Use of electrical coupling information in AF catheter ablation: A prospective randomized pilot study

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BACKGROUND Catheter contact is important for radiofrequency (RF) ablation. Local electrical catheter-to-tissue coupling has been described as a tool to objectively measure contact.

OBJECTIVE We hypothesized that pulmonary vein isolation (PVI) ablation using electrical coupling information (ECI) would yield higher rates of PVI than an approach without ECI.

METHODS Forty patients with atrial fibrillation were prospectively included. In each patient, 1 pair of pulmonary veins (PVs) was randomly chosen to be encircled with ECI available while the other pair was encircled without use of ECI.

RESULTS The rate of PVI was significantly higher in PVs encircled with ECI available (58% vs 30%; $P = .024$). PV encircling with coupling resulted in slightly longer procedure (26.5 [interquartile range {IQR} 22–32.5] vs 23.5 [IQR 19–26.5] minutes; $P = .019$), fluoroscopy (9.0 [IQR 6–12] vs 6.9 [IQR 4–8.6] minutes; $P = .011$), and RF (20.0 [IQR 16.5–23.5] vs 17.3 [IQR 15.1–20.6] minutes; $P = .015$) times. For nonisolated PVs, the coupling group had significantly fewer gaps (3.0 [IQR 1.8–7] vs 6.0 [IQR 4–11]; $P = 0.021$) and gap mapping/closure needed shorter procedure (9.0 [IQR 4–16] vs 13.0 [IQR 11–21] minutes; $P = .04$), fluoroscopy (3.9 [IQR 2–7.1] vs 6.0 [IQR 4.6–7.9] minutes; $P = .038$), and RF (1.9 [IQR 0.9–5] vs 5.2 [IQR 3.3–8.6] minutes; $P = .016$) times.

CONCLUSIONS The use of ECI improved lesion deployment measured as higher rates of PVI after anatomical encircling. For nonisolated PVs, fewer gaps and faster gap closure were found using ECI.

KEYWORDS PV encircling; Catheter contact; Coupling information; AF ablation; RF energy

ABBREVIATIONS AF = atrial fibrillation; **ECG** = electrocardiogram; **ECI** = electrical coupling information; **IQR** = interquartile range; **LA** = left atrial; **MRT** = macroreentrant tachycardia; **PV** = pulmonary vein; **PVI** = pulmonary vein isolation; **RF** = radiofrequency

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Introduction

Safety and efficacy of radiofrequency (RF) catheter ablation are fundamentally influenced by the amount of contact and the subsequent energy transfer between the ablation electrode and the endocardial tissue surface. Traditionally, electrophysiologists have used a combination of qualitative measures such as tactile feedback, fluoroscopy, and electrogram information to assess catheter-to-tissue contact.

Recently, technologies and sensors have been developed to objectively measure contact either as a surrogate for the mechanical force applied to the catheter tip or as an assessment of the local electrical characteristics (local impedances).[1–3]

While there are numerous in vitro studies validating the different contact technologies and attempting a correlation of contact measurements with lesion formation, few data are available in humans on the use of such technologies in the clinical setting of RF catheter ablation of complex arrhythmias such as atrial fibrillation (AF).[4–7] There is especially an interest in comparative data analyzing the impact of such technologies on measurable electrophysiological end points, procedural parameters, safety, and efficacy.

Therefore, we conducted the first prospective randomized evaluation of an objective contact assessment technology (EnSite VeriSense system, St Jude Medical, St. Paul, MN) in the setting of wide circumferential pulmonary vein isolation (PVI) for the treatment of symptomatic AF. The aim was to compare rates of successful PVI using electrical coupling information (ECI) against a conventional RF ablation approach.

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Methods

This was a single-center randomized controlled study conducted at the Heart Center Leipzig in Germany between February 2009 and April 2009. The institutional review board approved the study, and participants provided written and verbal informed consent.

Patients

Participants were 18–75 years of age and had (1) paroxysmal or persistent symptomatic AF (documented on electrocardiogram [ECG]), (2) previously ineffective antiarrhythmic drug therapy (at least 1 antiarrhythmic drug), and (3) left atrial (LA) diameter <60 mm (transthoracic echocardiography, parasternal). Patients with permanent AF, prior LA ablation procedure, AF due to reversible cause, known intracardiac or other thrombi, pregnancy, or contraindication for anticoagulation were excluded.

Study design

Forty patients were randomized. The procedures were done by 2 experienced physicians (C.P. and G.H.). In each patient, ablation was performed with ECI available in 1 pair of ipsilateral PVs and with the operator blinded against ECI in the other. The pair of pulmonary veins (PVs) ablated with ECI and the pairwise order of PV ablation were assigned through randomization.

Following randomization, patients underwent preprocedural transesophageal echocardiography and 3-dimensional (3D) cardiac imaging (computed tomography or magnetic resonance imaging). Ablation of paroxysmal and persistent AF was performed as detailed below. Follow-up with serial 7-day Holter ECGs started at the first postinterventional day and was continued for 6 months. *Arrhythmia recurrence* was defined as ECG documented or other symptomatic episodes of AF and/or macroreentrant tachycardia (MRT) lasting >30 seconds.

Electrical contact technology

Technology, in vitro assessment, and clinical in-human validation have been described previously.[4,7] In brief, the electrical contact technology employs a 3-terminal circuit model to isolate and measure the complex local resistive and capacitive impedances at the catheter tip/tissue interface. The coupling information is displayed as ECI units within the 3D cardiac mapping system using (1) a real-time curve, (2) a contact meter, and (3) an adaptive color-coded beacon on the tip of the ablation catheter (Movie 1). The electrical contact technology is scaled to the individual patient by using a 3-step algorithm: (1) acquisition of noncontact ECI baseline values while the catheter rests free in the LA body, (2) definition of the patient-specific noncontact/contact threshold 15 ECI units above the noncontact baseline, and (3) acquisition of an upper safety indicator while firmly pressing the catheter against the posterior LA wall (Movie 1). During the procedure, scaling of the technology is repeated every 30 minutes to adapt shifts in the noncontact baseline values.

Procedural setup

Patients were studied under deep propofol sedation with continuous invasive monitoring of arterial blood pressure and oxygen saturation.[8] In patients presenting with AF at the beginning of the procedure, electrical cardioversion was applied in order to proceed in sinus rhythm. After single transseptal puncture, mapping and ablation were performed under the guidance of NavX EnSite Velocity (St Jude Medical) supplemented by 3D image integration.[8] A steerable sheath (Agilis, St Jude Medical) was used in all patients.[9]

RF alternating current was delivered in a unipolar mode between an irrigated ablation-catheter tip electrode (M-Curve IBI Therapy Cool Path, St Jude Medical) and an external backplate electrode. The standard ablation settings were as follows: upper temperature limit 50°C, power 40 W, and flow rate 30 mL/min. Near to the esophagus, power delivery was reduced to 25 W and 20 mL/min, and further adapted according to the actual intraesophageal temperature increase (Sensitherm, St Jude Medical).[10]

Ablation

In all patients, circumferential ablation around ipisilateral PVs was performed at the atrial aspect of the PV antrum. Because of the single transseptal approach, no circular mapping catheter was present within the PVs during ablation. RF energy delivery was guided by anatomical information and electrogram reduction.[11] Randomization decided which PVs were ablated first and for which PVs ECI catheter coupling information was made additionally available to guide lesion deployment (Movie 2).

After PV encircling, ablation line validation and gap detection were performed by using the "pace-and-ablate" approach as described previously.[11] Bidirectional block was confirmed with a circular mapping catheter (Optima, St Jude Medical).

In addition to PVI, patients with persistent AF received a "box" lesion electrically isolating the posterior left atrium and a mitral isthmus line extending from the left lower PV to the mitral annulus. In patients with clinically documented isthmus-dependent right atrial flutter, ablation of the right atrial cavotricuspid isthmus was performed. All ablation lesions beyond PVI were deployed with ECI catheter coupling information available to the operator.

Postprocedural care and follow-up

Serial 7-day Holter ECGs (Lifecard CF, DelmarReynolds Medical, Irvine, CA) were recorded immediately postablation and at 3 and 6 months postablation. Reablations for symptomatic drug refractory recurrences of AF and MRT were scheduled after ≥ 3 months of follow-up. Patients undergoing reablation were handled as patients with arrhythmia recurrences during follow-up and data analysis.

Antiarrhythmic medication was discontinuediii postablation and patients received a beta-blocker. In the case of