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Efficacy of multi-electrode duty-cycled radiofrequency ablation in patients with paroxysmal and persistent atrial fibrillation

Edward Koźluk, Paweł Balsam, Michał Peller, Marek Kiliszek, Piotr Lodziński, Agnieszka Piątkowska, Sylwia Małkowska, Dariusz Rodkiewicz, Janusz Kochanowski, Grzegorz Opolski

1st Department of Cardiology, Medical University of Warsaw, Warsaw, Poland

Abstract

Background: *Radiofrequency (RF) catheter ablation is a first-line therapy for patients with drug-refractory atrial fibrillation (AF). Complete isolation of electrical potentials at the ostium of pulmonary vein (PV) is a challenging procedure. There are different techniques and devices used for PV isolation (PVI). The objective of this study was to evaluate the efficacy and safety of PV ablation catheter (PVAC).*

Methods: *A total of 67 consecutive patients with paroxysmal and persistent AF were treated with the PVAC. The patients' information were obtained from clinical charts. Follow-up was obtained by one day Holter monitoring at 2, 4, 6, 8, 10 and 12 months after ablation and ECG registration if any symptoms or arrhythmia occurred.*

Results: *The median follow-up duration was 16 months (IQR: 12–20 months). In the population which was available at follow-up (n = 60), 22 (36.7%) patients were in sustained sinus rhythm (SR) without anti-arrhythmic drugs (AAD). Overall 26 (43.3%) patients were in sustained SR with and without AAD. In the paroxysmal AF group, after a single PVAC ablation procedure (n = 39), 19 (48.7%) patients had sustained SR without AAD. In the persistent AF group (n = 15), after the single PVAC ablation, 2 (13.3%) patients had sustained SR without AAD.*

Conclusions: *PVI with PVAC is a safe procedure with 48.7% efficacy in patients with paroxysmal AF. The efficacy of PVAC in patients with persistent or long-standing persistent AF is not acceptable.* (Cardiol J 2013; 20, 6: 618–625)

Key words: atrial fibrillation, pulmonary vein isolation, catheter ablation, arrhythmia

Introduction

Radiofrequency (RF) catheter ablation is a first-line therapy for patients with drug-refractory atrial fibrillation (AF) [1]. At the very beginning ablation strategy consisted of focal ablation of triggers inside the pulmonary veins (PV) [2]. Because of PV stenosis, this method was modified to isolation of the PV by segmental isolation at the ostium of the veins [3]. Isolation of triggers within the PVs is the main treatment strategy in these patients [2]. Traditional techniques use a ring-shaped mapping catheter and an ablation catheter that applies RF energy in a unipolar fashion. Comple-

Address for correspondence: Paweł Balsam, MD, PhD, 1st Department of Cardiology, Medical University of Warsaw, ul. Banacha 1a, 02–097 Warszawa, tel: +48 22 599 29 58, e-mail: pawel@balsam.com.pl

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te isolation of electrical potentials at the ostium of PV is a challenging procedure which requires a long learning curve. Strategies were evolving to include wide area encircling of the PV antrum using 3-dimensional mapping systems that could reconstruct anatomy of atrium to guide ablation and limit fluoroscopy time [4]. The evolution in ablation procedures led to increasingly complex and time consuming procedures and the need for high-technology equipment. Computed tomography/magnetic resonance imaging integration, intra-cardiac echocardiography have been proposed as new tools for making the procedure easier. Little progress has been made in the development of ablation catheters. Traditionally, AF ablation is performed with a single-tip catheter with point-by-point ablation process. This technique requires a high degree operator skill, and the procedures are lengthy. Additionally, creating contiguous transmural lesions is a difficult art. Therefore, there is a place for specialized RF ablation catheters specifically designed for AF ablation. The objective of this study was to evaluate the efficacy and safety of pulmonary vein ablation catheter (PVAC) (Medtronic, Ablation Frontiers, Carlsbad, CA, USA) in a Polish cardiologic centre which performs about 200 AF ablations per year.

Methods

Patients

A total of 67 patients with paroxysmal or persistent AF, who underwent elective PV isolation (PVI), were included in a retrospective registry. The characteristics of patients are presented in Table 1. Patients were admitted 24 h prior to the ablation procedure. Transesophageal echocardiography was performed to assess inter-atrial septum and to rule out intra-cardiac thrombus. Routine blood tests were performed, including electrolytes and cardiac enzymes.

Informed consent was obtained from all patients.

Ablation procedure

After vascular access through femoral veins was achieved, a steerable catheter was placed in the coronary sinus via the left femoral vein and a non-steerable catheter was placed in the right ventricular outflow tract. A transseptal puncture was performed using fluoroscopic imaging and pressure monitoring with the use of a long 8-Fr sheath (Biosense Webster PREFACE Sheath). After administering a heparin bolus (100 IU/kg), additional heparin of 1000 IU/h was given throughout the procedure. The Preface sheath was then replaced by a deflectable, 12-Fr, long sheath (FlexCath® Steerable Sheath) for advancing the PVAC catheter. The long sheath was perfused with heparinized saline solution. Thereafter, selective angiography of the PVs was performed with about 40 mL of contrast agent in left anterior oblique and right anterior oblique projections.

Table 1. Basic characteristics of population (n = 67).

Age	55.6 ± 10.3
Years from diagnosing AF	4.0 (2.0–8.0)
Age of AF diagnose	50.3 ± 10.1
Persistent AF	25.4%
No. of AF episodes in month	4.5 (2–12) [n = 36]
Coronary artery disease	6.0%
Hypertension	68.7%
Diabetes mellitus	10.5%
Chronic heart failure	4.5%
Lone AF	26.9%
History of hyperthyroidism	11.9%
Hyperlipidemia	31.3%

AF — atrial fibrillation

The PVAC is a circular decapolar 9-Fr bidirectional catheter with 3-mm-long platinum electrodes, inter electrode spacing of 3 mm, and a diameter of 25 mm. The PVAC is advanced over a 0.032-inch wire, which is positioned selectively in each PV or its branch to give support and stability to the ablation catheter. Selective cannulation of specific branches of the veins is very important to optimize catheter to wall contact during large common ostia isolation. With PVAC it was possible to map local signals, to stimulate and to apply RF over all or selected electrode pairs. The catheter is connected to the dedicated RF generator — GENius (Medtronic Inc.). It delivers RF in a combination of 1 or more of the 5 bipolar channels. Each electrode is supplied with a thermocouple, which permits a continuous local temperature monitoring. Target temperature during our procedures was 50–60°C with a maximum power of 8–10 W (8 W for 4:1 ratio, 10 W for 2:1 ratio). The ratio 4:1 or 2:1 is proportion for bipolar/unipolar power delivery. In 4:1 ratio 80% of energy is delivered in bipolar constellation and 20% in unipolar, in 2:1 ratio the percentages are 66.6% and 33.3%, respectively. If the created lesion was estimated to be nontransmural with the 4:1 setting the RF ablation was set in a 2:1 bipolar/unipolar proportion. The lesions were estimated

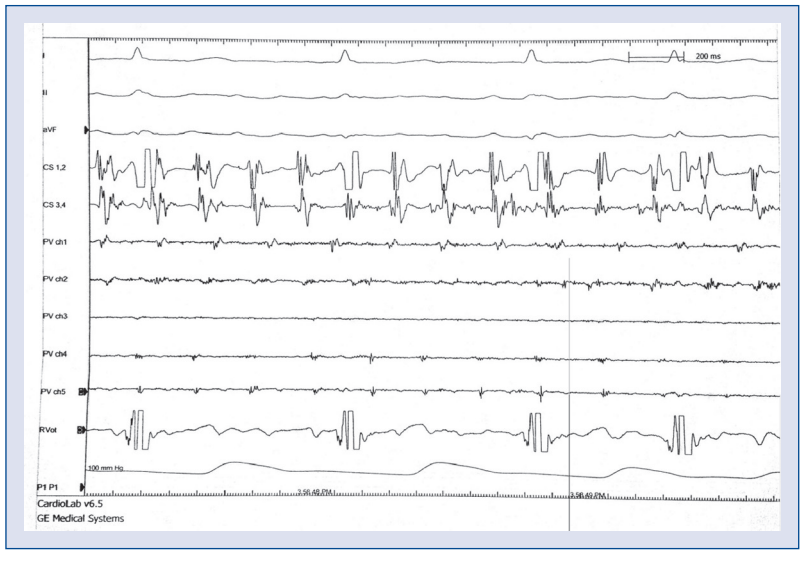

Figure 1. Pulmonary vein potentials during atrial fibrillation in right superior pulmonary vein; CS — coronary sinus catheter; PV — pulmonary vein ablation catheter; RVOT — catheter placed in right ventricle outflow tract.

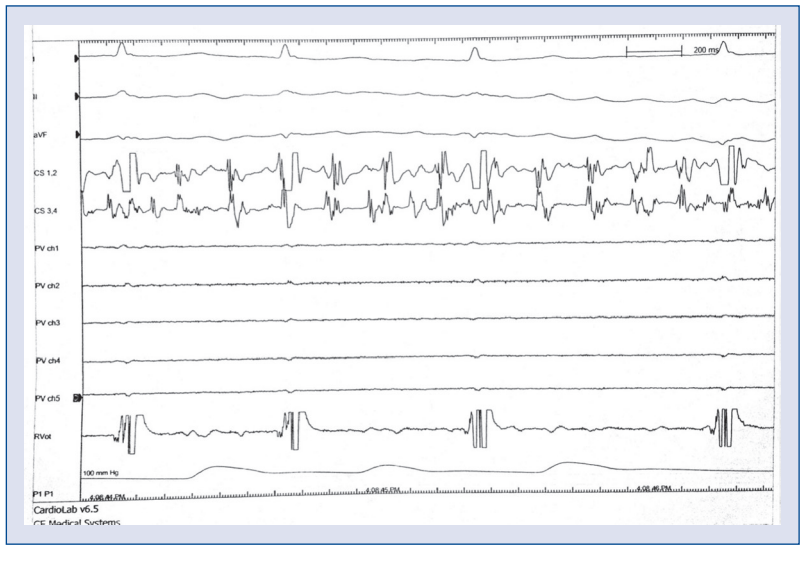

Figure 2. Potential form the ostium right superior pulmonary vein after isolation; CS — coronary sinus catheter; PV — pulmonary vein ablation catheter; RVOT — catheter placed in right ventricle outflow tract.

to be transmural according to local ECG. Impulse duration was 60 s. We generally avoided premature termination of ablation which was stopped in case of strong pain or catheter dislodgement. After several RF applications over all electrode pairs, the PVAC was rotated around the ostium of PV, looking for the earliest pulmonary vein potential (PVP) to completely isolate the vein. Once the region of interest had been localized and perfect contact of the PVAC with antral tissue was achieved, RF was delivered only over selected electrode pairs. While performing ablation of large common ostia, electrode pairs that had suboptimal contact to the atrial tissue were deactivated, to avoid ineffective energy delivery. The end point was complete electrical isolation of all PVs. Figure 1 shows PVP during AF in the right superior pulmonary vein (RSPV) and Figure 2 shows potentials form of the ostium RSPV after complete isolation. Whenever it was possible, we confirmed the electrical block by advancing at least some PVAC electrodes into the PVs and demonstrating entrance and exit block.

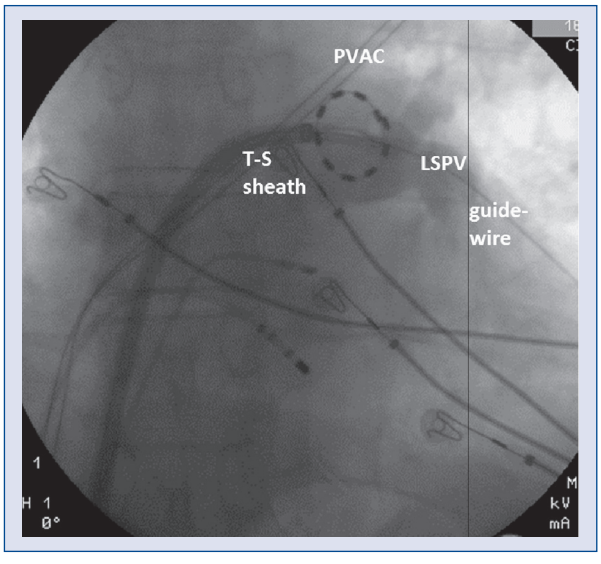

Figure 3. Radioscopic image of the pulmonary vein ablation catheters (PVAC) catheter over the antrum of the left superior pulmonary vein ablation catheter; T-S sheath — transseptal sheath; LSPV — left superior pulmonary vein.

The protocol did not include routine confirmation of the PV isolation with a conventional circular diagnostic catheter. Figure 3 shows an example of a fluoroscopic image of the PVAC catheter over the antrum of the left superior PV. Differential pacing was used while assessing the isolation of the lateral veins by pacing in the distal coronary sinus or left atrial appendage. Transthoracic echocardiography was performed 1 day after the procedure in all patients. Oral vitamin K antagonists (VKA) were discontinued 5 days before procedure, low-molecular-weight heparin was given from the day of discontinuation of VKA. VKA was introduced on the next day after ablation and continued for at least 3 months. Low-molecular-weight heparin was given until the international normalized ratio was between 2.0 and 3.0.

Follow-up

At discharge from hospital all the patients were encouraged to perform a 24 h Holter monitoring at 2, 4, 6, 8, 10 and 12 months after ablation and ECG registration if any symptoms or arrhythmia occurred. The results were sent by mail. Antiarrhythmic drug (AAD) therapy was used in patients with early and recurrent episodes of symptomatic AF. Freedom from AF was defined as the absence of AF or atrial flutter or tachycardia lasting > 30 s. All patients who required a redo procedure within the follow-up period were classified as a primary failure of the initial ablation procedure. Patients were also followed-up by phone contact performed by physicians.

Statistical analysis

Categorical data were presented as percentages and in case of subgroups the frequency was also noted. All continuous variables normally distributed were presented as mean value and standard deviation (SD). For non-normally distributed continuous variables median value and interquartile range (IQR) were used. Normal distribution was accessed by Shapiro-Wilk test with an alpha level set at 0.05. Survival curves were made by Kaplan-Meier estimator, including patients with complete follow-up. To determine the risk factors of AF recurrence univariate and multivariable Cox proportional-hazards regression were performed. There were considered all pre-procedural, procedural and post-procedural factors. Statistical significance was considered for P-values lower than 0.05. Statistical analyses were made using SAS software, version 9.2.

Results

Clinical characteristics of the patients

A total of 67 consecutive patients, aged 55.6 ± ± 10.3 years, with paroxysmal (n = 50) or persistent (n = 17) drug refractory AF, who were referred for PVI with PVAC between November 2009 and December 2011, were included in the retrospective study. All patients had documented AF episodes with a median AF duration of 4 years (IQR: 2–8 years). Six patients from paroxysmal AF group had previous PVI procedure (4 mm non-irrigated ablation catheter, circular mapping catheter, with LocaLisa system). Those patients were excluded from analysis of success rates for single PVAC procedure. Clinical characteristics of the patients are summarized in Table 1. Echocardiographic recordings demonstrated an average left atrial size of 4.34 cm in the parasternal long-axis view.

Procedural success

The median total procedure time was 120 min (IQR: 105–155 min), including the advancement of femoral approach, transseptal puncture and pre- and post-ablation mapping of the PVs. PV angiography was performed prior to ablation. Nineteen patients had a left common trunk, 6 with persistent AF and 13 with paroxysmal (Table 2). Five patients had

Table 2. Procedural data.

Parameters	Median (IQR) or percent
Time of procedure [min]	120 (105–155)
Time of X-ray [min]	17 (14–21)
Mean duty cycled radiofrequency ablation time [min]	39 (31–50)
Presence of common trunk of PV	34.3%
Complete isolation of PV	99.6%
Isolation of vena cava superior	43.3%
Presence of patient foramen ovale	29.7%
Cardioversion during AF procedure	3%
Procedure performed during AF	37.3%

AF — atrial fibrillation; PV — pulmonary vein

right common trunk of PVs. Deployment of the PVAC was successful in all left and right PVs. In 29 (43.3%) patients the superior vena cava (SVC) was isolated using the PVAC. The median duty cycled RF ablation time required to achieve complete PV isolation was 39 min (IQR: 31–50 min). The median total fluoroscopy time was 17 min (IQR: 14–21 min). Acute success of PVI confirmed by entrance block was achieved in 66 of 67 patients (98.5%) and in 243 of 244 veins (99.6%).

Cardiac rhythm during follow-up

Seven (10.4%) patients were lost to follow-up. The median follow-up duration was 16 months (IQR: 12–20 months). The recurrence of AF was detected by 24 h Holter monitoring and/or by 12 lead ECG performed in case of any arrhythmia symptoms occurrence. During the blanking period (3 months) 23 of 60 patients (38.3%) had recurrence of AF. In the population which was available at follow-up (n = 60), 22 (36.7%) patients were in sustained sinus rhythm (SR) without AAD. Overall 26 (43.3%) patients were in sustained SR with and without AAD. In the paroxysmal AF group, after a single PVAC ablation procedure (n = 39), 19 (48.7%) patients had sustained SR without AAD. In the persistent AF group (n = 15), after the single PVAC ablation, 2 (13.3%) patients had sustained SR without AAD. The single and all procedures clinical success of an ablation procedure during the whole follow-up period can be described in many ways (Table 3). Mean time of recurrence of AF was 3.8 months. Forty-seven (78.3%) patients declared a significant improvement in symptoms associated with arrhythmia, 9 (15%) patients did not see the difference and 4 (6.7%) patients declared deterioration of symptoms. Of all the patients with recurrence 12 underwent one redo procedure

Table 3. Overall efficacy by definitions of success in patients with paroxysmal and persistent AF after a PVAC procedure and after redo procedures.

Definition	Success rate, no. (%)
Absence of AF/AFL/tachycardia, and patients were off class I or III AADs in whole group after single PVAC procedure	21/54 (38.9%)
Absence of AF/AFL/tachycardia, with or without class I or III AADs in whole group after single PVAC procedure	24/54 (44.5%)
Absence of AF/AFL/tachycardia, and patients were off class I or III AADs in paroxysmal AF group after single PVAC procedure	19/39 (48.7%)
Absence of AF/AFL/tachycardia, and patients with or without class I or III AADs in paroxysmal AF group after single PVAC procedure	21/39 (53.8%)
Absence of AF/flutter/tachycardia, and patients were off class I or III AADs in persistent AF group after single PVAC procedure	2/15 (13.3%)
Absence of AF/AFL/tachycardia, and patients with or without class I or III AADs in persistent AF group after single PVAC procedure	3/15 (20%)
Absence of AF/AFL/tachycardia, and patients were with or without class I or III AADs in whole group after all procedures (LocaLisa, PVAC, CARTO)	36/60 (60%)
Absence of AF/AFL/tachycardia, and patients were with or without class I or III AADs in paroxysmal AF group after all procedures (LocaLisa, PVAC, CARTO)	29/45 (64.4%)
Absence of AF/AFL/tachycardia, and patients were off I or III AADs in paroxysmal AF group after all procedures (LocaLisa, PVAC, CARTO)	23/45 (51.1%)
Absence of AF/AFL/tachycardia, and patients were with or without class I or III AADs in persistent AF group after all procedures (LocaLisa, PVAC, CARTO)	7/15 (46.7%)
Absence of AF/AFL/tachycardia, and patients were off I or III AADs in persistent AF group after all procedures (LocaLisa, PVAC, CARTO)	3/15 (20%)

AADs — anti-arrhythmic drugs; AF — atrial fibrillation; AFL — atrial flutter; PVAC — pulmonary vein ablation catheters

Table 4. Results of univariate Cox proportional hazard regression for AF recurrence.

Factor	Hazard ratio	95% CI	P
Isolation of vena cava superior	0.45	0.22–0.94	0.0324
History of chronic heart failure	5.18	1.45–18.57	0.0115
AF during hospitalization after procedure	2.84	1.44–5.59	0.0025
Procedure performed during AF	2.21	1.12–4.62	0.0221

AF — atrial fibrillation; CI — confidence interval

with CARTO system and 2 of them underwent 2 redo procedures. The overall success rate including redo procedures is 60% (36 of 60 sustained in SR with and without AAD).

Complications

There was 1 patient with stroke 1 day after the procedure (left upper limb paresis withdrawn on the next day). Symptoms withdrawn on the second day. In other patient there was cardiac tamponade/ /perforation (pericardial effusion up to 2 cm noticed during the procedure, which did not require the drainage) and also transient ischemic attack (TIA) episode at the same time. The patient's condition was stable, the blood pressure was 90/60 mm Hg. That is why we did not decide to perform the drainage. We administered 50 mg of protamine sulphate i.v. which is maximal dosage and the amount of fluid in pericardium stopped increasing. The symptoms of TIA (right upper limb paresis) withdrawn in 2 h.

Univariate and multivariate analyses

In the univariate Cox regression analysis the following pre-procedural, procedural and post- -procedural factors were associated with the outcome after isolation of PVs with PVAC: isolation of SVC, history of chronic heart failure, episode of AF during the hospitalization after the procedure and also performing the ablation procedure during AF (Table 4).

After backward elimination multivariate Cox- -regression analyses of pre-procedural, procedural and post-procedural factors did not show statistically significant correlations.

Discussion

The present data describe a consecutive group of 60 patients with complete follow-up, whose median is 16 months, after documented acute success PVI by phased RF energy with the decapolar PVAC. Arrhythmia follow-up was performed with ECGs and 24 h Holter. The data show an overall freedom from AF or any other left atrial arrhythmia

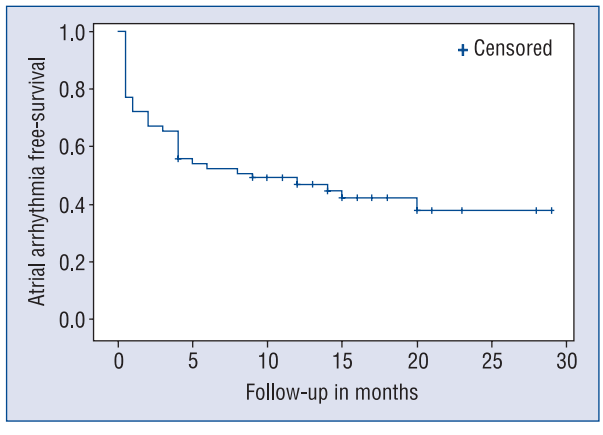

Figure 4. Kaplan-Meier curve demonstrating time to first atrial fibrillation recurrence after a single treatment with pulmonary vein ablation catheters for paroxysmal and persistent atrial fibrillation.

with and without AADs in 44.5% of patients after a single procedure with PVAC. Figure 4 presents the Kaplan-Meier curve demonstrating time to first AF recurrence after a single treatment with PVAC for paroxysmal and persistent AF.

Procedure performance of the PVAC

Generally, the performance of the PVAC catheter seems at least comparable to the other single shot devices. Using the high density mesh ablation (HDMA) catheter, Mansour et al. [5] showed efficacy in electrical isolation of 63% of the PVs and 40% of the patients after a mean of 12 min of ablation time for each vein. Data concerning the cryoballoon showed that successful isolation of the PVs was possible in up to 92.5% of the veins and 83% of the patients [6]. All these devices concentrate on transforming ablation of paroxysmal AF into a straightforward procedure: PVI with a minimum of applications in a minimum of time, with a minimum of catheters, without mapping tools, and all this without decreasing success rate or increasing complication rates.

We consistently validated the acute endpoint of PV isolation using the PVAC catheter in com-

bination with dedicated differential pacing and observed that cumulative PVAC ablation resulted in electrical isolation of 98.5% of the patients and 99.6% of veins. Boersma et al. [7] performed validation with a circular mapping catheter in the initial 19 patients and reported 100% isolation. However they did not perform differential pacing to differentiate potentials on the mapping catheter. In these patients PVI assessment was based only upon PVAC recordings and reported to be 100%. Other authors suggest using steerable sheath, enhanced fluoroscopy, different guidewire positions in different side branches of the PVs, and registration of ostial potentials to obtain high isolation rates with the PVAC [8]. They also hypothesize that the use of the PVAC catheter by its design results in general in an ostial ablation. This is also observed with the HDMA catheter and the cryoballoon [9, 10]. However, in case of a common ostium or when early branching is present, the guidewire can be positioned in different side branches of the PV resulting in different PVAC positions, creating overlapping ablation lines that as a whole result in a more wide circumferential PVI [8].

The PVAC is a combination of a mapping and ablation tool in 1 catheter. The cryoballoon technology has no mapping capabilities. Therefore, this ablation approach requires a second circular mapping catheter and multiple catheter exchanges. The only other single-shot device which combines diagnostic and therapeutic tools is the HDMA catheter. Mansour et al. [5] presented that 12% of the veins which seemed isolated on the HDMA, were not isolated on a regular circular mapping catheter. The other study showed that PVAC has a diagnostic accuracy of 95% [8]. Authors suggested that bipolar electrograms are less detailed (most likely due to larger electrode size) but allowed to correctly diagnose PVPs. To obtain high diagnostic accuracy with the PVAC catheter authors advocate: to torque the PVAC catheter within the PVs, to annotate baseline PVPs at fixed fluoroscopic references before any RF delivery, and to apply limited pacing maneuvers [8]. In our procedures we were mapping according to those tips.

The advantage of PVAC procedure which is presented in other publications is the reduction of time of procedure and also the time of fluoroscopy [11]. In other study comparing efficacy of PVAC vs. CARTO procedure AF recurrence was documented in 23% and 29% of patients in the PVAC and CARTO groups, respectively ($p = 0.8$), they also found significantly shorter procedural and fluoroscopic times in the PVAC group ($p < 0.0001$) [12].

The incidence of left common pulmonary vein (LCPV)

There is a variation in the percentages of LCPV between large studies, ranging from 13% to 29% [13–17]. In our population 34.3% of patients were with LCPV. The results of the statistical analysis show that the presence of LCPV in our cohort did not have a significant effect on the outcome of PVAC ablation.

Chronic success of procedure

The long-term success of AF procedure according to the HRS/EHRA/ECAS expert consensus statement of 2012 is defined as freedom from AF/atrial flutter/atrial tachycardia recurrences following the 3-month blanking period through a minimum of 36 months of follow-up from the date of the ablation procedure in the absence of Class I and III AAD therapy [1]. The PVAC procedure has been launched in our center in November 2009 so there is no data available for such a long follow-up. However, in comparison to other available publications on PVAC, our median follow-up period of 16 months is a big achievement [7, 8, 11, 13]. There is information about late recurrences which are defined as a recurrence of AF 12 months or more after ablation (Episodes of atrial tachycardia or atrial flutter should also be classified as a "recurrence".) [1]. The single and all procedures-clinical success of an ablation procedure during the whole follow-up can be described in many ways (Table 3). According to the actual HRS/EHRA/ECAS expert consensus statement on AF the minimal chronic acceptable success rate for paroxysmal AF at 12-month follow-up for a clinical trials is 50% off AAD therapy including a pre-specified blanking period. In our population of patients with paroxysmal AF we achieved 48.7% success rate without AADs after a single PVAC procedure and 51.1% success rate after all PVI procedures, however, the design of monitoring allows for recurrent AF events to be underdetected (particularly if they are asymptomatic) compared to studies that use longer-term continuous monitors. The success rate meets the criteria by slimmest of margins, with the possibility of underdetection of AF recurrence. The minimal chronic acceptable success rate for persistent AF at 12-month follow-up for a clinical trials is 40% and for longstanding persistent is 30% off AAD therapy including a pre-specified blanking period. In our group with persistent AF the success rate for single PVAC procedure off AADs was 13.3% and after PVAC and redo procedure 20%. That is why based on our results we decided to perform PVAC

procedures only for patients with paroxysmal AF. Our results are quite similar to data presented by Mulder et al. [17] of 2 year follow-up of patients with paroxysmal AF treated with PVAC which shows 55% success rate after 1 year and decrease to 49% after 2 years in patients off AADs. Those results are different from those observed in studies with shorter follow-up. Beukema et al. [13] (n = 102) showed a 61% success rate with PVAC at 1 year. In a 6-month follow-up on patients with paroxysmal AF, Boersma et al. [7] (n = 98) demonstrated an 83% success with PVAC, while Wieczorek et al. [18] (n = 73) showed a success rate of 86%.

Complications

In our group we a observed 3% risk of thrombo-embolic events (2 patients of 67). The incidence of thrombo-embolism associated with AF ablation is reported to be between 0% and 7% [1, 19–23]. The rate of cardiac tamponade reported in Updated Worldwide Survey on the Methods, Efficacy, and Safety of Catheter Ablation for Human Atrial Fibrillation is 1.3% [24]. In our group the rate was 1.5% (1 of 67 patients).

Conclusions

PVI with PVAC is a safe procedure with 48.7% efficacy in patients with paroxysmal AF. The efficacy of PVAC in patients with persistent or long-standing persistent AF is not acceptable.

Conflict of interest: none declared

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