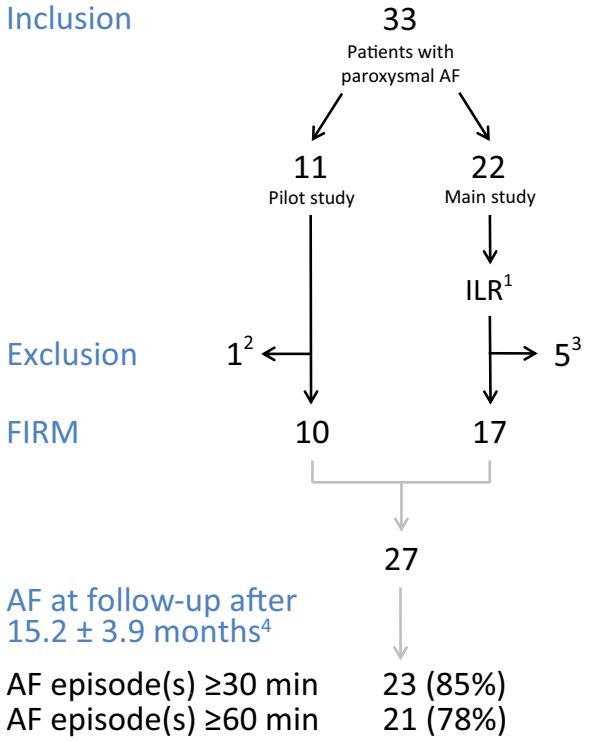

Figure 1 Study design and follow-up with main results. Superscript 1 indicates implantable loop recorder (ILR) implanted 3 months before source ablation; superscript 2 indicates exclusion due to no inducible atrial fibrillation (AF) at the electrophysiology (EP) study; superscript 3 indicates exclusion due to minimal AF burden (2 patients), atrial tachycardia only at the EP study (1 patient), and reallocation to pulmonary vein isolation (2 patients); and superscript 4 indicates documented AF episodes during follow-up outside the 3-month blanking period. FIRM = focal impulse and rotor modulation.

Ablation of localized sources

Locations displaying rotors (clockwise or counterclockwise rotational activation patterns) or focal impulses (centrifugal activation patterns) were considered AF-sustaining sources only if they showed a repetitive pattern with limited spatial variability. The rotors and foci were then targeted by RF ablation using a 3.5-mm irrigated tip catheter (NaviStar ThermoCool, Biosense Webster) advanced to the RA through a standard long sheath (Preface, Biosense Webster). RF energy output was limited to 30 W with a maximum temperature of 48°C. The catheter was irrigated with heparinized saline infused at a rate of 20 mL/min during RF application, otherwise 2 mL/min. RF energy was produced by a standard generator (Stockert EP Shuttle, Biosense Webster). RF energy was then applied at each source region (typically 1–2 cm^2) until it was eliminated as judged by repeated mapping. Mapping was then performed in the LA. If AF was still ongoing after ablation of the LA sources, RA mapping was repeated. If no additional sources were found, the patient was converted to sinus rhythm pharmacologically or electrically. If typical atrial flutter had been recorded during the procedure, ablation resulting in bidirectional cavotricuspid isthmus block was performed.

Patients were on oral anticoagulant therapy for at least 1 month before the procedure. In patients anticoagulated with warfarin, the international normalized ratio was required to be between 2.0 and 3.0 on the day of the procedure, while dabigatran, rivaroxaban, or apixaban was held for 24 hours before the procedure. Before insertion of the basket catheter,