Validation of a novel spiral mapping catheter for real-time recordings from the pulmonary veins during cryoballoon ablation of atrial fibrillation

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BACKGROUND The Achieve mapping catheter allows real-time recordings from the pulmonary veins (PVs) during cryoballoon (CB) ablation of atrial fibrillation (AF).

OBJECTIVE To assess the clinical applicability of the Achieve mapping catheter and the value of real-time recordings from the PVs during CB.

METHODS Patients with paroxysmal AF undergoing CB ablation were studied. Recordings from the PVs were analyzed during (real-time recordings) and after CB ablation and validated by using a variable circumferential mapping catheter (Achieve group; n = 20). A comparison was made by using a group of patients in whom CB ablation with a guidewire and a variable circumferential mapping catheter was performed (Guidewire group; n = 20).

RESULTS Forty patients (age 58 ± 11 years; ejection fraction 0.59 ± 0.07; left atrial size 40 ± 6 mm) with paroxysmal AF were included. In the Achieve group, real-time recordings from the PVs could be obtained in 40 of 80 (50%) PVs and could be seen more often at the left-sided PVs (25 of 39, 64%) than at the right-sided PVs (15 of 41, 37%; $P = .02$). Validation with a standard circumferential mapping catheter confirmed PV isolation in 75 of 80 (93%) PVs. After a single procedure and a follow-up of 14 ± 4 months, 25 of 40 (63%) patients were in sinus rhythm with no significant difference between groups.

CONCLUSIONS The Achieve catheter can be used as a substitute for a guidewire during CB ablation, but real-time recordings can be obtained only in half of the PVs and are not sufficient to accurately confirm isolation of all PVs.

KEYWORDS Cryoballoon ablation; Atrial fibrillation; Pulmonary vein isolation; Real-time recordings; Electroanatomic mapping

ABBREVIATIONS AF = atrial fibrillation; **CB** = cryoballoon; **EAM** = electroanatomic mapping; **PV** = pulmonary vein; **PVI** = pulmonary vein isolation; **RF** = radiofrequency

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Introduction

Pulmonary vein (PV) isolation (PVI) is an integral part of catheter ablation of atrial fibrillation (AF).[1–3] Ablation of AF using the cryoballoon (CB) catheter has become a valid alternative to radiofrequency (RF) ablation in patients with paroxysmal AF.[4–6] Disadvantages are the longer fluoroscopy times and higher radiation doses and the fact that the CB provides no feedback with regard to the effect of the ablation during the freezing cycle.[7] Hitherto, isolation of the PV could only be confirmed after ablation by a circular mapping catheter that mandates either a second transseptal puncture or the exchange of the CB catheter with a circular mapping catheter through a large sheath (15-F outside diameter steerable sheath, FlexCath, Medtronic, Minneapolis, MN), thereby increasing the risk of air emboli. In order to obtain real-time recordings from the PVs, a hexapolar spiral mapping catheter originally designed for the high-intensity focused ultrasound balloon catheter (ProMap, Prorhythm, Ronkonkoma, NY) has been used with moderate success.[8,9] Recently, a novel octapolar spiral mapping catheter specifically designed for the CB has become available (Achieve, Medtronic).[10] The catheter, available with a 15-mm-diameter (4 mm spacing) or 20-mm-diameter (6 mm spacing) loop, is

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used instead of a j-tipped guidewire. After insertion through the inner lumen of the CB catheter, it potentially allows real-time recordings from the PVs during the freezing cycle. Because the Achieve catheter is deployed relatively distally in the PV even if it is pulled back to the tip of the CB catheter, some concerns about the reliability of these recordings remain.

The aim of this study was to validate the Achieve mapping catheter based on its procedural applicability to perform CB-PVI, its ability to detect PV potentials during the freezing cycle (=real-time recordings), and its reliability to accurately confirm PVI.

Methods

Study population

The subjects of this nonrandomized single-center study were 40 patients with symptomatic drug-refractory paroxysmal AF undergoing CB ablation. Exclusion criteria were the presence of persistent AF, a history of a previous left atrial procedure for PVI, and left atrial diameter >55 mm (parasternal long axis). Intracardiac thrombi were ruled out by transesophageal echocardiography before the procedure. All patients underwent preprocedural imaging by using magnetic resonance imaging or computed tomography to assess left atrial anatomy with 3-dimensional (3D) reconstruction.

Study design

This study validates (1) the procedural applicability to perform CB ablation with the Achieve mapping catheter instead of a guidewire and its main functional specifications, namely, (2) the recordings of real-time PV potentials and (3) the assessment of PVI after ablation.

The former was conducted by comparing the Achieve group ($n = 20$) with the Guidewire group ($n = 20$) undergoing CB-PVI in conjunction with a j-tipped guidewire and a variable 20-pole circumferential mapping catheter (Lasso 2515, Biosense Webster, Diamond Bar, CA).

The latter were performed in a data set of 20 patients (Achieve group), in which the signals from the Achieve catheter were compared to the gold standard, a variable 20-pole circumferential mapping catheter, in the same patient. First, ostial PV activity was documented in all PVs prior to ablation by using the variable 20-pole circumferential mapping catheter. Then, the Achieve catheter was placed at the ostium of the PV and was subsequently inserted deeper into the PV in order to appropriately place the CB catheter in the PV antrum. At that time, the Achieve catheter was usually too distal in the PV to record PV potentials. After positioning the CB and demonstrating PV occlusion by contrast injection, the Achieve catheter was pulled back to the tip of the CB catheter in order to potentially allow recordings of PV potentials. Because of the current design of the CB catheter with a relatively long tip distal to the balloon (Figure 1), recordings of PV potentials cannot be expected in all cases. Therefore, we determined the percentage of PVs in which real-time recordings of PV potentials were feasible (after pulling the catheter back to the tip of the CB). If PV potentials could be recorded on the Achieve catheter and could be eliminated during the first energy application, the time to disappearance of these PV potentials ("time to effect") was determined. An example of the disappearance of PV potentials during CB ablation is shown in Figure 2. After the completion of the freezing cycle, the Achieve catheter was placed at the ostium of the PV to determine whether the PV was isolated. In case the recordings from the Achieve catheter indicated PVI, validation of PVI using the 20-pole circumferential mapping catheter was performed under fluoroscopic guidance at the same position to set the gold standard. In case the 20-pole circumferential mapping catheter did not indicate PVI, isolation of the PV was performed as described below. Early PV reconnection may occur after CB ablation and was defined as documented recovery of conduction after CB ablation within a time window of at least 15 minutes after isolation.

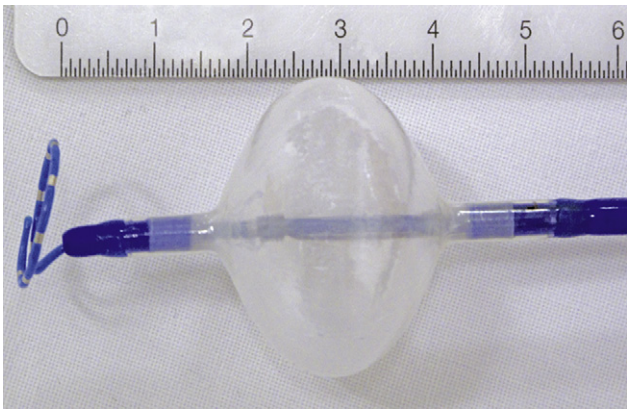

Figure 1 Inflated 28-mm cryoballoon catheter demonstrating the distance of the proximal pole of the Achieve mapping catheter to the pole (17 mm) and the equator (28 mm) of the balloon.

The Achieve catheter offers the possibility to be visualized in a 3D electroanatomic mapping (EAM) system. Therefore, in a subset of 10 patients in the Achieve group, CB ablation was performed in conjunction with an EAM system (EAM-group) and compared to the 10 patients of the Achieve group undergoing PVI without an EAM system (non-EAM group). During the recording of PV potentials in all PVs with the conventional circumferential mapping catheter, a 3D electroanatomic map was acquired by using the EnSite Velocity system (St Jude Medical, St Paul, MN), enabling the visualization of the Achieve catheter on the 3D map.

CB ablation

Informed consent was obtained from all patients prior to the procedure. Ablation was performed under conscious sedation by using midazolam, fentanyl, and propofol. Access was obtained via the right femoral vein. A deflectable decapolar catheter was inserted into the coronary sinus as a reference for transseptal puncture and for pacing. Phrenic nerve stimulation was performed during CB ablation at the right-sided PVs. Double transseptal puncture was performed under