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Original article

Cryoablation for paroxysmal and persistent AF in patients with structural heart disease and preserved ejection fraction: Clinical outcomes from 1STOP, a multicenter observational project

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ABSTRACT

Background: Pulmonary vein isolation (PVI) is an accepted strategy for paroxysmal atrial fibrillation (PAF) and persistent AF (PerAF) ablation. Limited data are available on outcomes of cryoballoon (CB) PVI in patients with structural heart disease (SHD). The purpose is to assess the clinical efficacy of a single CB-PVI procedure in patients with PAF or PerAF who also have SHD.

Methods: From April 2012, 460 AF patients with concomitant SHD underwent CB-PVI and were followed prospectively in the framework of the 1STOP ClinicalService® project. Data on procedural outcomes and long-term freedom from AF recurrence were evaluated. Out of 460 subjects, 282 patients (61%) had PAF and 178 (39%) PerAF.

Results: SHD patients were predominantly male (80.9%), old (62.8 ± 8.9 years), with preserved functional capacity (New York Heart Association class >1: 39.4%), high cardioembolic risk (CHA_2DS_2VASc score ≥2: 69.3%), and conserved left ventricular ejection fraction (56.5 ± 8% LVEF). Both subjects with PAF and PerAF had similar baseline clinical characteristics except for left atrial diameter (43.8 ± 7 vs. 45.7 ± 7 mm) and area (22.9 ± 5.2 vs. 25.1 ± 4.4 cm^2), respectively. Procedure time and fluoroscopic time as well as the rate of procedural complications were not different between subjects with PAF and PerAF. After a mean follow-up of 12 months, antiarrhythmic drug therapy had dropped from 71.7% before ablation to 33.6% post-ablation ($p < 0.001$) and the freedom from symptomatic AF recurrence was 78% for PAF and 77% for PerAF ($p = 0.793$). Furthermore, atrial arrhythmia recurrence rate was not related to SHD.

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Conclusions: In a large multicenter, real-world cohort, CB-PVI was used to treat patients with PAF and PerAF who also had SHD. The arrhythmia recurrence after a single procedure was not related to either the degree of cardiac structural remodeling or the type of AF, and the rate of AF recurrence was lower than previously reported in patients with SHD in other cohort series using focal radiofrequency catheter ablation.

Clinical trial registration: clinicaltrials.gov (NCT01007474).

Introduction

Atrial fibrillation (AF) is the most prevalent atrial arrhythmia, afflicting approximately 3% of the adult population [1,2]. AF is associated with increased morbidity and mortality primarily due to the higher risk of cardiovascular complications [3–5], and it is even more prevalent in patients with structural heart disease (SHD) [6]. The European Society of Cardiology (ESC) guidelines indicate that AF is secondary to SHD when associated with left ventricular (LV) systolic or diastolic dysfunction and/or long-standing hypertension with LV hypertrophy and/or other SHD [7]. The increased prevalence of AF in patients with SHD, demands further investigation into the treatment of AF in this population.

Several studies have demonstrated that catheter ablation is more effective than antiarrhythmic drugs (AADs) in reducing AF recurrence and symptoms, and together have established pulmonary vein isolation (PVI) as the cornerstone of AF ablation [7–14]. According to current ESC guidelines, AF ablation is indicated in symptomatic patients with and without SHD as an alternative to AADs (Class IIa; level of evidence B) or when AADs are ineffective [7]. However, ablation is thought to be less effective in patients with more extensive compromise of atrial structure or with persistent forms of AF [15,16]. Therefore, additional lesion sets have been tested for the treatment of patients with persistent AF (PerAF) or long-standing PerAF, but these studies have produced conflicting results [17–23]. Due to the lack of consistent data supporting the efficacy and safety of more extensive ablation strategies [23–28], PVI-only catheter ablation is recommended for the index procedure in patients with either paroxysmal AF (PAF) or PerAF [7,24].

Clinical characteristics of patients with SHD are thought to undermine the efficacy of PVI for the treatment of AF. Indeed, these patients have compromised atrial structure, which has been shown to reduce the efficacy of catheter ablation [29], and SHD patients often present with PerAF for which there is uncertainty about the optimal ablation targets [22–24,26–28]. Despite the apparent challenges in treating AF in SHD patients, evidence suggests that ablation has been effective in improving LV function and quality-of-life in patients with heart failure and reduced ejection fraction (HFrEF) [9–14,30,31]. To date, SHD patients are seldom represented in AF ablation clinical studies [32,33]. Consequently, we retrospectively evaluated the efficacy of cryoballoon (CB)-PVI in a large cohort of PAF and PerAF patients with concomitant SHD. Furthermore, we sought to identify predictors of clinical success in this patient population.

Methods

Population

Patients with AF who had undergone CB-PVI (Arctic Front or Arctic Front Advance; Medtronic, Inc., Dublin, Ireland) in 36 Italian institutions from April 2012 to November 2017 were prospectively followed through in-hospital visits according to each center's clinical practice through the framework of the Italian ClinicalService® project. During the baseline visit, each center identified patients as having SHD according to the 2016 ESC AF guidelines as the presence of LV systolic or diastolic dysfunction and/or long-standing hypertension with LV hypertrophy and/or other SHD [7,34]. For this analysis, only patients with SHD comprised the studied cohort.

Project design and procedure overview

CB-PVI was performed by positioning the cryoballoon catheter within each active vein under fluoroscopic guidance. After pulmonary vein (PV) occlusion was confirmed by radiopaque contrast agent injection, circumferential ablation was achieved by delivering coolant into the balloon. PVI was demonstrated by the elimination of conduction of atrial impulses into the PVs. In case of failure to obtain PVI, the addition of further focal lesions to complete isolation was left to each center practice.

Acute procedural success was defined as the ratio between the number of effectively isolated PVs and the number of target PVs. The first 90 days after AF ablation were considered a blanking period during which any atrial arrhythmia detection was not counted as a long-term follow-up failure event(s) [8]. Recurrence of AF was defined as the detection of AF [including focal atrial tachycardia and flutter, both symptomatic or asymptomatic, lasting $\geq$30 s in duration when assessed with electrocardiogram (ECG) monitoring] occurring after the blanking period [7]. Since AAD management following CB-PVI was left to each center's practice, without any standardized protocol, we analyzed AF recurrence both in the entire population, regardless of the usage of AAD, and in patients who were off AADs.

Project organization

The patients included in the present analysis were followed up in a network of 36 cardiology centers which participated in the Italian ClinicalService® framework [Clinical Trial Registration: NCT01007474, One Shot to Pulmonary vein isolation (1STOP) project]. This is a national medical care project aimed at evaluating and improving the use of medical therapies in clinical practice. The project consists of a shared environment for the collection, management, analysis, and reporting of data from patients in whom Medtronic therapies have been applied. An independent scientific committee of physicians prospectively identifies key clinical questions on a yearly basis for analysis and publication. A charter assigns the ownership of data to the centers and governs the conduct and relationship of the scientific committee and Medtronic.

The project was approved by each site's medical ethics committee or medical director, and it conforms to the principles outlined in the Declaration of Helsinki. Each patient provided informed consent for data collection and analyses [33]. At the baseline visit, patient clinical characteristics were collected, including: age, sex, hypertension, valvular disease, baseline cardiopathy, previous thromboembolic events, thromboembolic risk index, and atrial dimensions (diameter and area by echocardiography). During the procedure, data on procedural duration times and adverse events were recorded and collected. Follow-up visits were made in accordance with the clinical practice of each

Table 1
Baseline clinical features of the total population and comparisons between subjects with paroxysmal and persistent atrial fibrillation.

Baseline characteristics	Total ($N=460$)	Paroxysmal ($N=282$)	Persistent ($N=178$)	p-Value
Age at first ablation (years)	62.8 ± 8.9	62.9 ± 9.0	62.6 ± 8.8	0.741
Gender (female)	19.1% (88)	20.9% (59)	16.3% (29)	0.219
Body mass index	28.0 ± 3.9	27.7 ± 3.9	28.4 ± 3.9	0.075
Any symptom of atrial arrhythmia	92.2% (424)	91.5% (258)	93.3% (166)	0.491
Duration in atrial tachyarrhythmia	53.7 ± 66.8	56.1 ± 72.5	49.9 ± 56.6	0.886
Previous therapy using >2 AADs	59.3% (230)	55.3% (135)	66.0% (95)	0.039
History of heart failure	8.6% (39)	6.8% (19)	11.6% (20)	0.080
Hypertension	78.5% (357)	76.4% (214)	81.7% (143)	0.182
History of stroke or TIA	5.5% (25)	5.8% (16)	5.2% (9)	0.803
Left atrial diameter (mm)	44.5 ± 7.3	43.8 ± 7.0	45.7 ± 7.6	0.005
Left atrial area (cm^2)	23.7 ± 5.0	22.9 ± 5.2	25.1 ± 4.4	<0.001
Left ventricular ejection fraction (%)	56.5 ± 8.0	57.2 ± 7.7	55.3 ± 8.5	0.074
CHA_2DS_2VASc				0.145[a]
0	9.2% (40)	9.6% (26)	8.4% (14)	
1	26.5% (116)	27.0% (73)	25.7% (43)	
2	33.6% (147)	29.6% (80)	40.1% (67)	
3	20.4% (89)	21.5% (58)	18.6% (31)	
4	6.4% (28)	6.7% (18)	6.0% (10)	
5	3.0% (13)	4.4% (12)	0.6% (1)	
≥6	0.9% (4)	1.1% (3)	0.6% (1)	
Type of cardiomyopathy				
Primary	12.7% (56)	11.5% (31)	14.6% (25)	0.335
Hypertensive	60.9% (280)	56.7% (160)	67.4% (120)	0.022
Ischemic	27.3% (124)	32.5% (91)	19.0% (33)	0.002
Mitral valve disease	8.3% (38)	7.5% (21)	9.7% (17)	0.410
Aortic valve disease	2.9% (13)	2.8% (8)	2.9% (5)	0.987
Tricuspid valve disease	0.7% (3)	0.7% (2)	0.6% (1)	1.000
Pulmonary valve disease	0.2% (1)	0.4% (1)	0.0% (0)	1.000
Other cardiovascular diseases	6.0% (27)	5.8% (16)	6.3% (11)	0.836
NYHA				<0.001[a]
1	60.6% (228)	73.0% (176)	38.5% (52)	
2	36.2% (136)	25.3% (61)	55.6% (75)	
3	3.2% (12)	1.7% (4)	5.9% (8)	
4	0.0% (0)	0.0% (0)	0.0% (0)	
Diabetes	11.0% (46)	11.3% (29)	10.6% (17)	0.835
Chronic kidney disease	5.8% (25)	4.9% (13)	7.3% (12)	0.287

[a] The comparison was performed using the Chi-square test for categorical data.
AADs, antiarrhythmic drugs; NYHA, New York Heart Association; TIA, transient ischemic attack.

center, including: every 3 months during the first-year after the index CB-PVI ablation and every 6 months thereafter. The routine visits consisted of assessment of the patient AF-related symptoms, ECG or Holter monitoring examination, and drug therapy assessment.

Statistical methods

Baseline characteristics and clinical data have been summarized and compared between patients with PAF and PerAF using the appropriate summary statistics. Variables on a continuous scale have been described as means with standard deviations, median with interquartile ranges, and minimum and maximum values. Discrete variables were presented as counts with percentages. Differences between continuous variables were tested by the Wilcoxon's test, and statistical differences between discrete variables were tested using a Fisher's exact or chi-square test, as appropriate. Statistical tests were based on a two-sided significance level of $p < 0.05$.

A survival analysis was conducted by means of the Kaplan–Meier method. Differences between groups were tested by log-rank methods and proportional hazards models were fitted. The hazard ratio (HR) and 95% confidence interval (CI) were calculated. The annual rates of complications were reported, together with the 95% Poisson CI. The Poisson regression model was used to calculate the incidence rate ratio (IRR), with the *d*-scale option. Since the number of AF recurrence per patient during follow-up was not available, only the survival analysis was performed for this long-term efficacy endpoint. To find predictors of AF recurrence, a Cox regression was imputed for univariate analyses, and multivariate analyses were conducted only when univariate interactions were statistically significant. Parameters with significant univariate interaction (with a $p < 0.10$) were also analyzed in a multivariate model (where statistical significance was set at $p < 0.05$). Statistical tests were based on a two-sided significance level of $p < 0.05$. Missing data were not imputed. SAS 9.4 software (SAS Institute Inc., Cary, NC, USA) was used to perform statistical analyses.

Results

This analysis included 460/2456 (19%) of patients in the entire 1STOP project who were classified with SHD and had completed at least one follow-up visit (as a minimum inclusion criteria requirement). Primary demographic and baseline clinical characteristics of the SHD patients are summarized for the total population as well as for the PAF (282/460; 61%) and PerAF (178/460; 39%) subgroups in Table 1. As expected, within the population, the PerAF cohort had significantly more cardiac remodeling (left atrial area: 25.1 ± 4.4 vs. 22.9 ± 5.2 cm^2; $p < 0.001$ and left atrial diameter: 45.7 ± 7.6 vs. 43.8 ± 7.0 mm; $p = 0.005$), more previous AADs prescribed (66.0% vs. 55.3%; $p = 0.039$), and more advanced New York Heart Association class (61.5% vs. 27.0%; $p < 0.001$), while it had less ischemic cardiomyopathy (19.0% vs. 32.5%; $p = 0.002$), compared to the PAF cohort. At the time of ablation, 88.4% of patients were on anticoagulants (vitamin K antagonist or

Table 2
Procedural characteristics of the total population and comparisons between subjects with paroxysmal and persistent atrial fibrillation.

Baseline characteristics	Total ($N = 460$)	Paroxysmal ($N = 282$)	Persistent ($N = 178$)	p-Value
Procedure duration (min)	106.9 ± 45.1	106.9 ± 41.5	106.9 ± 50.0	0.357
Fluoroscopy duration (min)	29.2 ± 15.1	28.7 ± 14.7	30.1 ± 15.6	0.341
Ablation time (min)	31.1 ± 84.8	26.9 ± 60.7	37.3 ± 111.5	0.938
Number of targeted PVs	4.0 ± 0.4	4.0 ± 0.4	4.0 ± 0.3	0.440
Acute success rate[a]	98.3% (1703)	98.9% (1037)	97.4% (666)	0.020
Pre-ablation sinus rhythm	63.7% (274)	83.5% (212)	35.2% (62)	<0.001
Cardioversion	24.8% (114)	10.3% (29)	47.8% (85)	<0.001
Post-ablation sinus rhythm	91.5% (390)	95.3% (241)	86.1% (149)	<0.001

[a] Treated/targeted pulmonary veins.
PVs, pulmonary veins.

Table 3
Acute complications after the index procedure of the total population and comparison between subjects with paroxysmal and persistent atrial fibrillation.

Complications	Total ($N = 460$)	Paroxysmal ($N = 282$)	Persistent ($N = 178$)	p-Value
Patients with at least one complication	3.9% (18)	3.9% (11)	3.9% (7)	0.986
Transient diaphragmatic paralysis	1.1% (5)	1.4% (4)	0.6% (1)	0.653
Pericardial effusion	0.2% (1)	0.4% (1)	0.0% (0)	1.000
Cardiac tamponade	0.2% (1)	0.4% (1)	0.0% (0)	1.000
Hematoma	0.9% (4)	0.7% (2)	1.1% (2)	0.643
Arteriovenous fistula	0.4% (2)	0.4% (1)	0.6% (1)	1.000
Femoral pseudoaneurysm	0.2% (1)	0.0% (0)	0.6% (1)	0.387
Other complication(s)	0.9% (4)	0.7% (2)	1.1% (2)	0.643

direct oral anticoagulants), 6.7% were on antiplatelet medications, and 3.2% were on neither therapy.

Procedural data

Index procedure data and acute results are summarized in Table 2. One or more anatomical PV variant(s) was found in 38/460 patients, including: 18 with single common PV trunk, 4 bilateral common ostia, and 22 with supernumerary PVs. The overall average acute success rate was 98.3% with a different rate of acute isolation in the PerAF subgroup versus the PAF subgroup (97.4% vs. 98.9%, respectively; $p = 0.020$). No differences in acute success rate were found in normal vs. complex PV anatomy. In 11/460 patients focal radiofrequency touch-up lesions were added to obtain acute PVI. As expected, significantly more PAF patients were in sinus rhythm prior to ablation compared with PerAF patients (83.5% vs. 35.2%; $p < 0.001$), fewer patients with PAF required cardioversion (10.3% vs. 47.8%; $p < 0.001$), and sinus rhythm was more frequently achieved following ablation in PAF patients (95.3%) than PerAF patients (86.1%; $p = 0.001$). There were no significant differences in the procedural duration between PAF and PerAF patients ($p = 0.357$).

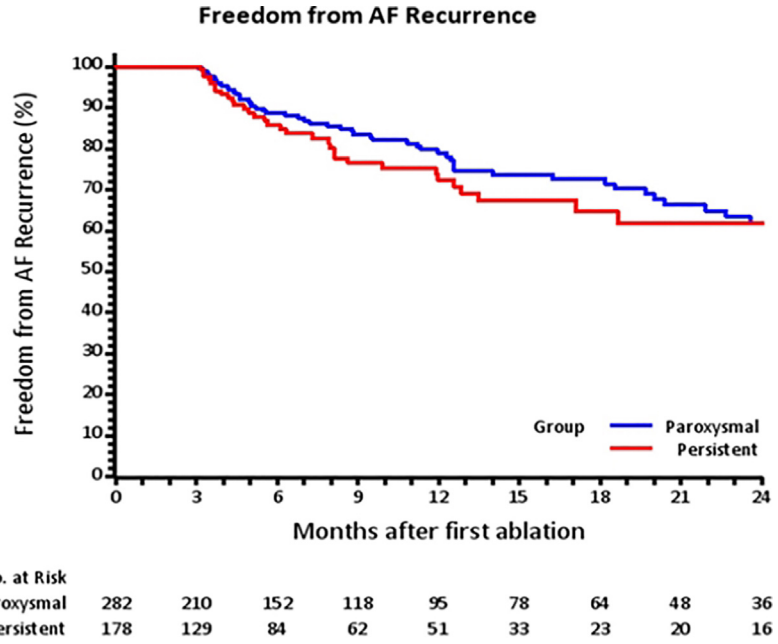
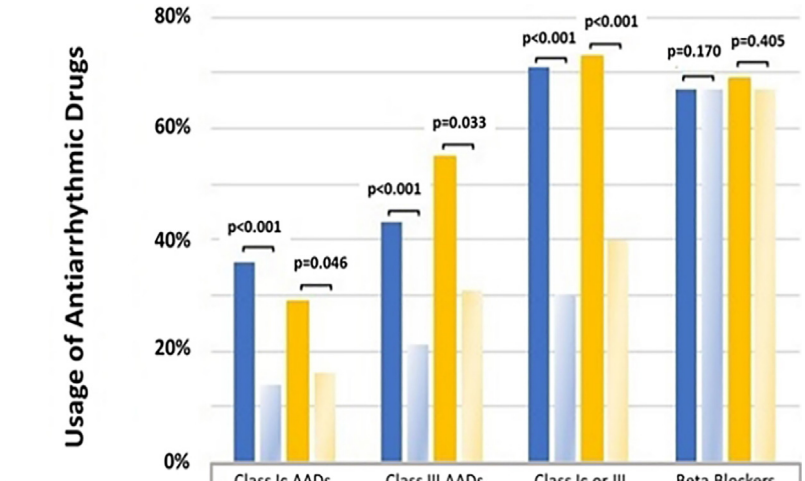


Fig. 1. Freedom from atrial fibrillation (AF) recurrence after the index cryoballoon catheter ablation of the pulmonary veins. During long-term follow-up, there was no significant difference in AF recurrence rates between subjects with paroxysmal and persistent AF (log-rank $p = 0.793$).



	Class Ic AADs	Class III AADs	Class Ic or III	Beta Blockers
Paroxysmal Baseline	36%	43%	71%	67%
Paroxysmal Last FUP	12%	21%	29%	62%
Persistent Baseline	29%	55%	73%	69%
Persistent Last FUP	16%	31%	40%	67%

Fig. 2. Antiarrhythmic drug(s) (AAD) usage before (baseline) and after index ablation [last follow-up (FUP)] by pulmonary vein isolation method in subjects with paroxysmal and persistent atrial fibrillation.

Safety

Acute procedural complications are reported in Table 3. Importantly, there were no deaths, permanent phrenic nerve palsies, pulmonary vein stenosis, atrial-esophageal fistulas, strokes, or transient ischemic attacks.

AF recurrence

The average follow-up was 12.2 ± 11 months. AF recurrence was observed in 22.4% of cases (Fig. 1), which was not statistically different between PAF and PerAF subgroups (22.0% and 23.0%, respectively; $p = 0.793$). At the end of the follow-up period, 33.6% of the total patient cohort was on class Ic or III AADs, which was significantly reduced from 71.7% of patients prior to the index ablation ($p < 0.001$). Fig. 2 demonstrates the change in AAD usage observed in PAF and PerAF subgroups. In patients without AADs, the AF recurrence at 12 months was 18.9% (95% CI: 14.0–25.3%).

Since AF recurrence was documented in 22.4% of patients, a Cox regression analysis was utilized to identify baseline characteristics that were associated with recurrence. None of the following baseline features were identified as predictors of recurrence with univariate analysis, including: age, gender, body mass index, classification of AF (PAF vs. PerAF), etiology of SHD (as individual etiologies and as primary and secondary SHD – i.e. ischemic plus hypertensive), New York Heart Association class, CHA_2DS_2VASc score (as a composite nor as each of its individual components), AAD usage, left atrial size, or LVEF. Consequently, multivariable analyses were not conducted by statistical rule.

Discussion

This retrospective, real-world analysis investigated CB-PVI for AF in patients with SHD. In this subset of patients, a single CB-PVI procedure was demonstrated to be both safe and effective, with a low atrial arrhythmia recurrence rate for both PAF and PerAF subgroup cohorts. Further, the degree of functional and structural impairment of the heart did not predict the longer-term efficacy of the catheter ablation procedure.

Procedural characteristics

Neither the paroxysmal or persistent nature of AF nor the severity of SHD (as indicated by LVEF and left atrial size) influenced either procedural or fluoroscopy duration (Table 2). Mean procedure and fluoroscopy duration were both lower than mean times reported by Andrade and colleagues in a review of 23 PAF and PerAF studies, in which SHD patients accounted for just 11% of the population [35]. More recently, studies that utilized a second-generation CB (Arctic Front Advance), investigated a PAF patient population, or a mixed population of PAF and PerAF patients, had fewer than 30% of cases classified as SHD and reported procedural and fluoroscopic times comparable to ours [32,35–37]. Chierchia and colleagues demonstrated much lower procedural and fluoroscopy duration in a series of PAF patients of whom 30% were classified with SHD, but they were treated in a single (high-volume) center [38]. Together, these data indicate that CB-PVI in SHD patients did not require longer procedural or fluoroscopy duration to complete the procedure as compared with other clinical reporting of mixed patient cohorts (PAF and PerAF).

The complication rate in our 1STOP project was low. Particularly, we observed a lower incidence of transient diaphragmatic paralysis (1.1%) than rates reported in large studies with the second-generation CB (Chierchia et al. = 8%; Aryana et al. = 7.6%) [37,38]. However, we cannot definitively exclude that the differences in transient diaphragmatic paralysis rates were due to under reporting into our registry database or under diagnosis (no monitoring criteria were pre-defined in our analysis). Overall, our data do not suggest a greater incidence of complications in patients with SHD.

Recurrence of atrial fibrillation

The recurrence rate of 22.4% for a single procedure over an average follow-up period of about 12 months is amongst the lowest reported in studies on AF ablation, most of which include fewer or no SHD patients [33,35–38]. We observed a significant reduction in potentially harmful medications following CB-PVI ablation. Prior to ablation, approximately 1/3 patients were taking

Class Ic AADs despite their SHD and about 1/2 were on amiodarone. The reduction in AAD usage and an improved adherence to guidelines following CB-PVI, might be associated with an overall increase in safety in patients with SHD.

Patients with SHD are expected to have a high rate of AF recurrence and are typically less responsive to catheter ablation compared to non-SHD [39,40]. SHD (e.g. LV hypertrophy, chronic heart failure, and valvular heart disease) is associated with atrial dilation, extracellular matrix remodeling, autonomic unbalance, and calcium handling defects, all of which have a proarrhythmic effect [41,42]. Reduced efficacy of ablative strategies for the treatment of AF in patients with atrial fibrosis and remodeling has been previously demonstrated by Marrouche and colleagues [29]. In HFrEF, the recurrence risk after a single procedure and the need for repeated ablations are highest [10,14,27,43–45]. Although, CASTLE-AF and CAMERA-MRI have recently shown a significant improvement in functional and echocardiographic parameters after AF ablation [30,31]. These observations were not confirmed in our population of SHD, which consisted of subjects with moderate atrial enlargement (thus with some degree of atrial overload and remodeling), but minimal or no reduction of the LVEF and was not comparable to the severely compromised cohorts enrolled in those previously mentioned studies.

Age, hypertension, prior transient ischemic attack, left atrial dilation, and reduced LVEF have previously been associated with atrial disease progression [7,46–49], but in our analysis, these clinical parameters were not predictors of recurrence in our population of patients with SHD. The absence of a large hemodynamic atrial overload might have blunted the correlation between atrial remodeling and recurrence, consequently justifying the low rate of AF recurrence observed in our analysis. However, after radiofrequency catheter ablation even the moderate LA dilation that we have reported in our patients has been identified as a strong predictor of AF relapse [50,51], whereas the lack of correlation between LA dilation and AF recurrences does not support this hypothesis in our patient population that were treated by CB-PVI.

In fact, a surprising observation from this analysis is that PerAF was not a predictor of AF recurrence. It has been consistently reported that patients with PerAF are more likely to recur than patients with PAF after either radiofrequency or cryoballoon ablation [52–55]. Although an area of active investigation, the interaction between AF and SHD remains currently unclear. One hypothesis for further investigation is that in early stage SHD, PAF and PerAF patients present with similar atrial disease/electrical disruption, which limits the utility of the typical AF classifications.

Clinical implications

This analysis provides insight into the safety and efficacy of CB-PVI for the treatment of AF in SHD patients with preserved ejection fraction. According to current ESC guidelines, class I AADs and sotalol should not be used for the prevention of AF recurrence in SHD patients even with preserved LVEF [7]. Our data suggest that CB-PVI might be a reasonable, effective, and safe alternative to AADs for the treatment of AF in patients with SHD without major LV systolic dysfunction.

Limitations

From the 1-STOP Italian project, this analysis was retrospective and observational, and therefore, it did not include a control group for rigorous demonstration of efficacy of CB-PVI in this patient population. The definition of SHD we utilized to select patients for the analysis, although reflective of the ESC guidelines, was non-specific and not based on objective parameters. Moreover, the centers' standard practices are to use alternative, non-ablative, treatment plans for patients with advanced cardiomyopathies and very low LVEF heart failure, *de facto*, excluding more extensive SHD patients from this cohort. Thus, our results cannot be applied to the broad spectrum of SHD patients, but are reflective of less advanced, real-world scenario SHD patients with preserved LVEF. Also, in our analysis no biomarker (e.g. B-type natriuretic peptide or N-terminal pro B-type natriuretic peptide) or imaging data (e.g. magnetic resonance imaging) were collected which might have further defined the hemodynamic status and the degree of atrial remodeling within this cohort.

Because detection of AF recurrence during follow-up was not standardized, AF recurrence was based both on arrhythmia symptoms and ECG/Holter monitoring assessments. Therefore, efficacy of PVI might be overestimated due to a lack of continuous detection of arrhythmia episodes which may have occurred following AF ablation [56]. Additionally, no recommendations were provided to the participating 1-STOP centers in terms of pharmacological treatment following CB-PVI. Thus, it is unknown whether AADs were simply continued after the blanking period as per center practice (or due to individual case-specific considerations).

Conclusions

In this large multicenter, real-world observational cohort, we demonstrated that CB-PVI to treat PAF and PerAF in SHD patients with preserved LVEF was both safe and effective. The procedural success was comparable to other CB-PVI studies, and the recurrence rate after a single procedure was lower than previously reported in other large series and meta-analyses. Neither the degree of structural remodeling nor the type of AF was predictive of atrial arrhythmia recurrence following catheter ablation. Future studies are needed to investigate whether these results can be extended to other techniques of PVI or are specific to CB-PVI and whether CB-PVI is effective for patients with more advanced structural and functional cardiac compromise.

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Conflicts of interest

Giovanni B. Perego is a member of the Medtronic European Advisory Board. Claudio Tondo serves as member of the Medtronic European Advisory Board and Boston Scientific International Advisory Board. Prof. Tondo received lecture and proctor fees from Medtronic, Abbott Medical, Biosense Webster, Boston Scientific. Roberto Verlato received modest consultancy and speaker's fees from Medtronic, Giulio Molon received modest consultancy fees from Medtronic and Boston Scientific and speaker's fees from Medtronic, Boston Scientific, St. Jude, and Boehringer Ingelheim.

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