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ORIGINAL ARTICLE

Novel Technique for Atrial Fibrillation Ablation: Use of Anatomically Designed Pulmonary Vein Ablation Catheter

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ABSTRACT

BACKGROUND: Catheter ablation of atrial fibrillation (AF) has been increasingly used in experienced electrophysiology centers. A novel ablation system delivering duty-cycled phased radiofrequency energy via an over-the-wire multipolar circular ablation catheter (PVAC™, Medtronic) to perform linear continuous ablation has been tested for isolation of pulmonary veins (PVs).

METHODS: Consecutive patients with indication for AF ablation have been included. Patients underwent PV isolation using the novel ablation system and the PVAC catheter. PV isolation was confirmed by mapping of PV potentials using the PVAC catheter demonstrating entrance and exit block. Success was defined as no AF (no documentation of AF episodes >30 seconds during 7-day Holter EKG analysis and no symptomatic recurrences after a 3-month blanking period).

RESULTS: 152 patients (35 female) with a mean age of 55 (±12) years were included. 106 patients (70%) had paroxysmal and 46 patients (30%) persistent AF. During the ablation procedure, 594 out of 598 (99%) PVs were effectively isolated during a mean procedure duration of 100 (±26) min and radiation duration of 20 (±8) min. During a median follow-up of 6 months, 65% of paroxysmal patients and 47% of persistent AF patients had no AF documented after a single ablation procedure.

CONCLUSIONS: Using a novel duty-cycled phased radiofrequency ablation system is effective and safe in treating AF patients. PV isolation can acutely be achieved in 99% of targeted veins. Mid-term success using a stringent criterion of no AF after a blanking period of 3 months is 65% for paroxysmal and 47% for persistent AF patients using mainly PV-isolation alone.

KEY WORDS: *PVAC, duty-cycled phased RF ablation, atrial fibrillation*

Abbreviations
AF = atrial fibrillation
PV = pulmonary vein(s)
PVAC = pulmonary vein ablation catheter
RF = radiofrequency
SR = sinus rhythm

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INTRODUCTION

The number of patients with atrial fibrillation (AF) treated by non-pharmacological options is increasing steadily.[1] Using catheter ablation or surgical AF treatment, the pulmonary vein (PV) regions are a critical target to suppress PV foci. Therefore, there is a growing demand for catheter ablation systems tailored to perform fast, easy and effective PV isolation.[1,2]

Recently, an innovative radiofrequency (RF) ablation system has been introduced

for pulmonary vein isolation procedures. This novel system consists of a specifically designed decapolar circular mapping and ablation catheter (PVAC™ = pulmonary vein ablation catheter; Medtronic, USA) and a multichannel RF generator (Genius™; Medtronic, USA) enabling synchronous uni- and bipolar RF energy delivery to selected (or all) electrodes of the PVAC. With this novel technique contiguous nearly circular linear lesions can be produced. Initial studies on the acute and mid-term efficacy have provided excellent rhythm outcome for patients with paroxysmal and persistent AF.[3-7]

CONCEPTS/TECHNIQUE

The PVAC™ (Fig. 1) is a 9-Fr. over-the-wire steerable catheter with 10 platinum electrodes arranged on an eccentric nitinol nearly circular frame. With this design tissue contact is unidirectional and each electrode has a thermocouple positioned towards the area of intended tissue contact. Electrodes are small (length 3 mm, surface area 14 mm^2) and when applying a power of 10 Watts current densities equivalent to regular 4 mm single-tip catheters are achieved. The multichannel RF generator GENius™ (Fig. 1) can independently deliver energy in unipolar and bipolar mode to any of the PVAC electrodes via a duty-cycle with phase differences between adjacent electrodes. The chosen ratio of bipolar-to-unipolar energy delivery (4:1, 2:1 or 1:1) tailors lesion depths (determined by unipolar RF ratio) and fill in between adjacent electrodes (determined by bipolar RF ratio). Ablations are temperature controlled (60˚C) and limited to 8 or up to 10 Watts.[3,4] Using this novel ablation system contiguous lesions of up to 80 mm length in a nearly circular fashion can be achieved with a single 60-sec ablation. In 4:1-bi-to-unipolar ablation mode, mean lesion depth is 3.6 mm.[1,4]

The PVAC is an over-the-wire steerable catheter allowing for exact location and ablation of the targeted PV. Usually the PVAC (diameter 25 mm) is positioned in the antrum of the targeted PV and bipolar recordings of the PVAC electrodes display two components in sinus rhythm (SR): The first component is left atrial local electrogram and the second component may be PV potentials (Fig. 2). Ablation therefore may produce abatement of PV potentials and also reduce local electrogram amplitude. This specific position of the PVAC may lead to problems with signal interpretation and effective PV isolation may only become documentable when positioning the PVAC deeper in the PV where no atrial far field sensing is seen. In addition to entrance block into the PVs during SR, exit block during stimulation at multiple sites within the PV can identify the electrophysiological endpoint of complete PV electrical disconnection.

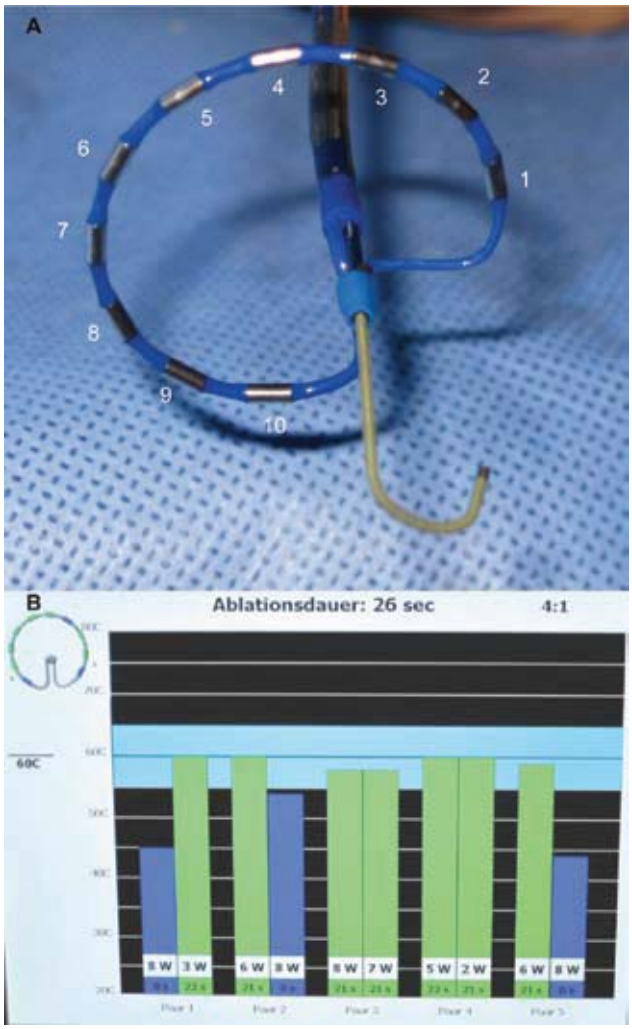

FIGURE 1. PVAC™ (A) and monitor view of the GENius™ generator (B). A - The PVAC™ catheter is an eccentric over-the-wire catheter with 10 platinum electrodes mounted on a nitinol frame. B - The GENius™ generator displays measured temperatures and indicates applied energy in bars for each PVAC electrode. Green bars indicate electrodes achieving the target temperature zone (55 to 65˚C).

RESULTS

So far over 3000 cases have been treated worldwide. In the published series of patients effective isolation of targeted PVs has been documented to be 93% using this single catheter approach. Nearly 85% of treated patients had effective isolation of all targeted PVs. Effective PV isolation has been controlled with conventional circumferential mapping catheters or using electroanatomic voltage mapping indicating complete abolishment of electrical signals within the ablated regions.

The mid-term success is published to be 79.5% of mostly

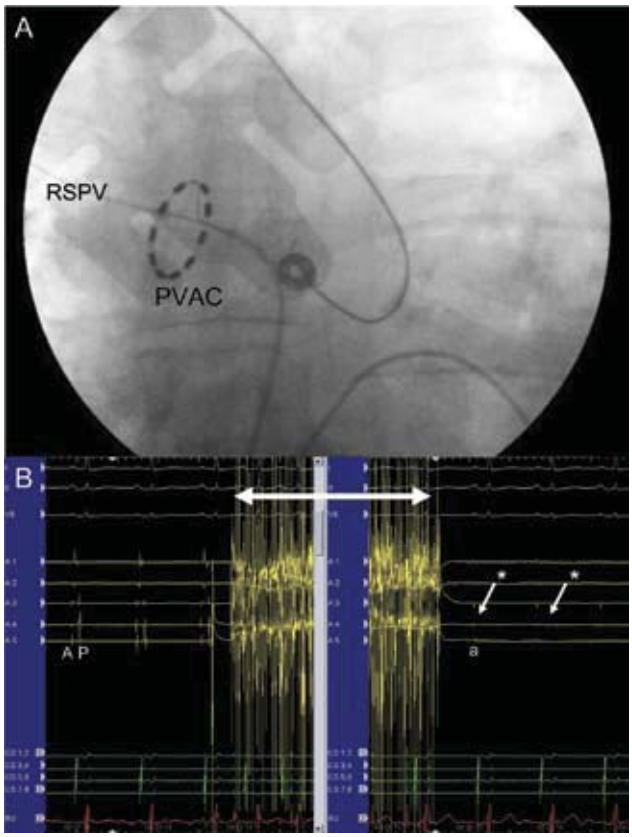

FIGURE 2. Radioanatomic view and intracardiac signals during isolation of a right superior PV. A - Radiograph of a PVAC in the right superior PV (RSPV) with the wire reaching deeply into the vein and the PVAC being in the antral part of the PV ostium. B – Intracardiac signals (yellow = PVAC, green = coronary sinus catheter, red = right ventricular apex catheter) indicating PV potentials (PV) and a local atrial electrogram (A) when positioned in the ostium of the PV. After ablation (←→) atrial signal show lower amplitude (a) and PV potentials are abated (* →) indicating entrance block into the PV.

paroxysmal atrial fibrillation patients determined by 7-day Holter monitoring at 6 months. Procedural complications appear to be low (<2.0%) indicating the simplicity of the application of the PVAC ablation device. Further studies need to evaluate long-term success and safety aspects are needed to define the role of this ablation technique in clinical practise.

In our institution 152 patients (35 female) with a mean age of 55(±12) years were studied. 106 patients (70%) had paroxysmal and 46 patients (30%) persistent AF. 594 out of 598 (99%) PVs were isolated during a mean procedure duration of 100 (±26) min demonstrating entrance and exit block (radiation duration of 20 (±8) min and total RF energy duration of 28 (±9) min). A mean of 8 (±3) ablation impulses (at 60 seconds) were needed for isolation of the left superior PV, 6 (±3) for the left inferior PV, 7 (±3) for the right superior and 5 (±2) for the right inferior PV (left common ostium 14 (±4) ablation sequences). In patients with persistent AF, PV isolation alone was performed in 28 pts, additional ablation on the left sided atrial septum was done in 16, and ablation of complex fractionated left atrial electrograms was attempted in 7.

During a median follow-up of 6 months, 68% of paroxysmal patients and 49% of persistent AF patients had no AF documented after a single ablation procedure (no episode of AF in consecutive 7-day Holter recordings or symptoms susceptible of AF after a blanking-period of 3 months). Twelve (8%) underwent redo procedures. Five (3%) patients reported procedure-related groin access complications. Comparing the first 25 paroxysmal AF patients to the last 25 patients with completed follow-up there is a reduction in procedure duration (112±31 vs. 98±18 min) and radiation exposure (23±9 min vs. 18±7 min). Fifty six percent (56%) of the first and 68% of the last patients had no AF documented during follow-up indicating a learning curve with PVAC ablation.

CONCLUSIONS

The novel RF ablation technique using synchronous uni- and bipolar energy delivery via a decapolar steerable over-the-wire mapping and ablation catheter offers potential for fast, safe and effective treatment of patients with symptomatic AF. Due to the complexity of left atrial ablation to treat AF including documentation of the electrophysiological endpoint (effective PV isolation), these procedures should be performed in centers with high expertise.

Unresolved issues with this new ablation system are the occurrence of collateral damage e.g. to the esophagus during PV isolation using the PVAC. In addition, when ablating within the left atrium without consistent cooling of the catheter tip (non-cooled ablation) thrombus or coagulation formation due to the ablation may occur. Whereas thrombus formation may be reduced by effective heparinization, coagulation at the catheter tip may not be influenced by anticoagulation because coagulum formation is due to direct heat-related denaturation of fibrinogen. Further studies need to evaluate the exact relation of the intensity of heparinization during the procedure and potential thromboembolic events.

Further refinements of the catheter design and technique (e.g. different diameters of the PVAC tip) are warranted to better evaluate PV isolation and further increase the efficacy of PVAC-based AF catheter ablation procedures.

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