Three-Dimensional, Anatomically-Designed Catheter and Multi-Channel Duty Cycled Radiofrequency for Ablation of Paroxysmal Atrial Fibrillation

Christoph Scharf MD, Lam Dang PhD
Klinik im Park | Zürich, Switzerland

INTRODUCTION

Radiofrequency catheter ablation (RFCA) has been widely accepted as a primary therapy for treatment of drug-resistant paroxysmal atrial fibrillation (PAF)[1]. Implementation in regular practice however, has been limited by long procedure times, procedural complications, and variability in clinical outcomes[2]. Typically, a lesion set is created by applying radiofrequency (RF) energy through a tipped catheter positioned near the pulmonary veins (PVs), with the goal of electrical isolation of the veins from the atrium[3,4]. The catheter is usually steered manually using fluoroscopic guidance and the aid of a 3D electroanatomical mapping system[5]. This case report introduces the use of a 3D, anatomically designed catheter for efficient mapping and multi-electrode ablation outside the pulmonary veins. RF energy is delivered using a novel duty cycled RF generator. The procedure does not require 3D electro-anatomical mapping or robotically assisted steering.

CASE PRESENTATION

A 58-year-old male was referred for catheter ablation after experiencing typical symptoms of PAF, including palpitations, dyspnea, and fatigue, for approximately eight years. He had undergone dual-chamber pacemaker implantation approximately three years prior to the ablation procedure due to intermittent sinus bradycardia. Common antiarrhythmic agents, including beta-blockers, sotalol, flecainide, amiodarone, and verapamil, were poorly tolerated or ineffective for disease management.

METHODS

PRE-PROCEDURE

The patient received four weeks of therapeutic anticoagulation in advance of ablation procedure. On the day of catheterization, the patient underwent transesophageal echocardiography (TEE), which showed no evidence of thrombus in the left atrial appendage. Left atrial size was 3.8 cm (26 cc/m2) with no evidence of structural heart disease. Pacemaker interrogation showed approximately 30% AF burden, as evidenced by automatic mode switching (AMS)[6].

PROCEDURE

The patient entered the catheterization laboratory in AF. The procedure was performed under general anesthesia. Two return electrode patches were placed between the shoulder blades. One fixed-curve sheath and one steerable sheath (Channel, Bard, Lowell, Massachusetts, USA) were introduced into the right femoral vein. A 6F deflectable-tip decapolar diagnostic catheter (Dynamic Deca, Bard, Murray Hill, NJ, USA) was positioned via the fixed-curve sheath into the coronary sinus for purposes of mapping and stimulation. Access to the left atrium was attained with the steerable sheath via a patent foramen ovale. An initial bolus of 7500 U of heparinized saline was delivered though the transseptal sheath and ACT was maintained above 300s for the duration of the procedure. Selective pulmonary vein angiography was performed for all vessels using biplane fluoroscopy (45º LAO/RAO) to provide a geometric reference for catheter navigation (Figure 1).

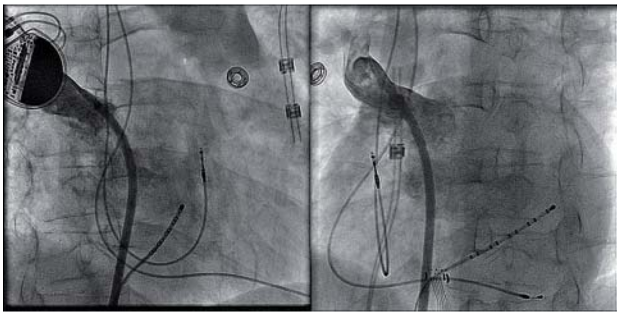
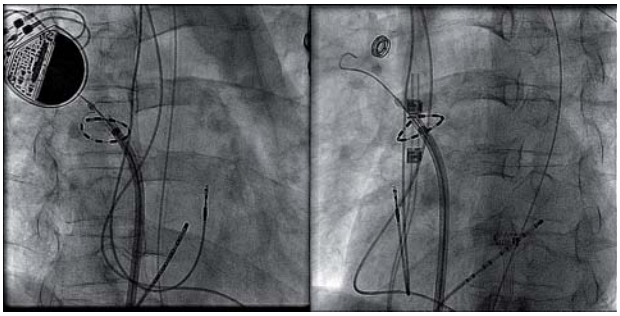


Figure 1: (A) RSPV pulmonary vein angiography in LAO/RAO



(B) Pulmonary Vein Ablation Catheter™ (PVAC) placed in the RSPV.

CATHETER DESCRIPTION

The Pulmonary Vein Ablation Catheter™ (PVAC) (Ablation Frontiers, Inc., Carlsbad, CA, USA) is a mapping and ablation catheter with a 25 mm helical electrode array (Figure 2).

Catheter navigation and positioning are supported by both bidirectional steering and an over-the-wire design. The adjustable array can be extended to assume a spiral configuration which allows for optimal tissue contact. The electrode array has a 25 mm diameter comprised of ten 3 mm platinum electrodes with 3 mm spacing. Each electrode contains a thermocouple located underneath the surface most distal from the catheter center axis. By rotating the catheter shaft with the distal tip engaged against anatomical structures, the diameter of the adjustable array can be effectively increased or decreased from 20 mm to 35 mm. Decreasing the array diameter with clockwise rotation allows for electrogram interpretation from inside the PV ostium. Counter-clockwise rotation will increase the array diameter, facilitating mapping and ablation of veins with larger diameters. The PVAC can be used to create a contiguous, lesion approximately 80 mm long and 3 mm wide with a single RF application. Settings on the RF generator are used to control lesion depth.

Figure 2: (A) PVAC showing 0.032″guidewire and control knobs on catheter handle. (B) distal portion of the PVAC showing ten 3 mm electrodes with 3 mm spacing.

GENERATOR DESCRIPTION

The GENius™ generator (Ablation Frontiers, Inc., Carlsbad, CA, USA) is a multi-channel RF generator capable of simultaneously delivering duty cycled energy to up to 12 operator-selected electrodes. The generator has 5 preset energy settings: bipolar, unipolar, and three ratios of bipolar-to-unipolar energy: 4:1, 2:1, and 1:1. Energy is delivered in a temperature-controlled, power-limited manner with a maximum of 10 W per electrode. Although peak power delivered to each electrode is lower with than a standard 4 mm tip catheter, the current density applied at the tissue surface is equivalent, due to the smaller surface area of the PVAC electrode. The result is an efficient application of RF with equivalent resistive tissue heating. The generator displays in real-time the temperature and power for each electrode, as well as the number of seconds each electrode was within 5°C of target temperature during the ablation (Figure 3).

Figure 3: Example of generator display during ablation with PVAC, with temperature and power for each electrode, number of seconds each electrode is within 5°C of the target temperature during the ablation.

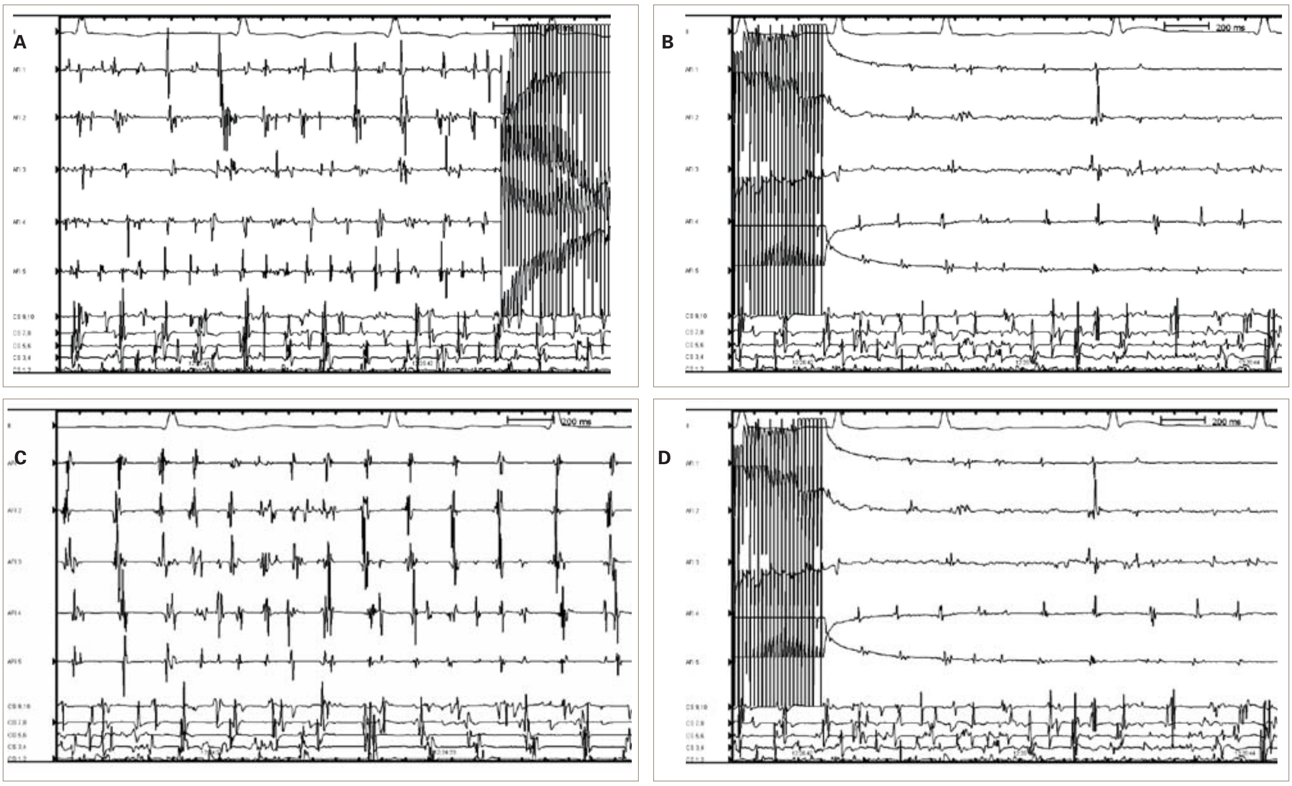


Figure 4: (A) Electrograms recorded from LSPV antrum showing initiation of ablation. (B) ECG recorded post the first RF application in LSPV. (C) Electrograms recorded in the RPSV antrum prior to ablation. (D) Conversion to sinus rhythm during RF ablation of RSPV.

ABLATION PROCEDURE

After visualizing pulmonary vein ostia by selective contrast injection, the PVAC was introduced into the left atrium via the steerable sheath. Using a 0.032″ guidewire placed in the vein, the catheter was positioned at the antrum of each PV where activation potentials were observed (Figure 4).

RF energy was applied using the RF generator with a target temperature of 60ºC, 4:1 ratio between bipolar and unipolar energy, and 60 s duration. Multiple applications of RF were delivered until activation signals were no longer distinguishable by interpretation of electrograms from the antrum of each vein. Typical power applied to each electrode remained between 3–5 W using the 4:1 bipolar/unipolar setting during RF delivery. Thirty minutes after first venous access, following isolation of the LIPV and LSPV, the patient converted to sinus rhythm during RF application to the RSPV (Figure 4C & 4D). Recurrence of atrial fibrillation was noted, which converted to typical atrial flutter upon isolation of the RIPV. Standard RF ablation was then performed at the cavotricuspid isthmus using unipolar energy delivered via a standard 8 mm tip catheter (St Jude Medical, St. Paul MN, USA), during which atrial flutter converted to sinus rhythm. After demonstrating a complete isthmus block with a double potential of 106 ms and a transisthmus interval of 167 ms, the left atrium was recannulated. Complete isolation of the LSPV, LIPV, and RSPV were demonstrated without additional RF application. A single PV spike was found during sinus rhythm at the RIPV and eliminated by one application of RF with the PVAC (Figure 5).

AF was not inducible using atrial burst pacing up to 200 ms and isoproterenol infusion up to 20 mg/min. The procedure was completed after 90 min, during which 32 minutes of RF were applied in the left atrium and 4 minutes of unipolar standard RF in the right atrium. Total fluoroscopy time was 16 minutes, of which fewer than 10 were used for pulmonary vein angiography and isolation. The patient was discharged after 24 hours and treated with oral anticoagulation for 3 months. At 12 months follow-up, the patient presented without symptoms and 0% AF burden, as determined by AMS pacemaker interrogation.

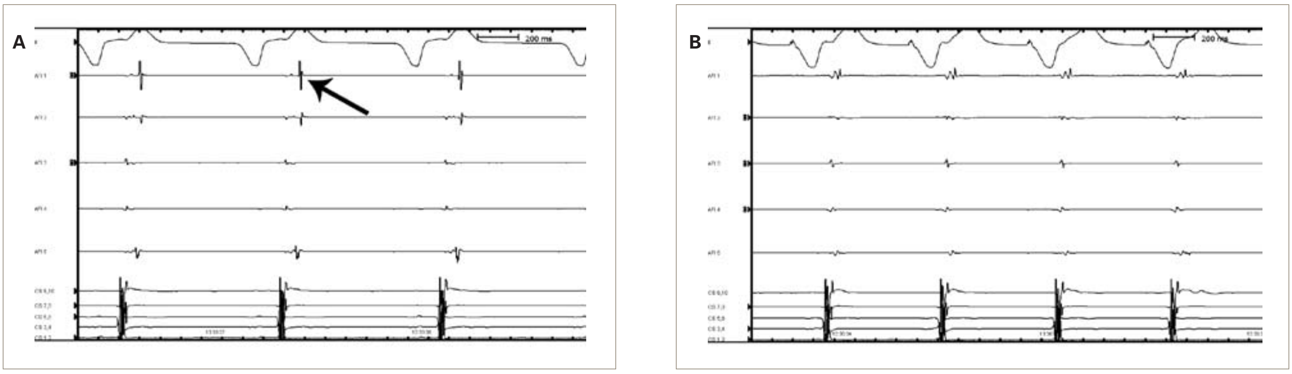


Figure 5: (A) Following successful RF ablation of cavotricuspid isthmus for AFL, a PV spike was observed in the RIPV. (B) Spike eliminated after one RF application with the PVAC.

DISCUSSION

RF ablation has become a highly successful therapy option for patients with PAF. Isolation of triggers within the pulmonary veins is the main treatment strategy in these patients. Conventional techniques use a ring-shaped mapping catheter and a second ablation catheter that applies RF energy in a unipolar fashion. Complete isolation of all electrical potentials at the pulmonary vein ostium is a technically challenging procedure requiring a long learning curve and extensive fluoroscopy[7]. In addition serious complications have been reported including creation of atrio-esophageal fistulas by inadvertent high power delivery[8].

New developments in catheter ablation of PAF have attempted to address these challenges in a variety of methods. Recent technical advances in robotic and magnetic steering have facilitated catheter manipulation and demonstrated reduced radiation dosage for the physician, but are likely to increase procedural complexity, cost, and time, thereby leaving the key challenges unsolved9,10. Variations on catheter design have also been proposed, with coiled electrodes implemented on helical and linear catheters demonstrating limited effectiveness and unsatisfactory complication rates[11,12]. Alternative catheter shapes combined with novel energy sources have been proposed and are being evaluated in the clinical setting, including balloon catheters that deliver laser, cryoablation, and ultrasound energy[13,14,15,16]. However, these approaches have yet to demonstrate the ability to consistently isolate all veins without supplemental ablation catheters, procedure or fluoroscopy times are not reduced, and reports have shown collateral damage complications such as phrenic nerve damage[17,18,19,20].

This case introduces a catheter ablation approach for PAF that uses an anatomically designed, over-the-wire catheter that can map PV potentials and ablate with highly efficient, duty cycled RF energy. These novel designs offer numerous advantages over current technology that could positively impact routine clinical practice. First, several possible safety advantages may be achieved due to the low-power, duty cycled RF energy. By limiting power to 10 W, this system may reduce the likelihood of complications related to excessive RF delivery, including atrio-esophageal fistulas. Also the ability to control lesion depth by unipolar-bipolar energy ratios may prevent collateral damage to anatomical structures such as the phrenic nerve.

Another potential safety advantage is a reduction in the formation of char due to electrode cooling achieved by duty cycling RF. In addition to the possible safety advantages, this technique reduces procedure time and complexity, since a single catheter creates wide-area, contiguous lesions with each RF application. Finally, this approach does not require 3D navigation or mapping and can be performed using only fluoroscopic guidance. Therefore, it is possible to perform this procedure in most laboratories, which could potentially increase the throughput of AF ablation procedures.

CONCLUSIONS

Duty cycled bipolar/unipolar radiofrequency ablation is effective in isolating pulmonary veins using relatively low power (<10 W). Simultaneous ablation at multiple electrodes appears to reduce procedure and fluoroscopy times. The approach proposes a shorter and more elegant alternative to the long, complex procedures typically performed for catheter ablation of PAF. A large, multi-center study is required to confirm the acute success can be reproduced and that safety and long-term efficacy meet or exceed current approaches.

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United States of America

Ablation Frontiers, Inc.
6354 Corte Del Abeto
Carlsbad, CA 92011

Tel: 760 438 4868
Fax: 760 438 4964
www.ablationfrontiers.com

Europe and International

Ablation Frontiers BVBA
NCI Business Center
Culliganlaan 1b
1831 Diegem, Belgium

Tel: +32 2 403 1750
Fax: +32 2 403 1710

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