

period of 24.3 ± 11.5 months. Patients with previous PAF showed stable SR in 30/40 (75%), while patients with previous PersAF showed 14/26 (54%) stable SR.

Conclusions: CB2-based PVI demonstrates a high long-term success rate as assessed by continuous atrial monitoring in patients with previously implanted cardiac devices comparable to standard follow-up methods. CB2-based PVI seems to be a safe and feasible approach in these patients.

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Cryoablation for paroxysmal and persistent AF in patients with structural heart disease. Clinical outcomes from multicenter observational project

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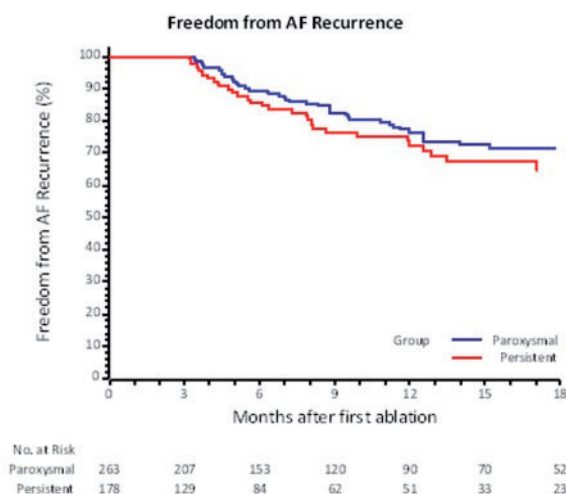
Background: Pulmonary vein isolation (PVI) is an accepted strategy for paroxysmal AF (PAF) and persistent AF (PerAF) ablation. Little evidence is available about acute results and late outcomes of CryoBalloon (CB) PVI in patients with structural heart disease (SHD).

Purpose: to assess the procedural results and the clinical effectiveness of a single CB-PVI procedure in paroxysmal AF population with and without SHD.

Methods: From April 2012 to May 2017, 2031 AF patients underwent CB-PVI and were followed prospectively in the framework of the One Shot TO Pulmonary vein isolation (1STOP) ClinicalService® project, involving 36 Italian Cardiology Centers. Our study population consisted of 441 cases (22%) fulfilling the criteria for SHD proposed by current ESC guidelines: Left Ventricular (LV) systolic or diastolic dysfunction, long-standing hypertension with LV hypertrophy, and/or other structural heart disease. Data on procedural outcomes and long term freedom from AF recurrence were evaluated.

Results: SHD patients were mostly males (80.3%), age 62.7 ± 8.8 yrs. As compared to non-SHD patients, they had lower functional capacity (NYHA class >1 41.9% vs. 17%; $p<0.001$), higher cardioembolic risk (CHA₂DS₂-Vasc score ≥ 2 : 63.6% vs. 37.3%; $p<0.001$), lower LV ejection fraction (56.6 ± 7.5 vs. 60.0 ± 6.2 ; $p<0.001$) and higher Left Atrial (LA) diameter (LA diameter 44.7 ± 7.1 vs. 40.8 ± 6.0 mm; $p<0.001$) and area (23.6 ± 5.0 vs. 21.6 ± 5.3 cm²; $p<0.001$), with no differences between PAF and PerAF. At the time of ablation 72.8% patients were on class Ic or III AADs. Procedure time (106.4 ± 45.5 min.), fluoroscopic time (29.3 ± 14.9 min) and acute success rate (98.7%) as well as the rate of acute procedural complications (3.4% of which 0.9% transient diaphragmatic paralysis) were not different in PAF and PerAF. After a follow up of 11.8 ± 11.2 months, the freedom from symptomatic recurrence was 79.1% for PAF and 77% for PerAF ($p = n.s.$) as shown in fig 1. Recurrence rate was not related to either LA size or LVEF. Class Ic or III AADs were taken by 34.7% patients (p 0.001 vs. baseline)

Conclusions: In a large real life observational cohort CB-PVI has been extensively applied to treat PAF and Per AF in SHD. The recurrence rate after a single procedure was not related either to the degree of structural remodeling or to the type of AF and was lower than previously reported in SHD in other large series and metanalyses on radiofrequency ablation. Further studies are needed to define whether these differences are specifically due to the ablation technique.



Abstract P279 Figure.

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Predicting application failure during cryoballoon ablation: how to decide for an additional-freeze-application?

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Background: Treatment of early manifest pulmonary vein (PV) reconnection or dormant reconnection unmasked by adenosine may improve outcome of AF ablation. We aimed to identify demographic, procedural and biophysical parameters that may predict early reconnection (ERC) of the PVs.

Methods: Consecutive patients with AF undergoing cryoballoon ablation (Arctic Front Advance) between 2014 and 2017 were retrospectively included. ERC defined as either early manifest or dormant reconnection unmasked with intravenous adenosine was evaluated 30 minutes after ablation. If present, an additional freeze-application of 240 seconds (s) was applied. Procedural characteristics including exact time-to-isolation and the number of unsuccessful freezes before achieving PV isolation and biophysical data including temperature of the balloon after 30 and 60 s, nadir balloon temperature, mean balloon temperature below 0°C, and three thawing times measured from the end of the freeze-application to 0, 15 and 20°C were evaluated as potential predictors for ERC.

Results: A total of 151 pts (60 ± 9 years, 108 male, 95% paroxysmal AF) were included. ERC was found in 40/151 (27%) patients (ERC group) and in 53/604 (9%) veins and was more prevalent in male patients (83% vs. 66%, $p=0.049$). Procedure time and total ablation time were longer in the ERC group compared to the non-ERC group (150 ± 40 min vs. 125 ± 34 min and 24 ± 5 min vs. 17 ± 4 min; $p<0.001$). The total number of applications (8 ± 2 vs. 5 ± 1) and the number of unsuccessful freezes (20 (38%) vs. 125 (24%) of the veins) were significantly higher in the ERC group. The exact time-to-isolation could be measured in 80% (481/604) of the veins during ablation and was significantly longer in the ERC group (70 ± 30 vs. 48 ± 28 s). The balloon temperature was significantly lower at 30 s (-39 ± 6 vs. -35 ± 6 °C, $p=0.004$) and the nadir temperature was higher in the ERC-group (-42 ± 9 °C vs. -47 ± 7 °C, $p<0.001$). In addition, significantly shorter thawing times were found at 0, 15 and 20°C in the ERC group (e.g. thawing time at 20°C was 31 ± 18 vs. 42 ± 18 s). The mean balloon temperature below 0°C was -35 ± 7 °C in the ERC group compared to -38 ± 5 °C in the non-ERC group ($p<0.001$). Multivariate analysis showed that a higher balloon temperature at 30s (HR 0.9[0.81 – 0.99], $p=0.036$), a higher nadir temperature (HR 1.2[1.1 – 1.3], $p<0.001$) and a longer time-to-isolation (HR 1.0[1.01 – 1.03], $p<0.001$) were independently associated with ERC.

Conclusion: Three easily available biophysical parameters were associated with ERC. Based on these parameters a cryoballoon ablation score can be developed to predict ERC after the initial freeze. Implementing this score in the cryo-console can help to avoid waiting period and adenosine challenge in selected patients.

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qualified bonus freezes - a rationale for added freezes with the cryoballoon

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Introduction: Cryoballoon-based pulmonary vein isolation is clinically successful, with high reported one-year success rates, of up to 90% in paroxysmal and 69% in persistent AF. Introduction of the 2nd gen. cryoballoon has rendered routine bonus freezes obsolete. But no accepted rationale exists concerning isolating freezes with indicators of bad efficacy, such as shallow nadir temperatures or long time-to-isolation. In current clinical practice, operators will apply or not apply a second freeze based on subjective parameters rather than data. To deduct a reproducible strategy for this dilemma, we retrospectively analysed data from cryoballoon-PVI's and from Redo-procedures.

Methods: We analyzed 5527 freezes from 722 cryoballoon-PVI's (2CB in n=558, 2CB-ST in n=164) and 57 redo-procedures.

Results: Nadir temperatures ("NTs") were different in each PV, and they were different for successful vs. unsuccessful attempt at isolation (LSPV: -47.9 ± 5.3 °C vs. -38.9 ± 7.7 °C, LIPV: -44.6 ± 5.3 °C vs. -36.7 ± 7.8 °C, RSPV: -50.5 ± 5.4 °C vs. -40.4 ± 9.9 °C, RIPV: -47.4 ± 5.7 °C vs. -37.8 ± 8.2 °C, p -values <0.0001 for all comparisons). NTs from bonus-freezes were slightly higher on average ($+0.6 \pm 4.7$ °C) than their preceding isolating freezes. To see if there was a relationship between the NT of an isolating and its bonus freeze, we grouped bonus freezes according to the NT of the preceding isolating freeze into tertiles. The 1st tertile contains bonus-freezes following isolating freezes with NTs from -64 °C to -51 °C. Similarly the 2nd tertile contains bonus freezes following isolating freezes from -50 °C to -45 °C and the 3rd tertile from isolating freezes from -44 °C to -25 °C. We found that bonus freezes following the coldest isolating freezes per average had "warmer" NTs (1st tertile, mean temperature difference: $+2.6$ °C). Conversely, bonus freezes following the warmest isolating freezes were "colder" (3rd tertile, mean temperature difference -1.8 °C). In the middle (2nd) tertile, the temperature difference was close to zero ($+0.3$ °C).

In a second step, we calculated "target temperatures" for each pulmonary vein using ROC-curves for acute isolation (LSPV: AUC 0.84, cut-off -43.5 °C, LIPV: AUC 0.83 cut-off -39.5 °C, RSPV: AUC 0.82, -46.5 °C, RIPV: AUC 0.84, cut-off -42.5 °C). These values were then validated in a cohort of redo-procedures, where we found that achieving a NT below the cut-off was associated with persistent isolation of a PV (binomial regression, estimate 2.0, $p < 0.0001$).

Conclusions: A bonus freeze after an isolating freeze with a shallow NT often achieves a lower NT. Specific target NTs for different PV's can be defined from ROC-curves using information about acute isolation.

In a cohort of Redo-procedures, these target values predict persisting PV isolation versus reconnection.

An isolating freeze with a NT missing its target value thus might justify a bonus freeze. Prospective data will be needed to confirm this approach.

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Value of high-resolution mapping in optimizing cryoballoon ablation of atrial fibrillation

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Background: No data are available on the use of high-resolution mapping during cryoballoon (CB) ablation for atrial fibrillation (AF) as the index procedure. The aims of this study were: 1) to assess the value of using a high-resolution mapping system during CB ablation procedures in terms of ability in acutely detecting incomplete CB lesions, 2) to compare the Achieve and Orion catheters with respect to pulmonary vein (PV) signals detection at baseline and after CB ablation, 3) to characterize the extension of the lesion produced by CB ablation by means of a high-resolution voltage mapping.

Methods: Consecutive patients with drug-resistant paroxysmal or early-persistent AF who underwent PV isolation (PVI) by CB ablation as the index procedure, assisted by a high-resolution mapping system, were included in this study.

Results: A total of 21 patients (17 males, 81%; mean age: 60±17 years, 17 paroxysmal AF) were included. At baseline, Achieve catheter revealed PV activity in 63 PVs (77%), while the Orion documented PV signals in all veins (100%). Failure of complete PVI by CB ablation was more frequently revealed by the atrial re-mapping with the Orion as compared to the Achieve catheter (33% vs 0%, p<0.001). (Table 1) A repeat ablation was performed in 7 patients. In 9% of cases, the Orion catheter detected far-field signals originating from the right atrium. A total of 18 patients (86%) remained free of symptomatic AF during a mean follow-up time of 10.2±3.7 months. Quantitative assessment of the created lesion by CB ablation revealed a significant reduction of the left atrial area having a voltage above 0.5 mV.

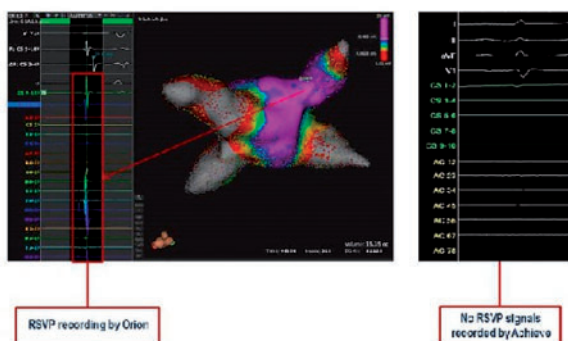
Conclusions: Atrial re-mapping after CB ablation by means of a high-resolution 3D mapping system improves the detection of areas of incomplete ablation, characterizes the extension of the cryo-ablated tissue and can identify abolishment of potential non-PVI related sources of AF.

Abstract P282 Table. Patients with real-time PV recordings

	Pre-Ablation Achieve	Pre-Ablation Orion	Post-Ablation Achieve	Post-Ablation Orion
LSPV	17/21 (81%)	21/21 (100%)	0/21 (0%)	1/21 (5%)
LIPV	16/21 (76%)	21/21 (100%)	0/21 (0%)	4/21 (19%)
RSPV	16/21 (76%)	21/21 (100%)	0/21 (0%)	1/21 (5%)
RIPV	14/21 (76%)	21/21 (100%)	0/21 (0%)	3/21 (14%)

Rate of patients with real-time PV recordings revealed by Achieve and Orion catheters before and after cryoballoon ablation.

LA-PV remapping after CB ablation



Abstract P282 Figure. High-resolution remap after CB ablation

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Can the continuous monitoring of cardiac rhythm after index pulmonary vein cryoballoon ablation improve the care of patients with paroxysmal AF?

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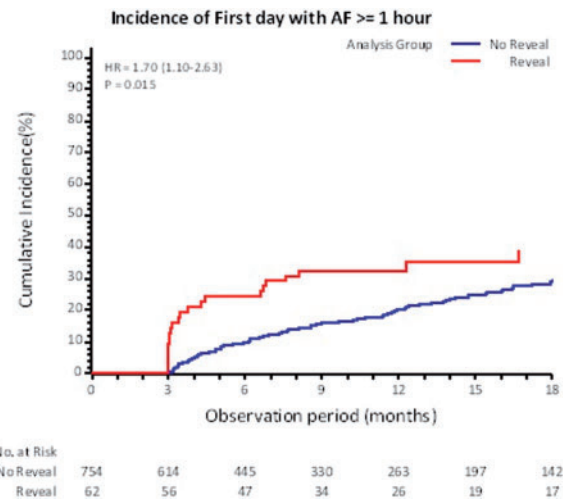
Background: Pulmonary vein (PV) ablation is an approved therapy in symptomatic, recurrent paroxysmal atrial fibrillation (PAF). The real ablation success and the subsequent patient management is still under investigation.

Purpose: To assess and compare the incidence of AF recurrence and the patient management in a cohort of PAF population performing a first-time PV one shot technologies ablation (CBA) in case of traditional follow-up vs continuous monitoring of cardiac rhythm.

Method: 838 consecutive patients (mean age 58 years, 69% men) underwent PV CBA for paroxysmal AF were considered for this analysis. Data were prospectively collected in the framework of the One Shot TO Pulmonary vein isolation (1STOP) ClinicalService® project in 36 centers. Recurrence of clinical relevant AF was defined as the detection of a daily burden of AF lasting at least 1 hour occurring more than 3 months after a single ablation procedure with or without the use of antiarrhythmic medications. The cohort of patients was divided into 2 groups according to the usage of continuous monitoring (CCM) of cardiac rhythm in the follow up (CCM group vs traditional group). In the traditional group AF related symptoms, ECG, and dynamic ECG were collected during 3/6 month in hospital visits according to the clinical practice of each center.

Results: The CCM group was composed of 84 (10%) patients, while the traditional group had 754 (90%) subjects. Both cohorts had similar baseline clinical characteristics. The acute success rate was 98.3% with no differences between the 2 groups. At the mean follow up duration of 13 months, 31 patients (37%) in the CCM group and 142 (18.8%) in the traditional group experienced at least one recurrence of clinical relevant AF. The incidence analysis for AF recurrence (Figure 1) showed a 12-month incidence probability equal to 33% in the CCM group as compared with 20% in the traditional group as shown in fig 1. Moreover, there was a significative higher rate of repeat procedure in the CCM group (rate *100 pt/years: 13.40 in the CCM group vs 3.64 in the traditional group, p=0.001).

Conclusion: In this multicentric experience, the use of CCM in patients who underwent index PVI CBA procedure seems to suggest that using CCM allows to detect clinically relevant AF recurrence in a timely manner, and consequently to improve the clinical management of these patients over the time.



Abstract P283 Figure.

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Long-term clinical success of pulmonary vein isolation utilizing the second generation cryoballoon in patients with persistent atrial fibrillation: A multicenter study

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Background: Use of the second-generation cryoballoon (CB2) for pulmonary vein isolation (PVI) in patients with paroxysmal atrial fibrillation (AF) has demonstrated encouraging acute and long-term results. However, clinical follow-up in persistent AF is sparse.