

Voltage mapping and pacing to assess the level of pulmonary venous isolation achieved with a novel circular multielectrode ablation catheter[†]

Santi Raffa^{1,2*}, Anett Große¹, Michele Brunelli^{1,3}, Kristel Wauters¹,
and Johann Christoph Geller¹

¹Arrhythmia Section, Division of Cardiology, Zentralklinik Bad Berka, Robert Koch Allee, 9, Bad Berka 99437, Germany; ²Department of Clinical and Experimental Medicine and Pharmacology, University of Messina, Messina, Italy; and ³Division of Cardiology, Department of Internal Medicine, University of Genova, Genova, Italy

Received 13 December 2009; accepted after revision 22 March 2010; online publish-ahead-of-print 21 April 2010

Aims

The aim of the study was to determine the level of pulmonary vein (PV) isolation achieved with the use of a novel radiofrequency circular multielectrode ablation catheter [pulmonary vein ablation catheter (PVAC)] in patients with paroxysmal atrial fibrillation. Although some efficacy data have been presented, the level of PV isolation, which is crucial both for efficacy and safety of the ablation, has not been defined with this new ablation catheter.

Methods and results

Detailed sinus rhythm voltage maps using an electroanatomic mapping system and projected on 3D computed tomography-derived reconstructions of the left atrium (LA) were obtained before and after PV isolation with the PVAC. Left atrium–PV entry and exit block was assessed for each vein. The population consisted of 12 patients, mean age 57 ± 6 years, seven male. After ablation, an extensive zone of potential reduction that included the ostium of each PV was observed in all patients. Bipolar voltages were significantly reduced in all PVs and in the LA close to the vein ostia, the mean voltage reduction was $>80\%$.

Conclusion

Using the PVAC, (i) PVs are isolated at the level of the PV ostium and, importantly, outside the tubular portion and (ii) significant voltage reduction is also recorded at various extent proximal to the PV ostium at the level of the antral region.

Keywords

Atrial fibrillation • Pulmonary vein isolation • New ablation catheters • Voltage mapping

Introduction

Specifically designed catheters have recently been introduced^{1–8} to achieve pulmonary vein (PV) isolation that has been established as the cornerstone of ablation in patients with paroxysmal atrial fibrillation (AF).^{9–13} A number of studies have described the acute and midterm success rates achieved with one of these novel ablation tools, the Pulmonary Vein Ablation Catheter™ (PVAC, Ablation Frontiers, Inc., Carlsbad, CA, USA) an over-the-wire radiofrequency (RF) multielectrode circular catheter.^{2,3} However, the level of PV isolation achieved with this catheter has not yet been defined, although it is an important determinant of both success and complication rates. Therefore,

the aim of this study was to (i) meticulously determine PV isolation by demonstrating both entry and exit block and (ii) assess by voltage mapping the level of PV isolation achieved in patients with paroxysmal AF undergoing ablation with the PVAC.

Methods

Population

The population of the present study consisted of patients with paroxysmal AF undergoing PV isolation and consenting to the study protocol referred to our division from June 2008 to January 2009.

* Corresponding author. Tel: +49 36458/51201; fax: +49 36458/53506, Email: c.geller.kar@zentralklinik-bad-berka.de

[†] Part of the data was presented as an abstract at the Featured Poster Session of the 30th Annual Meeting of the Heart Rhythm Society (Boston, MA, USA, 13–16 May 2009) and at the 2009 EuroPace Meeting in Berlin.

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2010. For permissions please email: journals.permissions@oxfordjournals.org.

Electrophysiological study and catheter ablation

Following oral anticoagulation (INR < 2.5 at the day of the procedure) or low molecular weight heparin for at least the preceding 4 weeks and transoesophageal echocardiogram to exclude the presence of left atrial (LA) thrombi or masses, the electrophysiological study was performed using standard technique.

All patients underwent transseptal puncture using the electrophysiological catheters as anatomical landmarks and pressure recording. Antegrade LA angiography was always performed prior to transseptal puncture and allowed the characterization of the individual anatomy relevant for interatrial septal puncture. No other imaging tools have been used.

After transseptal puncture, intravenous heparin was given as a bolus (usually 5000 U) and repeated if necessary every 20 min in order to achieve and maintain an activated clotting time between 250 and 350 s throughout the procedure.

Ablation was performed using a novel circular decapolar catheter, the PVAC (Figure 1).^{2,3} Briefly, this is a 9 Fr, over-the-wire, circular, decapolar mapping and ablation catheter. The distal ring has a diameter of 25 mm. The distal part of the catheter can be steered in a bidirectional fashion, and the circular array, hosting the ten 3-mm electrodes, can be extended in a spiral configuration. Each platinum electrode contains one thermocouple, and the catheter is used with a specifically designed multi-channel RF generator (GENius™, Ablation Frontiers) that is capable of simultaneously delivering duty-cycled energy to all electrodes. The generator has five 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 power of 10 W per electrode.

After positioning the wire in one of the branches of the PVs, the PVAC was advanced at the PV ostium, trying to achieve the best catheter contact with all the electrodes. Both the fluoroscopic position and the electrograms were used to assess electrodes–tissue contact prior to ablation. Anatomical information regarding the angulation of the PVs with respect to the LA was obtained from the LA angiography and the computed tomography (CT)-derived LA 3D reconstruction and guided the positioning of the PVAC. RF energy was delivered for 60 s with a temperature limit of 60°C. The usual ratio of bipolar-to-unipolar energy used was 2:1 when the catheter was at the antrum of the PV and 4:1 if the position was more ostial. During energy delivery, monitoring of power and temperature values were used to assess catheter contact: low power (<3 W) and high temperatures (60°C) were considered indicators of excessive pressure, whereas high power (10 W) and low temperatures (<50°C) indicated poor catheter contact. In these situations,

the channels showing suboptimal values were switched off after 20 s. After every single application, the catheter was rotated on its axis and/or a different PV branch was selectively cannulated with the wire in order to achieve a different position and ablate the areas not covered by the previous lesion. Before every energy application, the new catheter position was checked using biplane fluoroscopy to reduce the risk of an extreme deviation of the PVAC from the PV long axis in order to avoid unnecessary applications. Energy was usually delivered from all the electrodes for the first lesions, while later on only the electrodes still showing local electrograms were selected for ablation. Ablation was continued until the demonstration of PV isolation. The same procedure was repeated for all PVs. In case of large PV ostia, selective cannulation of different PV branches with the wire, spiralling of the distal circular end of the catheter, and the use of the steering mechanism of the transseptal sheath enabled differential positioning of the PVAC, thus allowing complete PV isolation. In order to prevent phrenic nerve injury, particular care was taken during ablation at the ostium of the right superior PV. The maintenance of a proximal position of the PVAC during energy application was obtained by using sheath torque and selective wire cannulation of different PV branches and was checked at intervals during ablation. Furthermore, high output stimulation (10 V at 2.0 ms) from all electrode pairs of the ablation catheter prior to every energy application was performed, and ablation was only carried out from the pairs not showing phrenic capture.

Confirmation of pulmonary vein isolation

Confirmation of PV isolation was always performed using both the PVAC and an additional decapolar circular mapping catheter (Lasso™, BiosenseWebster, CA, USA). Entry block into the PVs was demonstrated by the absence of PV potentials in sinus rhythm or during pacing from the right interatrial septum for the right-sided PVs and during pacing from the distal coronary sinus for the left-sided PVs, respectively (Figure 2). In addition, exit block was assessed by pacing at maximum output (10 V at 2.0 ms) from all electrode pairs of the circular mapping catheter positioned proximal in the PV.

Repeated doses of adenosine (6–18 mg) were injected in order to assess LA–PV reconnection.¹⁴ In addition, isoproterenol challenge was performed at increasing rates (5–20 µg/min with steps of 2 min) in order to test the presence of extra PV foci triggering AF.¹⁵ When PV ‘reconnection’ was observed after drug challenge, additional lesions with the PVAC were delivered until this response was abolished.

Additional anti-arrhythmic drugs were not used during the procedure.

Voltage mapping

Computed tomography scans of the heart were obtained 24–48 h before the ablation with a 64-slice dual source device (Somatom™ Definition, Siemens AG, Munich, Germany). The 3D reconstruction of the LA from the digital CT data was performed using the Verismo™ customized software of the NavX system (EnSite NavX™, St Jude Medical, St Paul, MN, USA). The number of PV ostia for each patient was determined on the 3D reconstruction. A common PV ostium was defined as the presence of a unique take-off of contiguous PVs bifurcating more than 5 mm away from the LA–PV junction.¹⁶ Demarcation of the PV ostia was obtained on the 3D reconstruction of the LA prior to the ablation procedure, using the marker tool of the navigation system tracing a tangential line at the junction of the PV to the oval-shaped surface of the LA, following previously published criteria.¹⁷ Characterization of the proximal border of the antrum and the LA was not attempted because no standardized approach is yet available.



Figure 1 The PVAC catheter is an over-the-wire circular decapolar ablation catheter.

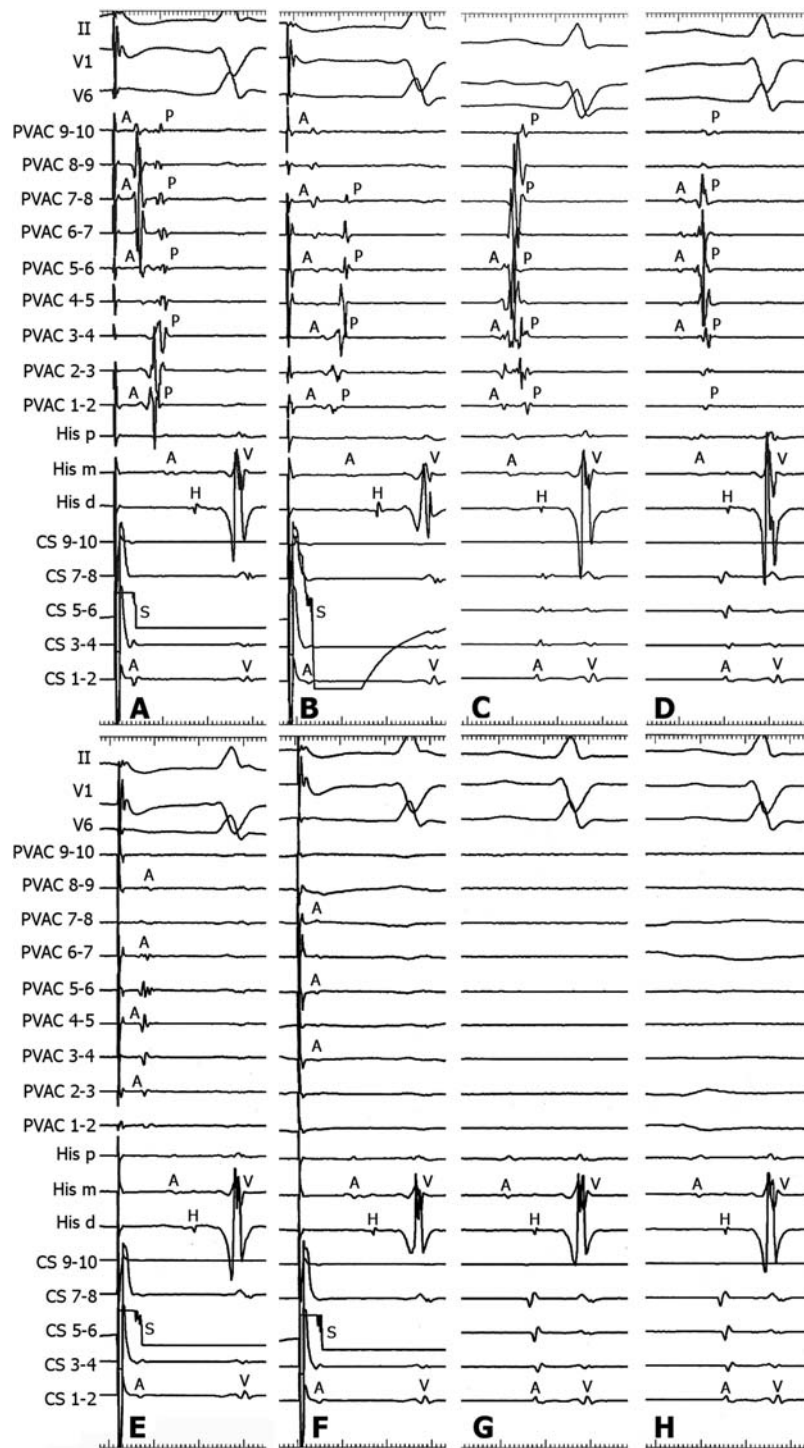


Figure 2 ECG leads II, V₁ and V₆ and intracardiac bipolar electrograms (EGMs) recorded (100 mm/s sweep speed) from the PVAC, a hexapolar catheter positioned at the anterior interatrial septum (His catheter), and a decapolar catheter placed in the coronary sinus (CS) are presented. EGMs were recorded by the PVAC at each pulmonary vein (PV) ostium both before (A–D: EGMs in the LSPV, LIPV, RSPV, and RIPV, respectively) and after (E–H: EGMs in the LSPV, LIPV, RSPV, and RIPV, respectively) successful PV isolation. Before PV isolation (A–D), a far-field atrial electrogram (A) was recorded ~60 ms after either the pacing stimulus (S) from the CS (A and B) or the beginning of the P-wave in the surface ECG (C and D) in each PV. This atrial EGM was then followed in the PVAC tracings by a sharp PV potential (P). After PV isolation (E–H), the far-field atrial EGM was still recorded 60 ms after the pacing stimulus from the CS in the left-sided PVs (E and F) but was no longer followed by a PV potential. In the right-sided PVs (G and H), a very small far-field atrial EGM and no PV potential were recorded after ablation. LSPV: left superior PV, LIPV: left inferior PV, RSPV: right superior PV, RIPV: right inferior PV.

The maximum and minimum diameters as well as the area of each PV ostium were measured using customized NavX tools. The diameter ratio was calculated off-line, in order to characterize the shape of the ostium as follows: round ≤ 1.2 ; oval > 1.2 and ≤ 1.4 ; flat > 1.4 .¹⁷

A quadripolar steerable mapping catheter (Livewire, St Jude Medical) was inserted into the LA for voltage mapping using the NavX electroanatomic system. After acquisition of a 3D geometry of the LA and of the proximal end of the PVs, fusion of the CT-derived LA anatomy with the catheter-acquired LA geometry was performed. Specific anatomic structures (PV ostia, ridges between ipsilateral PVs, ridge between left-sided PVs and the appendage, superior, inferior, and anterior LA walls, mitral annulus and interatrial septum) were then carefully visited with the mapping catheter and, if necessary, further fusion steps were performed in order to obtain the best match between the generated LA geometry and the CT-derived anatomy of the LA.

In sinus rhythm, a detailed bipolar voltage map was acquired with particularly dense mapping of the PVs, their ostia and antra (defined as the rim of LA encircling the PV ostia). Great emphasis was put on trying to acquire bipolar electrograms from all aspects of the PVs. The map was projected on the fused LA anatomy, and settings were as follow: interpolation of 10 mm, internal and external projections of 5 mm. Voltage maps were displayed using as superior and inferior cut-offs 0.5 and 0.05 mV, respectively. Normal electrograms were considered those having a voltage of > 0.5 mV and were displayed in purple. Areas of voltage < 0.05 mV were arbitrarily considered as electrically silent and displayed in gray. The spectrum of colours ranging from red to blue was attributed to areas of low voltages ranging from 0.05 and 0.5 mV. The map was considered complete when all PVs had been visited together with their ostia and antra and a sufficient surface of the LA. Map points were analysed after the procedure, and their voltage values in mV were collected in a patient-specific database where points were assigned to the following different anatomic structures: left superior PV (LSPV), left inferior PV (LIPV), right superior PV (RSPV), right inferior PV (RIPV), left-common PV (LCPV), right middle PV (RMPV), and LA. The same mapping procedure was repeated after isolation of the PVs with the PVAC. Voltage mapping was accompanied, in case of the presence of voltages > 0.2 mV inside the PVs, by pacing at high amplitude from the mapping catheter in order to reassess PV–LA exit block. Pacing was repeated from the mapping catheter at cardinal points of every PV ostium, as well.

Follow-up

After ablation, patients were monitored for at least 48 h with a telemetric electrocardiographic system, and arrhythmias were recorded. At discharge, patients were asked to report and preferably document with an electrocardiogram any arrhythmic episodes during follow-up.

Statistics

Continuous variables are expressed as mean values \pm standard deviation. Comparison of bipolar voltages before and after ablation for every PV as well as for the LA and for the overall maps were performed using the two-tailed Student *t*-test. A *P*-value < 0.05 was considered statistically significant.

Results

Characteristics of the population

Between June 2008 and January 2009, due to the extensive additional mapping required, 12 patients participated in this study. The patient characteristics are summarized in Table 1.

Table 1 General characteristics of the study population

	Study group (n = 12)
Age (years)	57 \pm 6
Gender (M/F)	7/5
Height (cm)	174 \pm 9
Weight (kg)	82 \pm 11
LA diameters (mm)	37 \pm 5
Left ventricular ejection fraction (%)	58 \pm 5
Number of anti-arrhythmic drugs ever used	1.7 \pm 0.8
CHADS ₂ score	0.8 \pm 0.6

Table 2 Dimensions of pulmonary vein ostia in the study group

	Study group (n = 12)			
	Maximum diameter (mm)	Minimum diameter (mm)	Diameter ratio	Surface (cm ²)
LSPVo	19.2 \pm 3.4	13.0 \pm 2.3	1.5 \pm 0.3	2.0 \pm 0.5
LIPVo	17.2 \pm 2.3	11.7 \pm 3.1	1.6 \pm 0.4	1.7 \pm 0.6
LCPVo	32.2 \pm 5.2	17.8 \pm 3.9	1.9 \pm 0.6	4.3 \pm 0.6
RSPVo	20.2 \pm 3.2	16.5 \pm 2.8	1.2 \pm 0.3	2.6 \pm 0.7
RIPVo	17.6 \pm 2.8	15.7 \pm 3.0	1.1 \pm 0.1	2.2 \pm 0.9
RMPVo	10.0	8.0	1.3	0.6

LSPVo: left superior pulmonary vein ostium; LIPVo: left inferior pulmonary vein ostium; LCPVo: left common pulmonary vein ostium; RSPVo: right superior pulmonary vein ostium; RIPVo: right inferior pulmonary vein ostium; RMPVo: right middle pulmonary vein ostium.

There was a relatively high prevalence of left common PVs (42%). The size of the PV ostia is shown in Table 2, and the shape of all PVs is presented in Table 3.

Pulmonary vein isolation

As required by the inclusion criteria, PV isolation was achieved with the PVAC alone in all patients. The mean number of energy applications per patient was 24 \pm 10 (range 10–46), the mean duration of energy delivery per patient was 20 \pm 6 (range 9–33) min. A total of 44 of 44 PVs (100%) including all LCPVs were isolated, as demonstrated by (i) pacing showing both entry and exit block and (ii) the drug challenge with adenosine and isoproterenol at the end of the procedure. There was no difference between assessment of PV isolation using the PVAC catheter and the Lasso catheter (data not shown). In 25% of PVs, additional PVAC lesions were performed after adenosine injection revealed acute reconnection. At the end of the study, persistent PV isolation was shown for all veins with repeated drug challenge. Isoproterenol infusion did not identify any extra PV focus and did not unmask residual LA–PV conduction.

Table 3 Shape of pulmonary vein ostia in the study group

	LSPVo	LIPVo	LCPVo	RSPVo	RIPVo	RMPVo
Pt #1	—	—	Flat	Round	Round	—
Pt #2	Oval	Flat	—	Round	Oval	—
Pt #3	—	—	Flat	Round	Round	—
Pt #4	Oval	Oval	—	Oval	Round	—
Pt #5	Flat	Flat	—	Oval	Round	—
Pt #6	—	—	Flat	Round	Round	—
Pt #7	—	—	Flat	Round	Round	—
Pt #8	—	—	Round	Round	Round	—
Pt #9	Flat	Oval	—	Flat	Flat	—
Pt #10	Flat	Flat	—	Round	Round	—
Pt #11	Flat	Flat	—	Flat	Round	—
Pt #12	Round	Flat	—	Oval	Round	Oval

Diameter ratios ≤ 1.2 , between 1.2 and 1.4, and > 1.4 defined round, oval, and flat shapes, respectively.

No significant complications (vascular access complications needing operation or blood transfusion, cardiac tamponade, TIA or stroke, phrenic nerve palsy, PV stenosis, atrio-oesophageal fistula) related to the ablation procedure occurred. Fluoroscopy times and X-ray doses were 57 ± 16 min and 9406 ± 2990 cGy cm^2 , respectively. Approximately half of this was due to the extensive mapping and catheter manipulation required for the voltage maps before and after ablation (data not shown).

Two patients (#4 and #8) underwent additional cavotricuspid isthmus ablation for documented typical right atrial flutter, and one patient underwent additional mitral isthmus ablation for documented atypical left atrial flutter (patient #10) during the index procedure. These ablations were performed with a standard irrigated-tip (Thermocool™, BiosenseWebster, CA, USA) ablation catheter.

Voltage maps to determine the level of isolation

The mean number of electrograms acquired before and after PV isolation was 168 ± 55 and 184 ± 57 , respectively ($P = \text{ns}$). Before ablation, voltage maps revealed areas of normal voltages (> 0.5 mV) inside the PVs with different degrees of penetration into the veins and distribution around their circumference (Figure 3A and B). After ablation, all voltage maps showed significant voltage reduction in all PVs and, to different extent, proximal to their ostia (Figure 3C and D) as demonstrated by the presence of colours ranging from grey (voltage < 0.05 mV) to red and blue (voltage > 0.05 and < 0.5 mV). Mean voltage reduction expressed as relative reduction was large: LSPV -86% , LIPV -82% , LCPV -85% , RSPV -90% , RMPV -90% , RIPV -92% .

The quantitative voltage analysis revealed that there was no significant difference between left- and right-sided PVs in the average voltage detected before ablation (1.11 ± 0.40 vs. 0.98 ± 0.36 mV, respectively, $P = \text{ns}$), whereas a significant difference was present after PV isolation (0.18 ± 0.05 vs. 0.10 ± 0.02 mV, respectively, $P < 0.005$) likely as a result of large far-field atrial signals due to the close proximity to the LA appendage. Moreover, ablation with the PVAC significantly reduced bipolar voltages in all PVs and also in

the LA itself close to the vein ostia (Figure 4). Although the body of the LA remained characterized by normal voltages (> 0.5 mV, depicted in purple), atrial tissue proximal to the PV ostia was often included in the low voltage area. Possibly due to the different shape of the respective PVs ostia, the antral voltage reduction was more obvious in the left-sided PVs. Left-sided PV ostia were mainly flat (13 flat, 4 oval, 2 round), right-sided PV ostia mostly had a rounded shape (17 round, 5 oval, 3 flat).

Follow-up

During the post-ablation in-hospital stay, two patients experienced frequent premature atrial contractions and short runs of atrial tachycardia (< 30 s), one patient (patient #1) had early recurrence of paroxysmal AF, and one patient (patient #6) had in-hospital documentation of frequent atrial extrasystoles inducing symptomatic paroxysmal AF resistant to drug treatment. This last patient underwent a second procedure 5 days after the index ablation. During the electrophysiological study, the presence of an extra PV focus at the roof of the LA was detected, and the PVs were still isolated. Ablation of the extra PV focus was performed. At hospital discharge, four patients were on anti-arrhythmic drugs (two patients on Class IC, two patients on Class III). At a mean follow-up of 235 ± 92 (range 135–447) days, no other clinical arrhythmic episodes have occurred in the study population.

No serious procedure-related complications occurred. One patient developed a groin haematoma that resolved spontaneously without sequelae.

Discussion

Main findings

This study shows several important findings: (i) PV isolation assessed by demonstration of both entry and exit block was achieved in all patients using the PVAC alone. (ii) Using the voltage criteria of this study, the level of PV isolation achieved with the PVAC is ostial, proximal to the venous tubular portion,

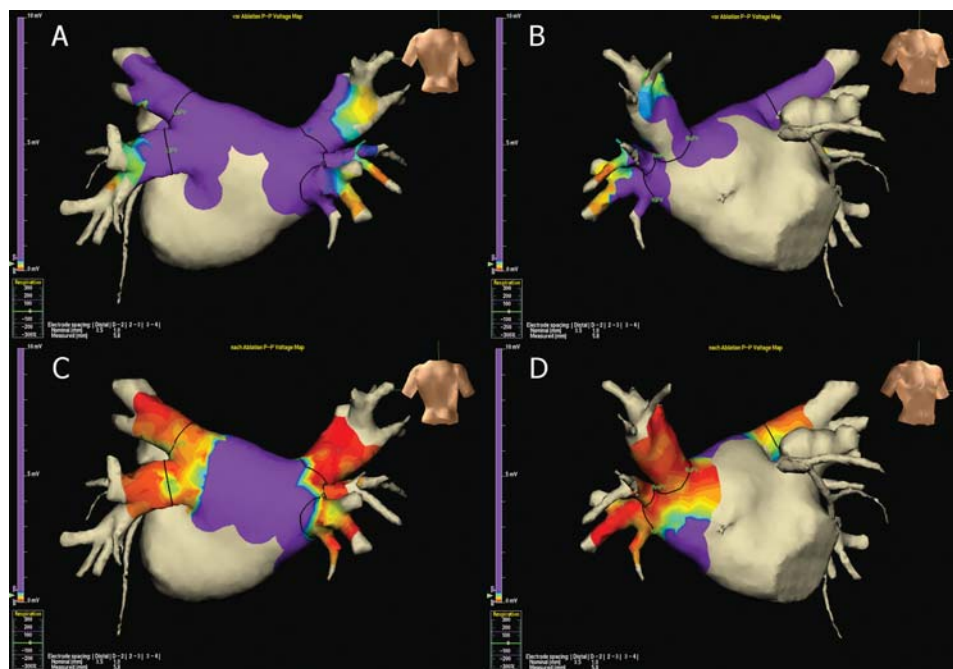


Figure 3 Posterior and anterior views of the voltage maps obtained before (A and B) and after (C and D) PV isolation using the PVAC in patient #12 and projected on the 3D reconstruction of the LA. The purple colour identifies areas with normal voltages (>0.5 mV), whereas the grey colour represents very low voltage areas (<0.05 mV). The colours ranging from red to blue correspond to areas with intermediate voltage values (>0.05 and <0.5 mV). Before PV isolation (A and B), normal voltages were recorded in the PVs with different degrees of distal penetration and circumferential distribution. After PV isolation (C and D), a dramatic voltage abatement can be seen in all PVs, starting proximal to their ostia.

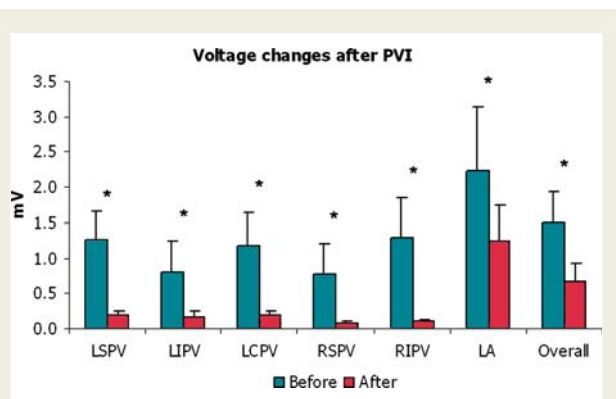


Figure 4 Mean voltages before (blue bars) and after (red bars) pulmonary vein isolation; $*P < 0.05$. PVI: pulmonary vein isolation; PV: pulmonary vein; LSPV: left superior PV; LIPV: left inferior PV; RSPV: right superior PV; RIPV: right inferior PV; LCPV: left common PV; LA: left atrium.

and significant voltage reduction was recorded at the antral level, particularly in left-sided PVs. (iii) Even left-common PVs were successfully isolated proximal to their ostium. (iv) Whereas bipolar voltages did not differ between right- and left-sided PVs before isolation, there was a significant difference after PV isolation, being higher in the left-sided PVs due to the far-field recording from the adjacent LA appendage.

Comparison with other ablation techniques

The acute success rate in PV isolation with the PVAC has been recently reported to be as high^{2,3} as that achieved with conventional-tip catheters^{18–20} and similar or higher than that obtained with other novel ablation tools such as the RF mesh catheter (63%),¹ the cryo-balloon (ranging from 60 to 98%),^{4,5} the endoscopic laser balloon (91%),⁸ and the high-intensity focused ultrasound balloons (87–89%),^{6,7} and in patients with paroxysmal AF, arrhythmia-free survival rates at 6 months were between 80 and 86% with PVAC,^{2,3} similar to that seen with standard point-by-point RF ablation strategy and new balloon-based technologies.^{4–8,21}

The level of PV isolation achieved with the PVAC in our study seems comparable to that obtained with standard tip-catheter-based approaches aiming at extra-ostial isolation. However, whether the level of isolation needs to be further proximal in the LA remains a matter of debate.^{22–28} Indeed, while ostial segmental isolation might leave arrhythmogenic foci proximal to the LA–PVs junction, wide antral ablation may be followed by higher rates of subsequent macroreentrant atrial tachycardias.

With new balloon catheters, using different energy sources (i.e. cryo, laser and high-intensity focused ultrasound), the level of PV isolation achieved has been recently reported to be relatively ostial, leaving the antral area mainly unaffected, and the level of

vein isolation depends greatly on the interaction of the ablation catheter with the patient-specific LA–PV anatomy.²⁹ When compared with the findings of Reddy *et al.*,²⁹ use of the PVAC results in a similar level of PV isolation and is characterized by the possibility of successfully isolating even large LCPVs ostia. Both cryo- and laser balloons require good contact with the atrial tissue. Therefore, in cases of larger veins, ablation inside the vein may be necessary in order to achieve sufficient catheter contact, hence increasing the risk of PV stenosis or phrenic nerve palsy. The recent introduction of a bigger diameter (29 mm) cryo-balloon may reduce this limitation.⁵ Another possible reason explaining the higher incidence of phrenic nerve injury using balloon-based catheters might be related to the mechanical stretch produced by these catheters at the atriovenous junction of the RSPV. The distension of the venous wall could increase the contact area to the phrenic nerve. This particular mechanism of phrenic nerve damage would not be shared by the PVAC. The highly focused ultrasound balloon represents an exception to the other balloon catheters, since it does not need contact with the tissue in order to effectively ablate, but on the other hand its use has been limited by the occurrence of complications and by the difficulty in orienting the ultrasound beam towards the area of interest.⁷

In addition, our study showed a difference in the shape of the ostia between the left-sided and the right-sided PVs, the first being mainly flat or oval and the second mainly round. This difference in shape of the PV ostia in our study might explain the different amount of atrial rather than atriovenous tissue in contact with the ring-shaped PVAC at the different LA–PV junctions and, hence, the difference in the lesion location, PV isolation being more ostial at round-shaped PV ostia and more antral at oval- or flat-shaped PV ostia.

In summary, the PVAC seems to be an attractive alternative to standard ablation catheters and to new catheter designs when PV isolation is the goal. In particular, standard-catheter manipulation in the LA requires skills and experience, particularly in order to achieve sufficient catheter contact during ablation at certain anatomic locations for example at the ridge between the left-sided PVs and the LA appendage or at the superior aspects of the upper PVs ostia. Furthermore, standard tip-catheter PV isolation often requires a double-transseptal puncture or multiple catheter exchanges through the transseptal sheath if confirmation of isolation using a circular diagnostic catheter is performed.

No serious procedure-related complications occurred in the present study. No imaging techniques have been used in our population to detect asymptomatic PV stenosis during follow-up. Recently, Fredersdorf *et al.*³ have reported no incidence of PV stenosis after PVAC-PV isolation. Nevertheless, PV stenosis could represent a complication of PV isolation using the PVAC if energy is delivered inside the PV. Therefore, we believe that careful characterization and understanding of the PV–LA anatomy (angiography and/or 3D CT reconstruction) is crucial to avoid this complication. During follow-up, one patient underwent a second ablation procedure because of recurrent paroxysmal AF. None of the PVs was reconnected during the second procedure. No clinical recurrences have been experienced by the remaining patients except one early recurrence of paroxysmal

AF, well controlled with an anti-arrhythmic drug that had previously failed.

Limitations

The present study might be limited by the relatively small sample size and the lack of a control group in whom an alternative ablation method was used. However, the study population is representing the population of patients with paroxysmal AF referred for catheter ablation as underlined by the patient characteristics in our study, and the level of PV isolation has already been described for some of the alternative ablation tools.²⁹

Although voltage mapping is very useful to understand the level of PV isolation, low-amplitude signals do not necessarily indicate evidence of no surviving myocardium. In addition, the far-field potential from the left atrial appendage can often be recorded in the left-sided veins. However, confirmation of PV isolation was not based on the results of voltage mapping but on (i) assessment of entry and exit block using pacing and (ii) the drug challenges.

Evaluation of the long-term follow-up was not the aim of the present study but represents key information in order to clinically judge the usefulness of any new ablative tool. Hence, further studies are warranted in order to investigate long-term success rate in treating paroxysmal AF with the PVAC.

Conclusion

- (1) The ability of the PVAC of achieving PV isolation is not affected by the size of the PV ostium. Even large LCPV can be successfully isolated with this new multielectrode ablation catheter.
- (2) In patients with paroxysmal AF, ostial PV isolation incorporating antral tissue to different extent is achieved with the PVAC, similar to conventional-tip catheter procedures not aiming for wide antrum isolation.
- (3) The relatively simple handling of the PVAC as well as the single transeptal puncture procedure constitute important advantages compared with the standard double-transeptal approach.

Hence, we believe that the PVAC will be a valuable tool because of the expected increase in the number of patients eligible for ablative treatment of AF over the next years.

Conflict of interest: J.C.G. was a consultant for AblationFrontiers in the past and is a consultant for AstraZeneca, BiosenseWebster, Meda Pharma, and Medtronic, and has received speakers fees from Biotronik, BostonScientific, Medtronic, St Jude Medical, AstraZeneca, Novartis, Meda, SanofiAventis, and Berlin Chemie. S.R. is a consultant for St Jude Medical and has received speakers fees from St Jude Medical. No other conflicts of interest exist.

Funding

S.R. has received a research grant from the University of Messina as part of the PhD programme in 'Cardiovascular Imaging'. M.B. has received a research grant from the University of Genova as part of the PhD programme in 'Cardiovascular Pathophysiology'.

References

- Mansour M, Forleo GB, Pappalardo A, Heist EK, Avella A, Laurenzi F et al. Initial experience with the Mesh catheter for pulmonary vein isolation in patients with paroxysmal atrial fibrillation. *Heart Rhythm* 2008;**5**:1510–6.
- Boersma LV, Wijffels MC, Oral H, Wever EF, Morady F. Pulmonary vein isolation by duty-cycled bipolar and unipolar radiofrequency energy with a multielectrode ablation catheter. *Heart Rhythm* 2008;**5**:1635–42.
- Fredersdorf S, Weber S, Jilek C, Heinicke N, von Bary C, Jungbauer C et al. Safe and rapid isolation of pulmonary veins using a novel circular ablation catheter and duty-cycled RF generator. *J Cardiovasc Electrophysiol* 2009;**20**:1097–101.
- Van Belle Y, Janse P, Rivero-Ayerza MJ, Thornton AS, Jessurun ER, Theuns D et al. Pulmonary vein isolation using an occluding cryoballoon for circumferential ablation: feasibility, complications, and short-term outcome. *Eur Heart J* 2007;**28**:2231–7.
- Chun KR, Schmidt B, Metzner A, Tilz R, Zerm T, Köster I et al. The 'single big cryoballoon' technique for acute pulmonary vein isolation in patients with paroxysmal atrial fibrillation: a prospective observational single centre study. *Eur Heart J* 2009;**30**:699–709.
- Nakagawa H, Antz M, Wong T, Schmidt B, Ernst S, Ouyang F et al. Initial experience using a forward directed, high-intensity focused ultrasound balloon catheter for pulmonary vein antrum isolation in patients with atrial fibrillation. *J Cardiovasc Electrophysiol* 2007;**18**:136–44.
- Schmidt B, Antz M, Ernst S, Ouyang F, Falk P, Chun JK et al. Pulmonary vein isolation by high-intensity focused ultrasound: first-in-man study with a steerable balloon catheter. *Heart Rhythm* 2007;**4**:575–84.
- Reddy VY, Neuzil P, Themistoclakis S, Danik SB, Bonso A, Rossillo A et al. Visually-guided balloon catheter ablation of atrial fibrillation experimental feasibility and first-in-human multicenter clinical outcome. *Circulation* 2009;**120**:12–20.
- Calkins H, Brugada J, Packer DL, Cappato R, Chen SA, Crijns HJ et al. HRS/EHRA/ECAS expert Consensus Statement on catheter surgical ablation of atrial fibrillation: recommendations for personnel policy procedures follow-up. A report of the Heart Rhythm Society (HRS) Task Force on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm* 2007;**4**:816–61.
- Natale A, Raviele A, Arentz T, Calkins H, Chen SA, Haissaguerre M et al. Venice Chart international consensus document on atrial fibrillation ablation. *J Cardiovasc Electrophysiol* 2007;**18**:560–80.
- Haissaguerre M, Jais P, Shah DC, Garrigue S, Takahashi A, Lavergne T et al. Electrophysiological end point for catheter ablation of atrial fibrillation initiated from multiple pulmonary venous foci. *Circulation* 2000;**101**:1409–17.
- Pappone C, Rosanio S, Oreto G, Tocchi M, Gugliotta F, Vicedomini G et al. Circumferential radiofrequency ablation of pulmonary vein ostia: a new anatomic approach for curing atrial fibrillation. *Circulation* 2000;**102**:2619–28.
- Ouyang F, Bansch D, Ernst S, Schaumann A, Hachiya H, Chen M et al. Complete isolation of left atrium surrounding the pulmonary veins: new insights from the double-Lasso technique in paroxysmal atrial fibrillation. *Circulation* 2004;**110**:2090–6.
- Tritto M, De Ponti R, Salerno-Uriarte JA, Spadacini G, Marazzi R, Moretti P et al. Adenosine restores atrio-venous conduction after apparently successful ostial isolation of the pulmonary veins. *Eur Heart J* 2004;**25**:2155–63.
- Oral H, Crawford T, Frederick M, Gadeela N, Wimmer A, Dey S et al. Inducibility of paroxysmal atrial fibrillation by isoproterenol and its relation to the mode of onset of atrial fibrillation. *J Cardiovasc Electrophysiol* 2008;**19**:466–70.
- Jongbloed MR, Dirksen MS, Bax JJ, Boersma E, Geleijns K, Lamb HJ et al. Atrial fibrillation: multi-detector row CT of pulmonary vein anatomy prior to radiofrequency catheter ablation—initial experience. *Radiology* 2005;**234**:702–9.
- Schmidt B, Ernst S, Ouyang F, Chun KR, Broemel T, Bänsch D et al. External and endoluminal analysis of left atrial anatomy and the pulmonary veins in three-dimensional reconstructions of magnetic resonance angiography: the full insight from inside. *J Cardiovasc Electrophysiol* 2006;**17**:957–64.
- Cheema A, Dong J, Dalal D, Vasamreddy CR, Marine JE, Henrikson CA et al. Long-term safety and efficacy of circumferential ablation with pulmonary vein isolation. *J Cardiovasc Electrophysiol* 2006;**17**:1080–5.
- Hocini M, Sanders P, Jais P, Hsu LF, Takahashi Y, Rotter M et al. Techniques for curative treatment of atrial fibrillation. *J Cardiovasc Electrophysiol* 2004;**15**:1467–71.
- Verma A, Patel D, Famy T, Martin DO, Burkhardt JD, Elayi SC et al. Efficacy of adjuvant anterior left atrial ablation during intracardiac echocardiography-guided pulmonary vein antrum isolation for atrial fibrillation. *J Cardiovasc Electrophysiol* 2007;**18**:151–6.
- Cappato R, Calkins H, Chen SA, Davies W, Lesaka Y, Kalman J et al. Worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. *Circulation* 2005;**111**:1100–5.
- Kanj MH, Wazni OM, Natale A. How to do circular mapping catheter-guided pulmonary vein antrum isolation: the Cleveland Clinic approach. *Heart Rhythm* 2006;**3**:866–9.
- Fiala M, Chovancik J, Nevalova R, Neuwirth R, Jiravský O, Nykl I et al. Pulmonary vein isolation using segmental versus electroanatomical circumferential ablation for paroxysmal atrial fibrillation: over 3-year results of a prospective randomized study. *J Interv Card Electrophysiol* 2008;**22**:13–21.
- Karch MR, Zrenner B, Deisenhofer I, Schreieck J, Ndrepepa G, Dong J et al. Freedom from atrial tachyarrhythmias after catheter ablation of atrial fibrillation: a randomized comparison between 2 current ablation strategies. *Circulation* 2005;**111**:2875–80.
- Nilsson B, Chen X, Pehrson S, Kober L, Hilden J, Svendsen JH. Recurrence of pulmonary vein conduction and atrial fibrillation after pulmonary vein isolation for atrial fibrillation: a randomized trial of the ostial versus the extraostial ablation strategy. *Am Heart J* 2006;**152**:537–8.
- Katritsis D, Wood MA, Shepard RK, Giazitzoglou E, Kourlaba G, Ellenbogen KA. Atrial arrhythmias following ostial or circumferential pulmonary vein ablation. *J Interv Card Electrophysiol* 2006;**16**:123–30.
- Mansour M, Ruskin J, Keane D. Efficacy and safety of segmental ostial versus circumferential extra-ostial pulmonary vein isolation for atrial fibrillation. *J Cardiovasc Electrophysiol* 2004;**15**:532–7.
- Liu X, Long D, Dong J, Hu F, Yu R, Tang R et al. Is circumferential pulmonary vein isolation preferable to stepwise segmental pulmonary vein isolation for patients with paroxysmal atrial fibrillation? *Circ J* 2006;**70**:1392–7.
- Reddy VY, Neuzil P, d'Avila A, Laragy M, Malchano ZJ, Kralovec S et al. Balloon catheter ablation to treat paroxysmal atrial fibrillation: what is the level of pulmonary venous isolation? *Heart Rhythm* 2008;**5**:353–60.