Circumferential pulmonary vein RF ablation in the treatment of atrial fibrillation: 3-year experience of one centre

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Abstract

Introduction: In patients with atrial fibrillation (AF), significantly symptomatic in particular, restoring and maintaining sinus rhythm is one of treatment strategias. Considering the limited efficacy and side effects of anti-arrhythmic agents, growing hopes are attributed to the developing techniques of percutaneous ablation.

Aim: To determine the efficacy and safety of circumferential pulmonary vein ablation performed using the CARTO system in patients with paroxysmal or permanent AF.

Methods: The study involved 94 patients (mean age 54 years, males 65%, structural heart disease 29.4%) with symptomatic, recurrent and AF resistant to antiarrhythmic agents (paroxysmal AF 63.8%), selected for circumferential pulmonary vein ablation with the Pappone method. Follow-up examinations were performed after 1, 3, 6, 9, and 12 months. The symptoms, ECG, 24-hour ECG monitoring and complications were recorded.

Results: Mean procedure and fluoroscopy durations were 4.5 hours and 22.4 minutes respectively. The long-term follow-up ranged from 3 to 24 months, with median time of 12 months. At six months, 47.8% of patients remained free from AF, and improvement in terms of infrequent arrhythmia occurrence and low incidence of symptoms in an additional 36.7% was observed. Efficacy was lower in patients with permanent AF (12 months 90% *vs* 70%). Complications were seen in six (6.4%) patients: cardiac tamponade in two patients; and pericardial effusion, retroperitoneal bleeding, stroke, and pulmonary vein thrombosis each in one patient.

Conclusions: Circumferential pulmonary vein ablation leads to resolution of arrhythmia or marked clinical improvement in about 75% of patients with symptomatic, resistant AF. The success rate is lower in patients with permanent rather than paroxysmal AF. As severe complications are not unlikely, the indications for such therapy must be carefully balanced.

Key words: atrial fibrillation, ablation, pulmonary veins

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Introduction

Atrial fibrillation (AF) is the most common type of clinically relevant arrhythmia. It occurs in 0.4% of the adult population, in persons aged >60 years in 2-4%, and aged >70 years in 11% [1]. In patients with AF, restoration and maintenance of sinus rhythm is one of the treatment strategies. Irrespective of the method of sinus rhythm restoration, the chance of its maintenance over a prolonged period of time is limited. At the same time, chronic antiarrhythmic treatment is associated with the risk of many side effects [1, 2].

In the late nineties, Haissaguerre et al. [3] showed that electrical potentials originating from the pulmonary

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veins may initiate AF, and introduced a method of their elimination, followed by a pulmonary vein isolation procedure (electrophysiological method). Using the CARTO electroanatomical navigation system, Carlo Pappone from Milan proposed a technique [4, 5] that was based on purely anatomical premises. It involves circumferential ablation of all pulmonary veins performed at ≥5 mm distance from the vein ostium, based on three-dimensional left atrium mapping (anatomical method). The excellent results reported by Pappone at al. [5, 6] were opposed by serious doubts and concerns expressed by electrophysiological method protagonists. To add to the discussion, we decided to present the results of our prospective three-year follow-up of patients treated with the anatomical method in our institution since 2001.

The study aimed to determine early and long-term efficacy and safety of circumferential pulmonary vein ablation with the CARTO navigation system in patients with different types of AF.

Methods

Patients

This prospective study involved 94 patients hospitalised between 2001 and 2003 for symptomatic AF, who after signing an informed consent form were qualified for circumferential pulmonary vein ablation with the CARTO electroanatomical navigation system.

The inclusion criterion was the presence of AF that was symptomatic, recurrent and resistant to medical treatment with at least two antiarrhythmic drugs (AAD). Such arrhythmias had to be documented at least twice by means of standard ECG. Patients were excluded from the study if thrombi in the left or right atrium were found despite adequate anticoagulation, or if a stable INR level within the range of 2.0-3.0 sustained for two months preceding the planned procedure could not be reached, or if contraindications to such anticoagulation were present.

Initial clinical evaluation included: medical history, physical examination, resting ECG, echocardiography, basic laboratory tests and transoesophageal echocardiography.

Patients were divided into two main groups: group 1 with paroxysmal AF, and group 2 with persistent or chronic (permanent) AF. Classification in groups was based on the patient's medical history and analysis of previous medical records. Atrial fibrillation classification was based on the criteria proposed by international groups of experts and included in the ACC/AHA/ESC guidelines of 2001 [1].

Ablation

All patients underwent the electrophysiological study with the use of the CARTO (Johnson/Biosense Webster) navigation system for electroanatomical heart mapping. The purpose of the electrophysiological study was to identify left atrium (LA) borders and all pulmonary vein left atrial ostia, to record local activation potentials (pulmonary vein potentials) and obtain voltage mapping of LA. Subsequently, radiofrequency circumferential pulmonary vein ablation according to Pappone [4, 5] was performed to electrically isolate the pulmonary veins. The success of RF application was assessed based on disappearance of electrical potentials within ablation lines, and consequently inability to induce and maintain AF (Figure 1).

Outpatient follow-up

Following the procedure, patients again underwent laboratory tests, echocardiography and 24-hour Holter ECG monitoring, and then were followed on an outpatient basis with evaluations at 1, 3, 6, 9, and 12 months. The efficacy of the procedure was assessed based on medical history, ECG and Holter monitoring records with respect to four categories: (1) no recurrent AF, no need for AAD, (2) no recurrent AF, need for AAD, (3) change of AF form to become infrequent and mildly symptomatic, (4) no improvement.

The study protocol was approved by the Ethical Committee.

Statistical analysis

T-test and ANOVA test for parametric variables and Chi2 and Fisher tests for nonparametric variables were used for comparisons between the groups. A p value <0.05 was considered significant.

Results

A group of 94 patients aged 54.3±9.8 years (26-71; median 54), including 61 (64.9%) males and 33 (35.1%) females, was studied. Patients' demographics are shown in Table I. These groups did not differ with respect to gender or age. Patients with paroxysmal AF had a longer history of arrhythmic events.

Table I contains also data on the primary disease, AAD used and history of electrical cardioversions. Structural heart disease was not found in 2/3 of studied patients, and was more prevalent in patients with permanent AF; however, this difference was not statistically significant. The high percentage (58.5%) of patients with arterial hypertension was noticeable. Atrial fibrillation coexisted with atrial flutter (AFL) in 31.9% (30 of 94): 35.0% (21 of 60) in group 1 and 26.5% (9 of 34) in group 2. The differences between the groups were not significant, either. All the patients received 2-7 (2.9±1.3; median 3) AADs. Groups 1 and 2 differed with respect to necessity of restoring sinus rhythm using

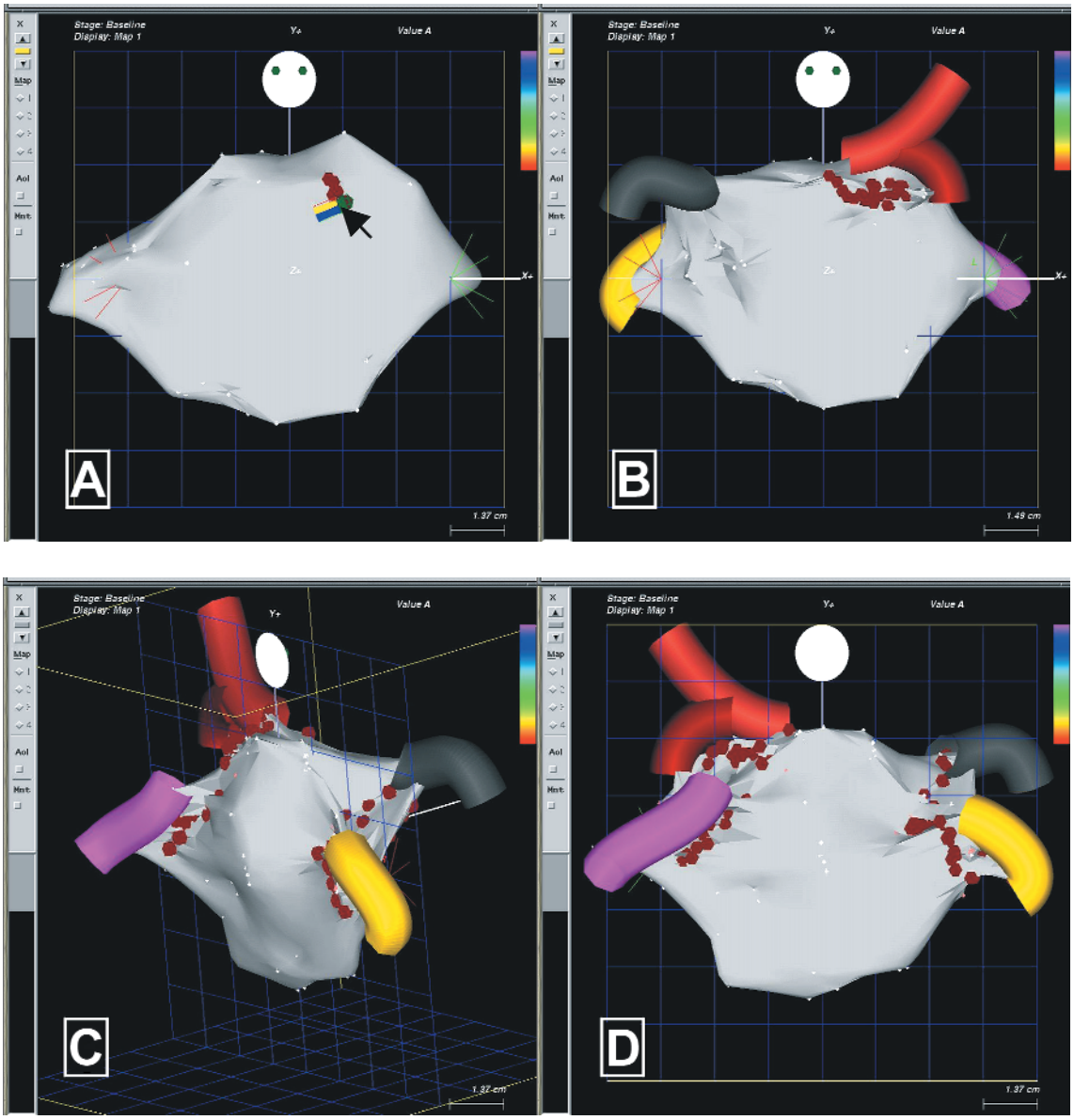

Figure 1. Anatomic map of the left atrium (LA): subsequent stages (a-d) of performing ablation lines encircling pulmonary veins (PV). Arrow shows the icon of ablation electrode tip

electrical cardioversion; additionally, cardioversion was significantly less effective in group 2.

The baseline echocardiographic parameters in both groups are shown in Table II. In 55.3% of patients dilatation of LA (>40 mm) was documented, and the groups differed with respect to LA diameter. In 75.5% of patients mitral regurgitation of at least first degree was found, but it was seldom severe.

Radiofrequency ablation was undertaken in 94 patients; however, in 2 of them circumferential pulmonary vein ablation could not be successfully completed due to procedural complications. In the remaining patients, isolation of all (3-5) pulmonary veins was attempted, but success was achieved in 91.3% of patients due to difficult anatomy: in 93.2% (55 of 59) patients in group 1 and in 87.9% (29 of 33) patients in group 2 (NS). Moreover, ablation of the right atrial inferior isthmus due to the incidence of AFL was performed in 5.0% of group 1 patients and in 3.0% of group 2 patients.

Ablation was performed during sinus rhythm in the majority of group 1 patients (61%) and in 33.3% of group 2 patients, p=0.0063. A mean of 152±21 RF applications were made (93-181).

Table I. Demographic and clinical characteristics of the studied patients

Parameter	Group 1 N=60	Group 2 N=34	p
AF type	Paroxysmal	Persistent/Chronic	
Males	65.0%	64.7%	NS
Females	35.0%	35.3%	NS
Age (years)	53.2±10.0 median 51.5	56.3±9.4 median 58.5	NS
Arrhythmia duration (years)	6.2±4.8 median 5.5	1.7±1.7 median 1.0	p<0.05
Underlying disease			
No structural heart disease	73.3%	61.8%	NS
Structural heart disease	26.7%	35.3%	NS
Coronary artery disease	21.7%	20.6%	NS
– including past myocardial infarction	13.3%	0%	NS
Valvular disease	3.3%	5.9%	NS
Cardiomyopathy	3.3%	11.8 %	NS
Past stroke/TIA	1.7%	5.9%	NS
Arterial hypertension	56.7%	61.8%	NS
Antiarrhythmic agents used previously			
Group I A agents	23.3%	17.6%	NS
Group I C agents	73.3%	79.4%	NS
Group III agents	76.7%	85.3%	NS
– including amiodarone	56.7	58.8	NS
Failed cardioversion	6.7%	20.6%	<0.05

TIA – transient ischaemic attack

The mean procedure duration of 7.1 hours in 2001 decreased along with the operators' experience to reach 3.5 hours in 2003. The mean fluoroscopy duration was 22.4 min, ranging from 11 to 41 min. The early success rate of the procedure is shown in Table III. Direct success in restoring sinus rhythm was achieved in 69.6% of patients, and in a further 22.8% sinus rhythm was restored with subsequent electrical cardioversion. During 2-4-day hospitalisation following the procedure, the recurrence of arrhythmia was observed in 41.3% of patients, and AF was terminated using propafenone or electrical cardioversion.

The long-term follow-up duration was 3 (all patients) to 24 months, median 12 months. The long-term results are shown in Table IV. After one month an improvement was recorded in 73.9% of patients. After three months the value was a little higher (79.4%), and stabilised at a level of approximately 80% for up to one year. The number of patients without arrhythmic events increased steadily during the first six months, reaching 47.8% at six months. The percentage of patients receiving AAD decreased beginning in the sixth month (6 *vs* 9 months and 6 *vs* 12 months, p<0.05), and the number of patients without arrhythmia and need for AAD therapy increased after one year.

These results are driven mostly by unexpectedly good effects in the early period seen in patients with persistent or chronic AF. There were more such patients presenting without arrhythmia and ADD up to six months than patients in paroxysmal AF group (after 3 months, group 1 *vs* group 2, p<0.02, Figure 2). Despite the time-dependent decrease in the number of patients in paroxysmal AF group free from arrhythmia, from over 50% at the beginning to less than 40% at one year, an increasing number of patients did not require AADs, so at 12 months 90% of all patients reported a significant improvement. In patients with persistent or permanent AF at baseline, an improvement was observed in about 70% during the entire follow-up.

Atrial flutter occurred in 25 (27.2%) patients during the follow-up. Some of them (18) had typical AFL prior to ablation documented, and despite that ablation of the right atrial inferior isthmus was not performed. However, de novo AFL occurred in seven patients,

Table II. Characteristics of patients: baseline echocardiographic data

Parameter		Group 1	Group 2	P
RV [mm]		22.1±2.8	22.4±2.3	NS
LVEDD [mm]		53.1±5.0	53.8±4.8	NS
LVESD [mm]		33.6±6.2	35.4±6.4	NS
LV EF [%]		58.9±5.6	56.4±7.5	NS
PW [mm]		9.5±1.3	9.2±1.3	NS
IVS ≥12 mm		10.5±1.8	11.1±3.7	NS
IVS ≥12 mm		23.3%	20.6%	NS
LA [mm]		39.1±4.7	41.9±6.2	<0.02
LA ≥40 mm		50.0%	64.7%	NS
LA ≥45 mm		11.7%	35.3%	<0.01
LA ≥50 mm		–	8.8%	<0.02
MV E wave		0.75±0.15	0.78±0.17	NS
MV A wave		0.66±0.18	0.65±0.09	NS
MV without regurgitation		30.0%	14.7%	NS
MV regurgitation	≥I°	70.0%	85.3%	NS
	≥II°	15.0%	32.4%	NS
	≥III°	3.3%	2.9%	NS

Abbreviations:
RV – right ventricle
LVEDD – left ventricular end-diastolic diameter
LVESD – left ventricular end-systolic diameter
LV EF – left ventricular ejection fraction
PW – posterior wall
IVS – interventricular septum
LA – left atrium
MV – mitral valve

raising a suspicion of being a consequence of ablation. Unfortunately, 12-lead ECG, enabling more detailed classification of AFL, was not recorded in all patients.

According to the designed study protocol, additional RF ablation was not performed in patients without AF improvement after the first ablation or in patients with AFL, but another pharmacological treatment modification was attempted.

Table III. Direct effect of circumferential pulmonary vein ablation in each group of patients

	Group 1 n=59	Group 2 n=33	P
Sinus rhythm	84.7%	42.4%	<0.0001
Cardioversion [DC]	8.5%	48.5%	<0.0001
Success rate of DC cardioversion	80%	100%	NS
Energy delivered [J]	236±98	227±80	NS
Sinus rhythm after DC	6.8%	48.5%	<0.0001
Persistence of AF	8.5%	9.1%	NS
Recurrence of AF before discharge	37.3%	48.5%	NS

Complications (Table V) were seen in six (6.4%) patients, who required prolonged or additional hospitalisation. Two patients required decompression of pericardial tamponade. Two patients presented hypersensitivity to heparin (HIT), which resulted in mild pericardial effusion in one case; the other one required surgery for retroperitoneal bleeding. On laparotomy no bleeding vessel within the abdominal cavity was found. In one patient a haemorrhagic stroke was recorded that resolved without any permanent neurologic defects.

Another patient had a persistent cough and haemoptysis directly after the ablation procedure. On TEE, the distal segment of the left superior pulmonary vein could not be visualised, and instead of typical venous flow in the proximal segment (12-15 mm from the ostium) a turbulent backflow from the left inferior pulmonary vein and LA was recorded. Spiral computed tomography (high resolution CT and angio-CT) showed that this was caused by left superior pulmonary vein thrombosis (diagnosis confirmed later in the Department of Thoracic Internal Diseases, Institute of Tuberculosis and Pulmonary Diseases – head: Professor Dr. Adam Torbicki, MD). Haemoptysis stopped after withdrawal of anticoagulation. The patient is now mildly symptomatic and has had no AF episode for over a 1.5-year follow-up.

Table IV. Ablation efficacy with respect to duration of follow-up

Follow-up duration	1 month	3 months	6 months	9 months	12 months
No. of observations	92	92	90	78	68
No AF, no drugs	7.6%	3.3% *	7.8%	10.3%	13.2%*
No AF, with drugs	33.7%	34.8%	40.0%**	24.4%**	22.1% **
Infrequent and mildly symptomatic AF	32.6%	41.3%	36.7%	42.3%	44.1%
Improvement	73.9%	79.4%	84.5%	77.0%	79.4%
No improvement	26.1%	20.6%	15.5%	23.0%	20.6%

** – p<0.02*
*** – p<0.05*

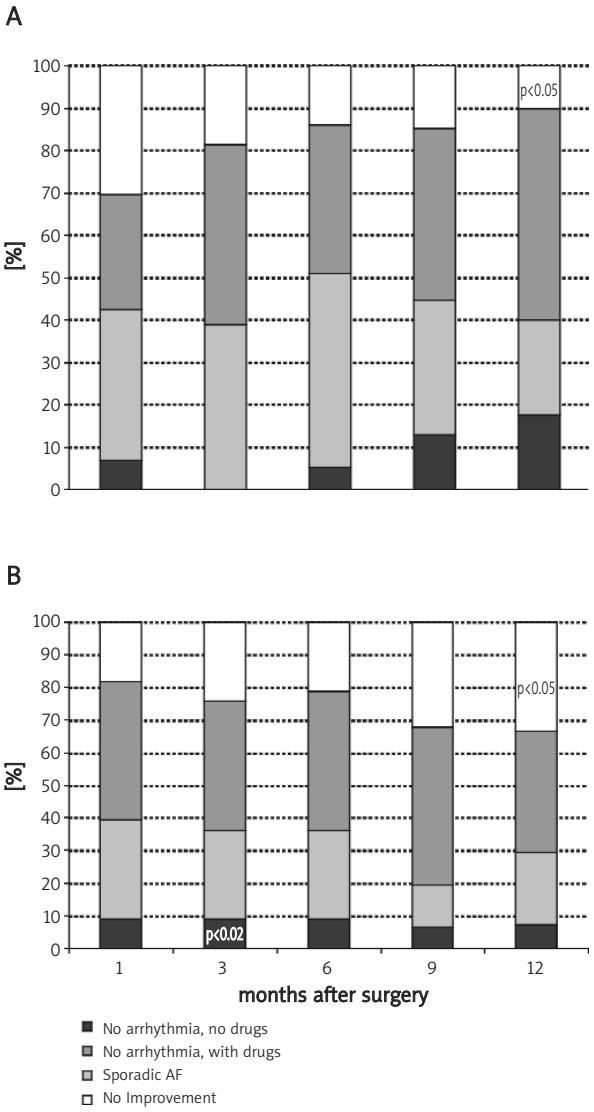

Figure 2. Efficacy of the ablation at 1, 3, 6, and 12 months.
A – paroxysmal atrial fibrillation
B – persistent/chronic atrial fibrillation

Discussion

Efficacy of ablation

The study was performed in a 94-patient group with AF that was highly symptomatic and resistant to pharmacological treatment, in whom the efficacy and safety of radiofrequency ablation was prospectively assessed. An improvement, mainly in terms of arrhythmia limitation which was infrequent and low symptomatic, was observed in a high percentage of patients (84.5% at 6-month follow-up). However, complete resolution of AF, in some patients without a chance to withdraw antiarrhythmic agents, was achieved in considerably fewer patients (47.8% at 6-month follow-up). Unfortunately, in 6.4% of cases complications were observed.

Table V. Complications of circumferential pulmonary vein ablation

Complication	N	%
Total	6	6.4
Pericardial tamponade	2	2.1
Hypersensitivity to heparin (HIT – *heparin induced thrombocytopenia*)	2	2.1
Pulmonary vein thrombosis	1	1.1
Haemorrhagic stroke	1	1.1

Ablation was performed using the technique proposed by Pappone [4, 5], which involves left atrial RF ablation encircling pulmonary vein ostia using the CARTO electroanatomical imaging system. The efficacy of this technique according to the original report is very high (84% of patients free from AF at one year), and probably results from the high number of procedures performed in this centre, as well as rather liberal success criteria. It is of note that implanted antiarrhythmic pacemaker internal memory analysis revealed that the arrhythmic episode might be asymptomatic even in 70% of cases. Reports of other investigators who applied more sensitive assessment tools after ablation than Pappone did, including seven-day Holter ECG monitoring or event recorders, provide evidence that recurrence of AF may also be seen in asymptomatic patients after RF ablation [7]. Recently published results in patients with AF (abstracts so far) in the European and World Registry are less promising, showing similar success rates to those observed by us [8, 9]. In the European Registry, including 6759 procedures performed in 30 leading centres, the mean efficacy was 51%, and ranged from 11% to 100%. Meanwhile, in the World Registry, which collects data on 8745 ablations performed in 100 centres, 52% of patients were asymptomatic, and improvement with AAD was observed in a further 23.9% of patients.

Currently, there are several types of ablations available in patients with AF, including the more commonly used (with various modifications) electrophysiological technique proposed by Haisseguerre et al. and Pappone's anatomical method used in our study [3-5, 10-12]. Until now, results of only small randomised trials conducted in very experienced electrophysiological laboratories comparing the efficacy and safety of the two methods have been published [13, 14]. The anatomical method was shown to be slightly more effective (67% vs 88%, 60% vs 75%), with

a similar low complication rate. However, it should be stressed that the modification of the anatomical method used in these studies included additional ablation lines in the mitral isthmus and posterior wall of LA, which were not performed in our series.

The electrophysiological method involves recording potentials of pulmonary veins using special catheters, and subsequent isolation of pulmonary veins at the level of the veno-atrial junction. Authors using this method stress the preferable efficacy of these procedures in patients with paroxysmal AF as opposed to persistent or permanent AF (70% *vs* 22%) [15]. However, Pappone and other investigators [5], using circumferential pulmonary vein ablation, reported good results in patients with persistent AF (68%), but slightly worse than in patients with paroxysmal AF (85%). Therefore, the improvement observed in about 70% of our patients with persistent or permanent AF is not surprising. According to the current understanding, the key patomechanisms of paroxysmal AF involve the presence of triggers, often in the pulmonary vein/veins, whereas in persistent or permanent AF in particular, the critical role of atrial muscle changes as an important arrhythmia substrate is postulated. Ablation as proposed by Pappone leads not only to pulmonary vein isolation, but also to electrophysiological modification of the atrial area surrounding the veins and the posterior atrial wall as well as to their denervation [5, 16].

In some of our patients AF resolved during the procedure, but reappeared in 41.1% of them during pre-discharge follow-up. Tanner et al. [17], based on repeated seven-day Holter ECG monitoring analyses performed over a long-term follow-up of patients after RF ablation, suggested that only the chronic healing that modifies the substrate and does not trigger elimination determined the final result. According to our observations, the efficacy of RF ablation may be definitively assessed in most patients after three months.

Complications

Ablation in patients with AF is associated with the risk of complications – in the World Registry a minimum of one major complication was found in 5.9% of cases [9], and this is very similar to our complication rate. There were no fatal complications. Heart tamponade was recorded in from 0% to as high as 11% of ablations and, for this reason, the personnel performing the procedure should be sensitive to its early symptoms, and should have echocardiography available and equipment for decompression ready; cardiosurgical backup should be available as needed.

Stroke was observed in only one of our patients and neurological symptoms resolved completely. According to the European Registry, such complications occurred in a mean of 1±2% patients after RF ablation [8]. Kok et al. [18] described strokes in as many as 3 of 56 patients treated with pulmonary vein isolation, and they were more common in patients with prior cerebral ischaemic episodes. In order to reduce the risk, patients should be prepared for the procedure with anticoagulation, have transoesophageal echocardiography performed prior to the ablation (preferably on the same day), and optimal intraoperative anticoagulation should be implemented. It has recently been suggested that additional intracardiac echocardiography performed during the procedure would contribute to the reduction of thromboembolic complications.

Another important complication that may be a consequence of pulmonary vein ablation is vein stenosis or occlusion. According to the European Registry, such complications were found in 1.8±3% (0-11%) of patients [8]. They were more common with the focal pulmonary vein ablation technique. Regular imaging with CT or MRI allows visualisation of asymptomatic stenoses even in a higher percentage of patients. There was no possibility of routine imaging at the time our study was conducted. It is worth remembering that pulmonary vein stenosis and its clinical symptoms may develop several months after the procedure, suggesting pulmonary disease as the cause of the symptoms [19, 20]. The most common symptoms include worsening of exercise capacity, cough or haemoptysis.

Atypical left AFL is a form of arrhythmia which may be induced by incomplete circumferential pulmonary vein isolation, which forms isthmus of the flutter circle. An additional procedure with identification of the re-entry circle and ablation is then required [21, 22]. Similar management is planned in our patients. Oral et al. and Pappone et al. [6, 13, 22] observed that left AFL was particularly specific to circumferential pulmonary vein ablation.

Conclusions

1. Circumferential pulmonary vein ablation with the CARTO electroanatomical system is a method providing definite resolution of AF or significant clinical improvement in about 70-80% of patients with highly symptomatic and resistant AF.
2. The beneficial effect can be expected not only in patients with paroxysmal AF, but also in patients with persistent or permanent AF, although the success rate is lower.
3. Severe complications are not unlikely and therefore the indications for this procedure should be carefully balanced, the patient's informed consent is required and the procedures should be performed preferably in experienced and well equipped centres.

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Ablacja okrążająca żyły płucne w leczeniu migotania przedsionków: 3-letnie doświadczenia jednego ośrodka

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Streszczenie

Wstęp: U chorych z migotaniem przedsionków (AF), szczególnie istotnie objawowym, przywrócenie i utrzymanie rytmu zatokowego jest jedną ze strategii leczenia. Wobec ograniczonej skuteczności leków antyarytmicznych i ich działań niepożądanych coraz większe nadzieje pokłada się w rozwijających się technikach przezskórnej ablacji.

Cel: Określenie skuteczności i bezpieczeństwa ablacji okrążającej żyły płucne z użyciem systemu CARTO u chorych z napadowym lub utrwalonym AF.

Metodyka: Badaniem objęto 94 chorych (średni wiek: 54 lata, mężczyźni: 65%, choroba organiczna serca: 29,4%) z objawowym, nawracającym i opornym na leki antyarytmiczne AF (napadowe AF: 63,8%) zakwalifikowanych do ablacji okrążającej żyły płucne wg metody Pappone. Badania kontrolne były prowadzone po 1, 3, 6, 9 i 12 miesiącach. Rejestrowano objawy, EKG, 24-godz. EKG i występowanie powikłań.

Wyniki: Średni czas zabiegu i fluoroskopii wynosił odpowiednio 4,5 godz. i 22,4 min. Obserwacja odległa trwała od 3–24 miesięcy, mediana 12. Po 6 mies. stwierdzono eliminację AF u 47,8% chorych, a poprawę w postaci arytmii sporadycznej i skąpoobjawowej u dalszych 36,7%. Skuteczność była niższa u chorych z utrwalonym AF (12 mies. 90% *vs* 70%). Powikłania wystąpiły u 6 (6,4%) chorych: tamponada u 2, płyn w worku osierdziowym u 1, krwawienie zaotrzewnowe u 1, udar mózgu u 1, oraz zakrzep żyły płucnej u 1.

Wnioski: Okrążająca ablacja żył płucnych pozwala na uzyskanie eliminacji arytmii lub znacznej poprawy klinicznej u ok. 75% chorych z objawowym, opornym AF – rzadziej w przypadku utrwalonego AF. Możliwe jest wystąpienie poważnych powikłań i dlatego wskazania do zabiegu muszą być bardzo wyważone.

Słowa kluczowe: migotanie przedsionków, ablacja, żyły płucne

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