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Original Article

Initial experience and treatment of atrial fibrillation using a novel irrigated multielectrode catheter: Results from a prospective two-center study

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ABSTRACT

Background: PV electrical isolation has become the cornerstone of catheter ablation for the treatment of atrial fibrillation (AF). Several strategies have been proposed to achieve this goal. The aim of this study was to assess the efficacy and safety of AF ablation using a new circular irrigated multielectrode ablation catheter designed to achieve single-delivery pulmonary vein (PV) isolation.
Methods: Thirty-five patients with drug refractory paroxysmal AF and normal ejection fraction from two centers were prospectively enrolled in this study. All patients underwent PV isolation with an nMARQ circular irrigated multielectrode ablation catheter guided by an electroanatomic mapping system. Magnetic resonance imaging was performed to exclude PV stenosis.
Results: PV isolation was achieved in 138 of 140 (98.57%) targeted veins. The mean procedure time was 79.5 min (SD 39.3 min). During a mean follow up of 16.8 ± 2.8 months, 27 of 35 (77.2%) patients were free of AF. No PV narrowing was observed. One case of pericardial effusion due to perforation of the left atrial free wall during catheter manipulation did occur.
Conclusions: PV isolation with a circular irrigated multielectrode ablation catheter is a feasible technique with a high acute success rate. The majority of patients remained asymptomatic during the midterm follow-up period. PV stenosis was not detected. While only a single serious adverse event occurred, this technique's safety profile should be tested in larger studies.

1. Introduction

Catheter ablation has become a first line approach for the treatment of patients with symptomatic atrial fibrillation (AF) resistant to antiarrhythmic medication and circumferential pulmonary vein (PV) isolation is currently considered to be the technique of choice. Catheter ablation using irrigated single-tip catheters and three-dimensional (3-D) mapping systems with point-by-point delivery of multiple applications has been reported to be an effective approach for the treatment of paroxysmal and persistent AF and is the most frequently used ablation procedure worldwide [1,2]. In the last decade, innovative technologies have been developed using so-called "single-shot" devices involving either balloon technology or circumferential multipolar ablation catheters. These new anatomically designed ablation tools allow for the delivery of different energy forms with the aim of creating linear lesions around PV ostia with only a few applications in order to achieve safer and simpler isolations [3–5].

Recently, a novel ablation system using an irrigated decapolar radiofrequency (RF) energy circular catheter (nMARQ, Biosense Webster, Diamond Bar, CA, USA) has been developed as an effective tool for circumferential PV isolation. However, the efficacy and safety of this new catheter has not yet been fully elucidated. Therefore, the aim of this study was to investigate the efficacy and safety of this novel tool. The primary end point was set as the acute isolation rate of targeted PVs and complications related to the procedure itself, as well as symptomatic AF recurrence during the follow-up period, were analyzed.

Abbreviations: PV, pulmonary vein; LSPV, left superior; LIPV, left inferior; RSPV, right superior; RIPV, right inferior; AF, atrial fibrillation; RF, radiofrequency; LA, left atrium; ACT, active clotting time; AAD, anti-arrhythmic drugs

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2. Material and methods

2.1. Patients

Patients with highly symptomatic and drug refractory paroxysmal AF and normal ejection fractions from two different centers (designated A and B) were prospectively and consecutively enrolled in this study. All patients presented with a history of at least one prolonged episode (greater than 30 min) per month within the previous 6 months and had been treated unsuccessfully with at least one antiarrhythmic drug (AAD) (class I or III). In all patients, AF was recorded using a 12-lead electrocardiogram (ECG) within the 6 month period prior to ablation. Exclusion criteria for this study included structural heart disease, congestive heart failure, left ventricular ejection fraction $<55\%$, left atrial (LA) dimensions >50 mm measured in the parasternal long axis, LA thrombus, known as bleeding diathesis or anticoagulant intolerance, pregnancy, and severe comorbidity. Written and informed consent was obtained from all patients. A computed tomography (CT) or magnetic resonance image (MRI) was acquired and used to guide manipulation of the catheter. In all patients, a 3-D reconstruction of the LA was generated prior to performing the ablation procedure in order to reveal the anatomy of the PV.

2.2. Ablation procedure

All patients were treated with oral anticoagulants at least 4 weeks prior to the ablation procedure. This treatment was subsequently withdrawn 3 days prior to ablation and replaced with subcutaneous heparin. Once the trans-septal puncture was performed, an unfractionated heparin bolus was administered. Intermittent bolus administration was initiated and doses were titrated to achieve an active clotting time (ACT) between 300 and 350 s. Measurements were routinely performed depending on the ACT. Following the procedure, low molecular weight heparin followed by oral anticoagulants were administered. LA thrombi had been previously excluded either by CT scan or transesophageal echocardiography.

The nMARQ catheter is an 8.4-F ablation and mapping decapolar irrigated RF system (Fig. 1). The catheter is composed of a circular array with an adjustable diameter between 20 and 35 mm and 10 platinum-coated electrodes (3 mm) with 4 mm spacing. Each electrode is surrounded by 10 irrigation holes and can be recognized by the CARTO3 mapping system (Biosense Webster, Diamond Bar, USA), which allows for 3-D anatomic mapping of the LA. RF ablations are delivered in temperature-controlled mode for a maximum of 60 s. Energy delivery can be individually controlled for each combination of electrodes up to a maximum of 25 W in unipolar mode and 15 W in bipolar mode. Ablations are typically performed via all 10 electrodes and increase in temperature, drop in local impedance, and energy delivery are all continuously monitored using the novel nMARQ Multi-Channel RF System Ablation Generator (Biosense Webster, Diamond Bar, USA). With this generator, RF energy delivery for each electrode can be controlled separately. The system provides a visual display of electrodes in contact with tissue using so-called TissueConnect™ technology. Current and voltage from each electrode are constantly measured. When an electrode is in close contact with the endocardium, which has a 4-fold higher resistance when compared with blood, the spread of the current and voltage graph changes (phase change). Using a propriety algorithm, a contact threshold of 6 g was used to differentiate between contact and no-contact indications.

The ablation was generally conducted under conscious sedation except in cases where general anesthesia was required. Blood pressure and oxygenation were continuously monitored. Venous access was obtained via the femoral vein and a diagnostic catheter was positioned in the coronary sinus for stimulation of the LA. A transseptal puncture was performed under fluoroscopic guidance by using a long 8-F guiding sheath (Biosense Webster Inc., California) and a Brockenbrough needle (BRK, St Jude Medical Inc.). A guidewire was introduced into the left superior PV via a fixed puncture sheath after retrieval of the needle. Under the protection of the guidewire, the sheath was introduced into the LA after which the nMARQ catheter was advanced. An electroanatomic map was obtained using the CARTO3 mapping system and fast anatomic mapping (FAM), defining the PV ostium and antral anatomy. The diameter of the circular array of the catheter was minimized and sequentially inserted into the veins in order to assess the PV electrogram. Once the catheter was inside the vein, the system was manipulated in order to enlarge the diameter of the antral region as defined by interpretation of a local electrogram and previously obtained electroanatomic mapping. Once

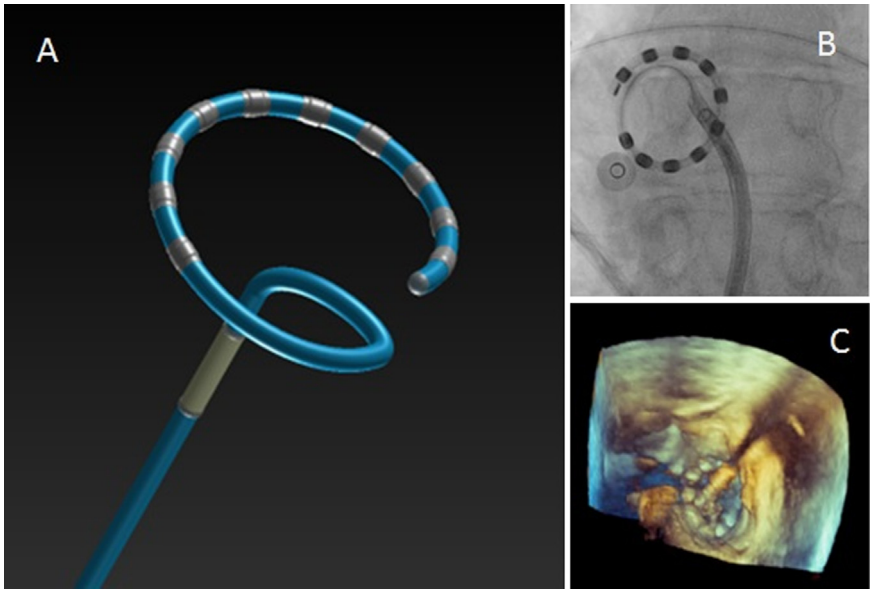

Fig. 1. (A) Ablation and mapping using the decapolar irrigated RF catheter (nMARQ TM, Biosense Webter). (B) Fluoroscopy imaging of the catheter. (C) 3-D transesophageal echocardiogram showing the catheter during application.