ORIGINAL ARTICLE

FIVE-YEAR EXPERIENCE OF SECOND-GENERATION CRYOBALLOON ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION FROM A TERTIARY CARDIAC CARE CENTER OF PAKISTAN: A RETROSPECTIVE CHART REVIEW

Muhammad Sarim Ansari[1], Ghazala Irfan[1], Zubair Mumtaz[1], Faisal Qadir[1], Maqsood Alam[1], Sajid Ali Shaikh[1], Abdul Mueed[1]

[1]National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan

Objectives: The study aimed at assessing the outcome of pulmonary vein isolation (PVI) using second-generation cryoballoon, Arctic Front Advance, Medtronic (CB-Adv) as a rhythm control strategy for drug-resistant paroxysmal atrial fibrillation (PAF) in a cardiac tertiary care center of Pakistan.

Methodology: Fifty patients had PVI with CB-Adv for symptomatic drug-resistant PAF at the National Institute of Cardiovascular Diseases, Karachi, Pakistan, during 2017-2022. Patients were followed-up in the clinic on the 1st, 3rd, and 6th month after the ablation. Twenty-four hours of Holter monitoring of electrocardiogram was obtained on each visit. We conducted a retrospective chart review after approval from the ethical review committee. We collected all the patients' demographic and clinical data, procedural results, and reports of Holter monitoring. The primary outcome was successful PVI and freedom from atrial tachyarrhythmia (Ata) on a 6-month follow-up.

Results: We enrolled all 50 patients (34 male, 68%; mean age 55.14 ± 7.94 years) treated with PVI using CB-Adv. The mean duration of symptoms was 30.28 ± 13.48 months. PVI with CB-Adv was found to be curative in 49 patients (98%). Following the procedure, pericardial effusion was found in one patient (2%), whereas one patient (2%) had a retroperitoneal hematoma. On a six-month follow-up, only one patient (2%) had a recurrence of Ata, which was PAF.

Conclusion: Our experience of PVI with CB-Adv has shown a high success rate of the procedure for rhythm control in patients who have PAF, which is resistant to antiarrhythmic drugs (AADs).

Keywords: Pulmonary vein isolation, cryoballoon ablation, second-generation cryoballoon, paroxysmal atrial fibrillation, atrial tachyarrhythmia

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INTRODUCTION

Atrial fibrillation (AF) is a prevalent supraventricular tachycardia affecting approximately 1 to 2% of individuals worldwide. Its complex pathophysiology involves rapidly firing foci and re-entry circuits within the atria. Atrial fibrosis leads to conduction slowing and barriers, facilitating unidirectional block and re-entry necessary for AF maintenance.[1] The management of AF encompasses rate control, rhythm control, and anticoagulation. The choice between rate control and rhythm control strategies has been debated. Recent evidence suggests that an early rhythm control strategy in patients with AF and cardiovascular conditions reduces adverse cardiovascular events and stroke compared to usual care.[2]

Catheter ablation using radiofrequency or cryoenergy has emerged as a promising technique for rhythm control. Pulmonary vein isolation (PVI) with cryoballoon (CB) ablation has shown superiority over antiarrhythmic drugs (AADs) in symptom alleviation and reducing the burden of paroxysmal AF (PAF).[3] In Pakistan, second-generation cryoballoon (Arctic Front Advance, Medtronic, CB-Adv) is used for PVI, offering improved design and a larger freezing zone, leading to higher ablation success rates.[4] International data supports the efficacy of PVI with CB-Adv in preventing AF recurrence.[5]

At the National Institute of Cardiovascular Diseases (NICVD) in Karachi, Pakistan, PVI with CB-Adv has been practiced since 2017. NICVD is a major cardiac tertiary care center, managing a significant number of patients with PAF in various healthcare settings. AF alone accounts for 6% of acute hospital admissions in Pakistan.[6] However, the introduction of PVI, a costly procedure, posed a challenge for the institute, given the lack of local outcome data. This retrospective study aims to present the six-month outcome of PVI with CB-Adv in patients with AAD-resistant PAF at NICVD. Sharing our experience and study findings can impact the future of this procedure in Pakistan, potentially influencing the management approach for PAF.

METHODOLOGY

Study Design and Patient Population: This study aimed to evaluate the efficacy of pulmonary vein isolation (PVI) using cryoballoon ablation (CB-Adv) for the treatment of symptomatic drug-resistant paroxysmal atrial fibrillation (PAF) in patients at the National Institute of Cardiovascular Diseases (NICVD) in Karachi, Pakistan. A total of 50 patients who underwent PVI with CB-Adv between January 2017 and June 2022 were included in the study. Patients with intracardiac thrombus detected through transesophageal echocardiography (TEE) or cardiac computed tomography (CCT) were excluded from the procedure. Patients with persistent or permanent atrial fibrillation were also not selected. The study was conducted as a retrospective chart review after obtaining approval from the Ethical Review Committee (Ref #: ERC-49/2022) of NICVD. Patient confidentiality was strictly maintained throughout the study.

Procedure Preparation: Before scheduling the procedure, all patients underwent transthoracic echocardiography (TTE) to assess their cardiac function. Additionally, a day before the procedure, patients underwent transesophageal echocardiography (TEE) and cardiac computed tomography (CCT) to evaluate the anatomy of pulmonary veins (PV) and left atrium (LA), as well as to rule out the presence of intracardiac thrombus. Patients were instructed to discontinue all antiarrhythmic medications at least five days before the procedure. For patients taking rivaroxaban or apixaban, these medications were held 24 hours or 12 hours before the procedure, respectively. However, warfarin was not stopped if the international normalized ratio (INR) was between 2 and 3.

Procedure Technique: All procedures were performed under general anesthesia. The left atrium (LA) was accessed using an 8 Fr transeptal sheath (SL series), a 0.032-inch J guide wire, and a Brokenbrough Needle (BRK) via a trans-septal approach. Transesophageal echocardiography (TEE) was used to guide the transeptal puncture. Once access to the left atrium was achieved, the left superior pulmonary vein (LSPV) was identified by advancing a 0.032-inch guide wire, and an intravenous bolus of unfractionated heparin (UFH) at a dose of 100 IU/kg was administered. Subsequently, a 12 Fr catheter (Flexcath; Medtronic) was advanced over the wire after removing the transeptal sheath. An octapolar mapping catheter (Achieve; Medtronic) of 20mm was then introduced through the Flexcath and positioned at the ostium of LSPV to record the baseline electrical activity. A double-walled deflated cryoballoon (Arctic Front, Cryocath) of 28mm was passed through the Flexcath over the Achieve catheter and inflated in the LSPV antrum, avoiding mechanical damage. The balloon was then advanced into the pulmonary vein (PV) to occlude the ostium, confirmed by contrast injection and fluoroscopy. A minimal leak was allowed to define the PV ostium better, and cryoenergy was applied using refrigerant nitrous oxide (N2O) to achieve PV isolation. Cryoenergy was applied for 3 minutes to each PV, with specific parameters indicating successful isolation: rapid cooling rate (reaching -40 °C in less than 60 seconds), time to PV isolation of 60 seconds or less, and achieving a nadir temperature of -35 °C or less. If these parameters were not met, a bonus freeze of 1 minute was delivered. The balloon was then thawed by allowing the balloon and tissue interface to reach a temperature of 35 °C before deflation. Cryoenergy delivery was immediately aborted if any signs of phrenic nerve palsy (PNP) were observed. Pulmonary vein isolation (PVI) was confirmed using the Achieve catheter by recording PV potentials. Ablation was first performed on the LSPV, followed by isolation of the left inferior pulmonary and right-sided veins. During the procedure, activated clotting time (ACT) greater than 250 seconds was maintained using UFH.

Monitoring and Post-Procedure Management: Phrenic nerve palsy (PNP) was monitored throughout the procedure, particularly during the ablation of the right-sided pulmonary veins. To monitor PNP, a decapolar catheter was placed in the superior vena cava and stimulated the right phrenic nerve (PN) at a cycle length of 1200ms. The diaphragmatic movement was confirmed using fluoroscopy and manual palpation. Cryoenergy delivery was immediately stopped, and the balloon deflated if diaphragmatic movement became less vigorous or ceased, indicating PNP.

Before discharge, all patients were monitored for 18 hours post-procedure. Anticoagulation therapy was initiated on the same day in the evening. Patients were discharged the following day after undergoing transthoracic echocardiography (TTE) to detect complications such as pericardial effusion. The groin area was also examined for hematoma or bruit. Patients were discharged on anticoagulation therapy and antiarrhythmic drugs (AADs).

Follow-Up and Outcome Measures: Patients were scheduled for follow-up visits at the electrophysiology clinic at NICVD in the 1st, 3rd, and 6th months following the procedure. Patients were assessed for symptom recurrence during each visit, and a 24-hour Holter monitoring was performed to document any atrial tachyarrhythmia (Ata). The first three months after the ablation was considered the blanking period (BP), during which all patients received AADs. The decision to continue AADs beyond three months was based on AF recurrence during the BP. Anticoagulation medications were prescribed for one month initially, and the decision to continue anticoagulation beyond one month was determined by the CHADS2-VASc score (≥2 in males or ≥3 in females). Patients were followed for a mean duration of 35.76 months (±23.46 months) beyond the initial six months.

The primary outcome measure was treatment failure, defined as either an inability to isolate any of the pulmonary veins during the procedure (i.e., not achieving a nadir temperature of less than -35 °C or not achieving a temperature of less than -40 °C in 60 seconds) despite a bonus freeze or recurrence of atrial tachyarrhythmia (Ata) during the six-month follow-up. Ata recurrence was defined as documented episodes lasting over 30 seconds on Holter monitoring during any follow-up visits.

Statistical Analysis: Collected data were entered and analyzed using IBM SPSS version 19. Summary statistics such as mean ± SD/ median [IQR] or frequency percentage were used to summarize the data, depending on the variable type.

RESULTS

We enrolled 50 patients (34 male, 68%; mean age 55.14 ± 7.94 years) with paroxysmal atrial fibrillation (PAF) who were resistant to 1 or more AADs and had PVI with CB-Adv in NICVD, Karachi, Pakistan. The patient's baseline characteristics are given in (Table 1).

Table 1: Baseline Characteristics

Total number of patients (n)=50	
Male gender	34 (68%)
Age (years)	55.14 ± 7.94
Duration of symptoms (months)	30.28 ± 13.48
Diabetes mellitus	27 (54%)
Hypertension	44 (88%)
Cardiomyopathy	15 (30%)
Non-Ischemic Dilated Cardiomyopathy	10 (20%)
Ischemic Cardiomyopathy	4 (8%)
Hypertrophic Cardiomyopathy	1 (2%)
Coronary artery disease	16 (32%)
Stroke	2 (4%)
LVEF (%)	45.74 ± 15.37
LA size (mm)	34.40 ± 10.70
CHA2DS2-VASc score	2.22 ± 0.99
Oral anticoagulation	50 (100%)
NOAC	45 (90%)
Warfarin	5 (10%)
Class I and III AADs	37 (74%)
Amiodarone	31 (62%)
Sotalol	5 (10%)
Flecainide	1 (2%)
Other drugs	
ACE inhibitors	5 (10%)
ARBs	22 (44%)
ARNI	24 (48%)
Beta blockers	45 (90%)
Calcium channel blockers	0% (0%)
SGLT2 inhibitors	21 (42%)

Continuous variables are expressed as mean ± standard deviation. Categorical variables are expressed as absolute and percentages.AADs, Antiarrhythmic Drugs; ACE, Angiotensin-converting enzyme; ARB, Angiotensin receptor blocker; ARNI, Angiotensin receptor neprilysin inhibitor; LVEF, Left ventricular Ejection Fraction; LA, Left Atrium; NOAC, Novel Anticoagulation; SGLT2, Sodium-glucose Cotransporter-2

All the procedures were done with 28mm CB-Adv, and all the PVs were successfully isolated. The procedural characteristics are given in (Table 2).

The complication rate during PVI with CB-Adv is low, similar to radiofrequency ablation.[7] In our data, procedure-related complications were present in 2 patients (4%). One patient (2%) had a retroperitoneal hematoma, and one patient (2%) had pericardial effusion, although none required any intervention, and were discharged on the 3rd and 2nd post-procedure days, respectively. The details of the possible complications are mentioned in (Table 3).

Only one patient (2%) had a recurrence of Ata on follow-up after one month, which was documented in 24-hour Holter monitoring. It was found to be PAF during Holter monitoring on the 3rd and 6th month. The patient was advised to continue AADs. Forty-nine patients (98%) were free from any Ata on the 1st, 3rd, and 6th-month follow-up, and their AADs were

discontinued after the BP of 3 months. Predictors for the recurrence of Ata were not identified.

Table 1: Procedural Characteristics

Mean procedural time (min)	52.68±18.18
Mean fluoroscopy time (min)	22.96±7.22
Time to Isolation LSPV (sec)	29.86±8.11
Time to Isolation LIPV (sec)	29.10±5.99
Time to Isolation RIPV (sec)	33.04±9.61
Time to Isolation RSPV (sec)	29.76±9.08
Mean temperature achieved in 60 seconds for LSPV (^{0}C)	-39.28±8.15
Mean temperature achieved in 60 seconds for LIPV (^{0}C)	-39.42±6.33
Mean temperature achieved in 60 seconds for RIPV (^{0}C)	-41.20±5.90
Mean temperature achieved in 60 seconds for RSPV (^{0}C)	-39.10±5.61
Mean minimal temperature in LSPV (^{0}C)	-47.24±4.34
Mean minimal temperature in LIPV (^{0}C)	-48.06±5.04
Mean minimal temperature in RIPV (^{0}C)	-47.68±4.87
Mean minimal temperature in RSPV (^{0}C)	-47.84±4.72
Total number of pulmonary veins isolated	204

Continuous variables are expressed as mean ± standard deviation. LIPV, Left inferior pulmonary vein; LSPV, Left superior pulmonary vein; RIPV, Right inferior pulmonary vein; RSPV, Right superior pulmonary vein

Table 2: Procedure-related Complications

	Total number of procedures (n)= 50
Phrenic Nerve Palsy	0
Atrioesophageal Fistula	0
Transient ST Elevation	0
Retroperitoneal Hematoma	1 (2%)
Groin Complications	0
Neurological Complications	0
Pericardial Effusion	1 (2%)
Pulmonary Vein Stenosis	0
Total number of complications	2 (4%)

DISCUSSION

NICVD, Karachi, is one of the largest centers in Pakistan which performs electrophysiological studies. For the last five years, NICVD has provided a cryoballoon ablation facility for patients who have PAF and are resistant to AADs. Till now, there has yet to be local data on the experience of cryoballoon ablation for AF in Pakistan. Our single-center data from NICVD is Pakistan's first study in this regard. The main findings of our study were that 98% of the patients had no recurrence of Ata following the procedure during a follow-up period of 6 months. Procedure-related complications were present in 4% of the patients. Our findings show a much lesser recurrence rate of Ata compared to a study conducted in Belgium by Irfan et al. on a much larger population of 393 patients, of which 331 had PAF (85.8% had recurrence after PVI at 1-year follow-up).[5] It was possibly due to our small sample size and a short span of monitoring which was six months.

Now the question arises, should we be treating PAF so aggressively? So studies have shown that if left untreated, the short runs of PAF can progress to persistent or permanent AF.[8] Progression of AF has shown an association with adverse cardiovascular events and stroke.[9] Moreover, intermittent AF has also shown adverse effects on quality of life.[10] Decades ago, the concept of rate control was used to manage AF. Still, the new data, such as from EAST-AFNET 4 trial, has made it clear that early rhythm control strategy is associated with reduced cardiovascular events and hospitalization for heart failure.[2] Rhythm control can be achieved with AADs or catheter ablation. Data has shown that patients with catheter ablation for AF had a better quality of life than those on AADs.[11] The recently published ATTEST trial has also shown that catheter ablation has better outcomes in preventing progression of AF [progression to persistent AF at three years was lower with ablation (2.4%), (95% CI; 0.6-9.4%) than with AAD therapy (17.5%), (95% CI; 10.7-27.9%); one-sided P = 0.0009].[12] The most obvious seemingly disadvantage of catheter ablation is the high cost of the procedure. A study from Canada has shown that catheter ablation is cost-effective in the long run if compared to overall hospitalizations, emergency visits, repeated echocardiograms, and the need for multiple cardioversions for those patients who did not have ablations for AF.[13]

Till now, the guidelines have recommended AADs as the first line of management for PAF, probably due to the lower success rate of arrhythmia suppression and higher rates of repeat procedures with radiofrequency (RF) catheter ablation in the previous studies.[14, 15] Lower success rate of RF ablation was due to the fact that it was more operator dependent. This led to a new ablation technique called cryoballoon (CB), which was much less operator dependent and had more reproducible lesions.[16] Today, PVI with catheter ablation is considered a cornerstone in the management of PAF.[17] Several studies have compared RF with CB ablation and have shown similar outcomes.[18] Conversely, some studies have shown lesser rehospitalizations and fewer repeat ablations with CB ablation (32.6% CB vs. 41.5% RFC; P = 0.01 and 3.2% CB vs. 6.4% RFC; P=0.04, respectively).[19] With the advent of second-generation CB, much larger and uniform lesions are achievable, resulting in improved short and long-term results.[20] These homogenous lesions are possible because second-generation CB has been equipped with eight refrigerant jets implanted more distally on the catheter shaft than first-generation CB, which had only four refrigerant jets.[4] Three recent randomized control trials (EARLY-AF, STOP-AF First, and Cryo-First)

compared CB ablation with AADs as a first line of management in AF. In these trials, a total of 724 patients got enrolled. These patients were in the early phase of the disease, highly symptomatic, and most had PAF (98%). All three trials showed the superiority of PVI with CB-Adv over AADs for preventing Ata recurrence.[21-23] In light of these recent trials, it is possible that the upcoming guidelines will recommend CB-Adv as the first line of management in symptomatic patients with PAF.

In a country like Pakistan, the prevalence of AF and the burden of health care expenditure on hospitalization for AF remain obscured. It is difficult to say whether CB-Adv for PVI will remain cost-effective compared to AADs for public sectors like NICVD. Each procedure costs almost a million rupees based on current (May 2023) USD≈PKR parity. Moreover, this technique requires well-trained operators and highly specialized centers, so performing such procedures in settings deprived of primary healthcare necessities is impossible. On the other hand, considering the high success rate of PVI and advancement in the field of cardiac electrophysiology in Pakistan, the future of PVI with CB-Adv for PAF still looks promising.

As far as the limitation of the study is concerned, first of all, the study was conducted on a small cohort of patients. Moreover, patients were monitored for only six months, and 24-hour Holter monitoring was obtained on each follow-up. It was possible that we could have documented more recurrence if we had a longer monitored follow-up and patients were implanted with an inner loop recorder. It was single-center data and operator-dependent. Hence results may vary among different centers.

CONCLUSION

Our study findings show an overall low recurrence rate of Ata after the procedure on a six-month follow-up. Once successful, one can enjoy a life free from AADs and its side effects. However, considering the high cost of the procedure and the requirement of specialized centers, currently, it isn't easy to offer this facility throughout Pakistan, especially in resource-limited settings. When the country's economy is much more stable and our healthcare system incorporates much more advanced treatment options, we can change our practices of managing PAF. It is possible that we can offer PVI with CB-Adv as a first line of treatment for PAF.

AUTHORS' CONTRIBUTION

MSA, GI and ZM: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. FQ, MA, SAS, and AM: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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Address for Correspondence:

Dr. Muhammad Sarim Ansari, Post Fellow Cardiac Electrophysiology, National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan.
Email: ansari.sarim@yahoo.com