

# Evaluation of safety and the success rate of cryoballoon ablation of the pulmonary vein ostia in patients with atrial fibrillation – a preliminary report

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## Abstract

**Background:** Cryoballoon isolation of the pulmonary veins has recently emerged as a promising technique for ablation of atrial fibrillation (AF).

**Aim:** To present our initial experience in cryoballoon isolation of the pulmonary veins in patients with AF.

**Methods:** Eight patients (5 males; age  $59 \pm 2$  years) with AF: 2 with persistent and 6 with paroxysmal (5 of them after unsuccessful RF ablation) with > 6 month follow-up after the procedure were included. One patient after myocardial infarction was treated with primary angioplasty with stent implantation. Another one had biatrial pacemaker. The procedure was performed with cryoballoon with 28 mm diameter (Arctic Front – Cryocath). After transseptal puncture mapping of the pulmonary vein ostia was performed with Lasso catheter (Johnson & Johnson). At each pulmonary vein ostium with pulmonary vein potentials 2 cryoapplications of 300 s duration was performed. Correct balloon placement before cryoapplication was checked using contrast injection into the pulmonary veins. During cryoapplication in the right pulmonary vein ostia permanent pacing of the phrenic nerve 30 beats per minute was performed to prevent its paralysis. After cryoapplications in all veins remapping with Lasso catheters was performed. In the absence of pulmonary vein potentials the procedure was finished, otherwise next cryoapplications were performed. During follow-up ECG was performed if any palpitations occurred, and 24-hour Holter monitoring was performed 1, 2, 4, 6, 8, 10 and 12 months after the procedure. A 2-month blanking period after the procedure was used. The lack of symptomatic AF and the absence of AF > 30 s on Holter ECG monitoring were defined as successful procedure. An improvement was defined as reduction of frequency/duration of AF paroxysm and reduction of the EHRA index  $\geq 1$ .

**Results:** During 8 procedures isolation of 31 pulmonary vein was performed. Procedure duration was  $3.5 \pm 0.85$  h, fluoroscopy time –  $33.55 \pm 15.44$  min, and total cryoapplication time –  $38.33 \pm 4.1$  min. There were no complications. After the follow-up of  $8.5 \pm 0.99$  months 6 (75%) patients were free from arrhythmia, including the patient after myocardial infarction and one patient with permanent AF prior ablation. In another patient an improvement was observed (EHRA score II/III to I) whereas in one patient with permanent AF the procedure was unsuccessful.

**Conclusion:** Cryoballoon ablation of pulmonary vein ostia is effective and safe, and can be an alternative to RF ablation. Easier procedure technique make possible shortening of the learning curve and increase the number of treated patients.

**Key words:** atrial fibrillation, cryoablation, balloon

Kardiologia Polska 2010; 68: 175-180

## Introduction

Atrial fibrillation (AF) is present in about 1% of the population. This often troublesome and persistent arrhythmia may result in dyspnea, reduced exercise tolerance, palpitations, or syncope. Atrial fibrillation is also associated with a significantly increased risk of thromboembolic events, particularly stroke. This clinical

picture, together with a limited effectiveness of drug therapy, resulted in a number of approaches to the invasive treatment of AF. The most important of these methods is ablation of the pulmonary vein (PV) ostia [1].

Various techniques utilising different sources of energy are used, most commonly radiofrequency (RF) current [1, 2], but also high intensity focused ultrasound (HIFU) [3], laser [4], and nitrous oxide (N<sub>2</sub>O) cryoablation [5].

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Received: 29 March 2009. Accepted: 28 October 2009.

Pulmonary vein ostial isolation using RF current is an established method of AF treatment [6]. According to the ACC/AHA/ESC guidelines, it is indicated in patients with symptomatic AF without a curable reversible cause and failure of treatment with at least one antiarrhythmic drug. However, due to a limited number of centers performing these procedures, this approach is not widely available, and the patient waiting times are very long. A new approach to treat AF is PV isolation using cryoablation balloon [7, 8]. This strategy appears to be less technically demanding and thus may result in shorter learning time, potentially leading to wider availability of the invasive treatment of AF.

The purpose of this study is to describe the initial results of balloon cryoablation procedures performed in our center.

## Methods

### Study group

We studied 8 patients with symptomatic AF documented in resting electrocardiogram (ECG) and/or 24-hour Holter monitoring. In all cases, arrhythmia was refractory to antiarrhythmic drugs [9, 10]. Persistent AF was diagnosed in 2 patients, and paroxysmal AF in the remaining 6 patients (including 5 after previous unsuccessful attempts of RF ablation). Stable coronary artery disease was present in two patients, with a history of an inferior wall myocardial infarction (1992), left anterior descending and left circumflex artery angioplasty with implantation of two stents, stent-graft implantation due to an abdominal aortic aneurysm, and the left atrial (LA) dimension of 5.1 cm and left ventricular ejection fraction (LVEF) of 0.40 in echocardiography in one of these patients. Batrial resynchronisation pacing device with a ventricular lead (BiA+V) had been implanted in one patient, with one atrial lead in the right atrial appendage, and the other in the coronary sinus (CS). Two patients had hypertension (HTN) that was well controlled with drugs before the procedure, and one patient has asthma that was controlled with inhaled glucocorticosteroid (Table I).

### Procedural details

Acenocoumarol and acetylsalicylic acid were stopped 4 days before the procedure and replaced with a low-molecular-weight heparin. The remaining medications were continued. Before the procedure, 16-slice multidetector computed tomography (CT) was performed in 8 patients and transesophageal echocardiography in 6 patients to evaluate LA and PV anatomy, and to exclude thrombi in the LA appendage or other cardiac chambers. In these studies, PV diameters were determined to choose optimal balloon diameter. In all patients, typical anatomy of four separate PV was present.

All patients signed informed consent for balloon cryoablation. A transfemoral approach was used, and midazolam, fentanyl and activated clotting time (ACT)-guided unfractionated heparin were administered during the procedure. A diagnostic lead to stimulate LA was placed in CS. Transseptal puncture was performed under the guidance of intracardiac pressure measurements. In one patient, patent foramen ovale described in a previous echocardiographic study was used for this purpose. Through a transseptal 8 F sheath, a circumferential mapping electrode was inserted to locate pulmonary vein potentials (PVP) originating in muscle bridges within the ostia of all four PV. Due to difficult anatomy, only 3 out of 4 PV could be mapped in one patient. The presence of arrhythmogenic potentials was confirmed in all mapped PV. Following replacement of the transseptal sheath with a 12 F one, a cryoablation balloon was inserted. We used 28 mm double lumen cryoballoons (Arctic Front – Cryocath) in all our patients.

After cryoballoon insertion into LA, the balloon was dilated and the adequacy of cryoballoon adherence to the PV ostium was checked by injecting a contrast agent (Urografin) to the PV lumen through the distal opening of the catheter. Lack of LA contrasting confirmed the adequacy of cryoballoon adherence.

Two cryoapplications were performed in each PV to isolate tissue outwards from its ostium. The N<sub>2</sub>O cooling temperature was used. In the internal balloon lumen, liquid

Table I. Patient characteristics

Patient no.	Age [years]	Type of AF	Previous RF ablation	Hypertension	Coronary artery disease	Other conditions
1	60	paroxysmal	yes	no	no	hypothyroidism
2	58	persistent	no	no	yes	
3	59	paroxysmal	yes	yes	no	cardiac pacemaker, hypothyroidism
4	54	paroxysmal	yes	no	yes	
5	59	paroxysmal	yes	yes	no	
6	58	paroxysmal	yes	no	no	asthma
7	60	paroxysmal	no	no	no	
8	60	persistent	no	no	no	

N<sub>2</sub>O evaporated, resulting in temperatures in the range from  $-33^{\circ}\text{C}$  to  $-75^{\circ}\text{C}$ . A single cryoapplication lasted 300 s, with the total duration of cryoapplications in all four PV of 40 min. In a patient, in whom only 3 PV were ablated, the total duration of cryoapplications was 30 min.

During cryoapplications in the right-sided PV, the electrode previously placed in CS was used to stimulate the phrenic nerve at the rate of 30/min and patient respiratory movements were observed, aiming to prevent phrenic nerve palsy complicating the cryoablation procedure [5]. No phrenic nerve palsy was noted in any of our patients and when all cryoapplications were finished, the cryoballoon was removed.

Then, circumferential mapping electrode was reintroduced and all PV were again mapped to confirm the disappearance of the PVP. In one patient, a small area of residual PVP was mapped in the right inferior PV. After additional three cryoapplications, further mapping using the circumferential mapping electrode showed no persisting PVP. In one patient, additional cryoapplications were necessary in the left-sided PV. After the procedure, all patients were monitored in an intensive coronary care unit. Transthoracic echocardiography was performed after 12 h to exclude any pathologic amounts of fluid in the pericardium, defined as 3 mm of fluid seen in during the diastole.

Oral anticoagulants were started during the first day after the procedure. Antiarrhythmic drugs were stopped, except in one patient in whom an AF episode occurred during the hospitalisation after the procedure, terminated with administration of 400 mg of antazoline. This patient was discharged on propafenone 150 mg tid. Follow-up ECGs during each clinical visit and Holter monitoring at 1, 2, 4, 6, 8, and 12 months after the procedure were scheduled to detect clinically silent episodes of AF and provide objective evaluation of any palpitations reported by the patients. It was shown that not all palpitations reported by patients after ablation are due to arrhythmia [11], and in some patients AF episodes do not lead to any clinical symptoms.

The period of scar formation to modify arrhythmia substrate was defined as the initial 2 months after the procedure. Any AF occurring in this period was not considered treatment failure. [6]. Our study included patients with the follow-up duration of more than 6 months. Successful treatment was defined as the lack of symptomatic AF episodes or clinically silent episodes lasting more than 30 s as documented by Holter monitoring. Partial improvement was defined as decreased frequency of arrhythmia, shorter-lasting and less troublesome AF episodes, and decrease in the European Heart Rhythm Association (EHRA) score by at least one grade [12]. If overall AF burden remained similar compared to the preprocedural period, treatment was considered ineffective.

## Results

During 8 procedures, 31 PV ostia were isolated. The mean total duration of the procedure was  $3.5 \pm 0.85$  h, total cryoapplication time was  $38.33 \pm 4.08$  min, and total fluoroscopy time was  $33.55 \pm 15.44$  min. No access site hematomas and false aneurysms were noted. Right phrenic nerve stimulation during cryoablation of right-sided PV and observation of patient respiratory movements protected all patients from the development of phrenic nerve palsy. Follow-up echocardiography did not reveal pathologic amounts of fluid in the pericardial space in any of our patients. No long-term complications were seen.

During  $8.5 \pm 0.99$  months of follow-up, 6 (75%) patients remained free of arrhythmia. In this group, 3 symptomatic episodes of AF, lasting 6 h and spontaneously reverting to sinus rhythm, occurred in one patient during the first 2 weeks after ablation. The patient was not hospitalised. The patient with a history of myocardial infarction was also among these patients. Sinus rhythm was maintained in the patient with an AF episode during the initial hospitalisation who was discharged on propafenone 150 mg tid. Partial improvement was seen in one patient, in whom decrease in EHRA score from grade II/III to grade I was seen, with reduced number and duration of AF episodes, and decreased severity of related symptoms. Treatment was ineffective in one patient with persistent AF.

## Discussion

In the recent years, dynamic progress in the techniques of percutaneous ablation of AF substrate is seen, aiming to increase safety and efficacy of these procedures, shorten their duration and simplify the learning curve, thus leading to wider availability of this treatment. In our study, we evaluated safety and efficacy of cryoablation using double lumen balloon (Arctic Front Cryocath). In our small group of patients, this method proved to be safe and efficacious, as in other earlier reports [5, 7, 8]. This technique has important advantages including less thrombogenic nature of the ablation procedure [12, 13], uniform PV ostial isolation, less pain during cryoapplication and increased safety due to partial reversibility of the cooling effect.

During cryoapplication, uniform and continuous lesions are created in the muscle tissue around PV ostia, resembling circumferential PV isolation using the CARTO system. However, an advantage of this approach is an increased stability of the catheter during cryoablation.

Another important feature seems to be less complicated nature of the procedures, potentially resulting in a shorter time necessary for training of new operators and thus increasing availability of this method. During patient selection for balloon cryoablation, particular attention should be paid to the PV anatomy. As cryoballoons are available in only two sizes, each PV must have a separate ostium [10].

Currently, two sizes of cryoballoons, 23 mm and 28 mm are in use. The choice depends on PV diameter as determined by CT or echocardiography. A 23 mm cryoballoon is used in PV ostia not exceeding 17 mm. In larger ostia, a 28 mm cryoballoon is used. Previous experience with cryoablation suggest higher safety of a 28 mm cryoballoon [5], as it is related with less risk of too deep placement within the right-sided PV, resulting in phrenic nerve palsy.

Phrenic nerve palsy is a significant complication reported in animal and human studies on cryoablation [5, 7, 8, 14, 15]. Sarabanda et al. performed PV ostial cryoablation in 8 dogs, inducing phrenic nerve palsy in 50% of these animals [13]. Sacher et al. reported that the rate of phrenic nerve palsy as a complication of ablation ranged from 0.11% to 0.48%, regardless of the source of energy used [15].

As far as we know this is the first report of 8.5-month follow-up after balloon cryoablation reported in the Polish literature. The limitation of our study was the small number of patients. Studies including larger groups of patients were reported in the literature [5, 7, 8, 14]. In July 2008, the 3-Center Study results were published [5]. That study included 346 patients with paroxysmal (n = 293) or persistent (n = 53) AF that was refractory to antiarrhythmic drugs. Cryoapplications were performed using 23 mm and 28 mm balloons, and Freezor Max catheter. The mean duration of the procedure was 170 min (range 140-195), on average shorter by 40 min compared to our study, while fluoroscopy time was 40 min (range 30-57), on average longer by 7 min compared to our study. Total cryoapplication time per patient was 46 min (range 30-57), duration of a single cryoapplication was 300 s (range 28-480), and the mean number of cryoapplications was 11 (range 9-13). The mean follow-up duration was 12 months (range 7-16), including more than 6 months in 264 patients and more than 12 months in 133 patients. Sinus rhythm was maintained without the use of antiarrhythmic drugs in 74% of patients with paroxysmal AF and 42% of patients with persistent AF. Complication included 5 inguinal hematomas, 2 false aneurysms and one arteriovenous fistula. In two patients, atrial flutter occurred after the healing period. During the procedure, ST segment depression was noted in the inferior wall leads in 2 patients, lasting less than 2 min. Of note, 26 cases of phrenic nerve palsy were seen in that study, including 24 with the use of 23 mm cryoballoon. Phrenic nerve function recovered in all patients by one year of follow-up. No deaths, strokes or esophageal lesions were seen.

Results of one-year follow-up after balloon cryoablation were published by Van Belle et al. [14]. Cryoablation was performed in 139 patients using 23 mm and 28 mm cryoballoons, and Freezor Max catheters (hybrid procedures). Fluoroscopy time was  $50 \pm 28$  min, longer than in our study, and the total duration of the procedure

was  $207 \pm 79$  min, similar to our results. Following the initial procedure, complete effectiveness of treatment was noted at 3 months in 49% of patients. That study showed that recurrences within 3 months after the procedure are predictive of treatment failure. In most studies, recurrences in this period are considered of no significance for long-term effectiveness. The procedure was repeated at 3 months in 24 (17%) patients. After the second procedure, arrhythmia recurrence was noted in 46% of patients. Complications included 8 cases of pericardial fluid, and hemopneumothorax in one patient. Phrenic nerve damage was seen in 4 patients, with recovery of normal diaphragmatic movements by 3 months in 3 patients and by 6 months in one patient. Freedom from arrhythmia recurrence without the use of antiarrhythmic drugs was 59% at one year.

Disadvantages of balloon cryoablation seem to include long duration of the procedures and a relatively large radiation exposure.

## Conclusion

Balloon cryoablation seems to be a useful and safe method in the treatment of paroxysmal and persistent AF, providing an alternative approach to RF current AF ablation.

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# Krioablacja balonowa w ujściach żył płucnych – ocena skuteczności i bezpieczeństwa u pacjentów z migotaniem przedsionków. Doniesienie wstępne

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## Streszczenie

**Wstęp:** Izolacja żył płucnych przy użyciu balonu do krioablacji jest nową metodą leczenia migotania przedsionków (AF). Wydaje się łatwiejsza technicznie, dzięki czemu stwarza szanse na skrócenie czasu nauki, a tym samym na zwiększenie dostępności leczenia zabiegowego AF.

**Cel:** Ocena wstępnych doświadczeń z wykorzystaniem tej metody w zakresie skuteczności i bezpieczeństwa.

**Metody:** Przy użyciu kriobalonów (Arctic Front-Cryocath) o średnicy 28 mm wykonano zabiegi u 8 pacjentów (5 mężczyzn, 3 kobiety; wiek  $59 \pm 2$  lata) z objawowym AF, opornym na leki antyarytmiczne. W 2 przypadkach było to przetrwałe AF, a w 6 – napadowe (w 5 po nieskutecznej ablacji prądem o częstotliwości radiowej – RF). Jeden pacjent przeżył zawał serca leczony angioplastyką z implantacją stentów, u innego wcześniej implantowano dwuprzedsiódkowy resynchronizujący układ stymulujący. Przed zabiegiem u 8 pacjentów wykonano 16-rzędową tomografię komputerową, u 6 chorych również badanie echokardiograficzne przezprzełykowe. Leki przeciwzakrzepowe odstawiano 4 dni przed zabiegiem i zastępowano je heparyną drobnocząsteczkową. Poprzez żyły udowe wprowadzano elektrody diagnostyczne do zatoki wieńcowej i prawej komory. W trakcie ablacji pacjenci otrzymywali fentanyl i midazolam. Po nakłuciu transeptalnym podawano heparynę niefrakcjonowaną w dawce 6000 IU (następnie 1000 IU/godz.) oraz wprowadzano sterowalną koszulkę transeptalną do lewego przedsionka (ptukana wolnym przepływem soli fizjologicznej z 1000 IU heparyny/500 ml). Elektrody Lasso mapowano żyły płucne. Następnie wymieniano elektrodę na balon. Wykonywano dwie krioaplikacje po 300 s w ujściu każdej żyły płucnej, w której zarejestrowano potencjały żyłne (PVP). W czasie krioaplikacji w żyłach prawych, elektrodą wprowadzoną do żyły głównej górnej (powyżej balonu) stymulowano nerw przeponowy z częstotliwością 30/min. W razie wystąpienia zaburzeń ruchu przepony konieczne jest natychmiastowe zaprzestanie krioaplikacji. Następnie ponownie wykonywano mapowanie ujść żylnych elektrodą Lasso. W przypadku utrzymywania się PVP wykonywano kolejne krioaplikacje weryfikowane mapowaniem Lasso. Pacjenci mieli zalecone wykonanie EKG przy każdej wizycie lekarskiej oraz EKG metodą Holtera 1, 2, 4, 6, 8, 10 i 12 miesięcy po zabiegu w celu oceny rytmu serca. Okres 2 miesięcy po zabiegu przyjęto za czas tworzenia się blizny modyfikującej podłoże arytmii. Jeśli w tym okresie wystąpiły napady arytmii, zabieg uznawano za nieskuteczny. Do badania włączono pacjentów, których okres obserwacji wynosił > 6 miesięcy. Zabieg definiowano jako skuteczny, jeśli nie wystąpiły objawowe oraz nieme napady AF trwające > 30 s w monitorowaniu holterowskim. Jako poprawę definiowano rzadsze występowanie arytmii, krótszy czas jej trwania i mniejszą uciążliwość (zmniejszenie wskaźnika EHRA przynajmniej o 1 pkt). Przy utrzymywaniu się napadów na podobnym poziomie zabieg uznawano za nieskuteczny.

**Wyniki:** Wykonano izolację 31 żył płucnych. Czas zabiegu wyniósł  $3,5 \pm 0,85$  godz., czas krioaplikacji  $38,33 \pm 4,08$  min, czas fluoroskopii  $33,55 \pm 15,44$  min. Zabiegi przeprowadzono bez powikłań. W okresie  $8,5 \pm 0,99$  miesiąca po zabiegu bez arytmii pozostało 6 pacjentów. W tej grupie u jednego pacjenta w okresie pierwszych 2 tygodni po ablacji wystąpiły 3 samoograniczające się napady AF. W grupie bez nawrotu arytmii znajduje się pacjent po zawale serca. U jednego pacjenta obserwowano zmniejszenie uporczywości arytmii (EHRA II/III na I), liczby napadów, czasu ich trwania oraz złagodzenie odczuwanych dolegliwości. U jednego pacjenta z przetrwałym AF zabieg był nieskuteczny.

**Wnioski:** Krioablacja balonowa jest skuteczną i bezpieczną metodą leczenia napadowego i przetrwałego AF. Krioablacja balonowa wydaje się alternatywą dla ablacji RF.

**Słowa kluczowe:** migotanie przedsionków, krioablacja balonowa

Kardiologia Pol 2010; 68: 175-180

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Praca wpłynęła: 29.03.2009. Zaakceptowana do druku: 28.10.2009.