



CRYO-BALLOON CATHETER ABLATION EFFICACY RESTORING AND MAINTAINING SINUS-RHYTHM IN PATIENTS TREATED FOR PERSISTENT LONG STANDING ATRIAL FIBRILLATION AFTER ACUTE COMPLETE ELECTRICAL ISOLATION OF THE PULMONARY VEINS..

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INTRODUCTION



The electrical disconnection of the pulmonary veins (PV) from the left atrium (LA), by Cryo-Balloon catheter ablation (CB) has proven effective in the definitive treatment of paroxysmal atrial fibrillation.





Clinical success rate published around **70-80%** in terms of maintenance of sinus rhythm^{(1-4),} in a short-medium-term followup.

- (1) Van Belle Y, et al. Pulmonary vein isolation using an occluding cryoballoon for circumferential ablation: feasibility, complications, and short-term outcome. Eur. Heart J. 2007; 28:2231-7
- (2) Neumann T, et al. Circumferential pulmonary vein isolation with the cryoballoon technique results from a prospective 3-center study. J Am Coll Cardiol. 2008;52:273-8.
- (3) Vogt J, et al. Long-Term outcomes after cryoballoon pulmonary vein isolation. J Am Coll Cardiol. 2013;61:1707-12.
- (4) Packer D.L, et al. Cryoballoon ablation of pulmonay veins for paroxysmal atrial Fibrillation: First results of the North American Artic Front (STOP AF) Pivotal trial. J Am Coll Cardiol.2013;61:1713-23





In the last few years (April 2012), a Second Generation CB has emerged into the Clinical practice with technical modifications (resulting in a larger and more uniform zone of Freezing on the balloon's surface) aiming to improve the procedural outcome in patients treated for Atrial Fibrillation.





And Comparison between the **First** and **Second** Generation **Balloon** showed significant differences (One year follow-up) in the general outcome of patients treated for **Paroxysmal** Atrial Fibrillation.(*)

> Freedom from AF (off/AA drugs)

• First Generation CB -



• Second Generation CB -



(*) Giovanni G.D, Wauters K, Chierchia G.B..et.al. " One -Year follow-up After Single Procedure Cryoballoon Ablation: A Comparison Between the First and Second Generation Balloon" J.Cardiovasc Electrophysiol . 2014;vol 25:834-839.





First study report

One-year Clinical oucome after Pulmonary Vein Isolation using the **Second** Generation 28- mm **Cryoballon** (*)

- Including small number of patients 14/50 (28%) with Short-Standing (<3 month duration) Persistent Atrial Fibrillation .
- Clinical Success Rate.
 - 81% PAF
 - 77% Short-Term Persistent AF
- One Year **success rate** improved from **52**% to **80**% (First Generation CB **Vs.** Second Generation CB)





However, the **isolated** efficacy of (**CB**) alone, restoring and maintaining sinus rhythm in patients with **persistent long standing** atrial fibrillation (**AF**) is less know in a medium-long term follow-up.





We analized the acute results and the **medium-long term follow-up** of our patients suffering **(AF)** and initially treated with the **CB**.



METHODS



A total of 40 patients with AF were treated with CB.

33 male (82.5%) mean age 60 ±10 **7** female (17.5%) mean age 64±5







The **mean time** duration of stable arrhythmia was **4±3** years (2-11).



METHODS



• All Patients were previously treated with antiarrhythmic drugs

- ßß: 33 patients (82.5%)
- **Class III**: 3 patiens (7.5%)
- Class 1C: 28 patients (70%)
- **ßß+ 1C**: 25 patients (62.5%)







Patients with Structural Heart Disease 7 (17,5%)

2 HOCM (5%)
2 Chronic IschemicHeart Disease (5%)
2 Dilated Cardiomyopathy (5%)
1 Non-compaction Cardiomyopathy (2,5%)



METHODS



All Medication were discontinued at least 5 half-lifes before **CB** procedure.

Angio-**CT**-Scan to asses **PV** anatomy.



METHODS



Same day transesophageal echocardiogram was performed in all patients to rule out intracavitary thrombus.



METHODS



Morphological and structural LA/PV and LV data.

Without structural heart disease.				With structural heart disease					
(33 patients)				(7 patients)					
Diameters (mm)	LA	PV	LCT	LVEF	Diameters (mm)	LA	PV	LCT	LVEF
AP	40±4 (33-49)	21±5 (14-30)	28±2 (25-30)	68%±6	AP	43±5 (34-48)	18±5 (14-28)	27	63%±5
SI	54±8 (42-70)	22±4 (9-32)	31±3 (30-35)	LA/Area (cm ²)	SI	60±4 (55-65)	22±5 (16-32)	30	LA/Area (cm ²)
LAT	46±7 (41-66)			24±5 (14-36)	LAT	50±7 (43-60)		(2	28±3 (24-33)



METHODS



All procedures were performed under general anesthesia.

- Propofol/iv for anesthesia induction.
- Neuromuscular relaxation with
 - **Cisatracurium** only at the time of intubation.
- Orotracheal intubation / mechanical ventilation with gas (Sevoflurane) maintained.
- Analgesia with Remifentanil in continuous perfusion.







Phrenic Nerve Phisyology

Was monitored in all cases during **RPV/CB** applications

By pacing SVC (2000mS Cl)

- Intermitent fluoroscopy.
- Tactile feedback placing the operator's hand on the patient's abdomen.







Before **CB**, Electrical **C**ardioversion **(CV)** was performed in all group.

153 PV and **7** Common Trunks **(CT)** were treated with the **CB**.



RESULTS



Electrical Cardioversion (CV) Restored Sinus Rhythm. 16 cases (40%) The remaining 24 / CB applications were performed in AF

> Reasume SR **8** (20%)

16 required **CV** After **CB** applications/ Checking for Bidirectional Block **(BB)**



RESULTS



- **153 PV** and 7 Common Trunks **(CT)** were treated with the **CB**.
- Bidireccional Block was demonstrated in **146** PV (96%)



All eliminated with focal **RF** applications.







Occlusion applications **CB**

Occlusion Grade III:

Occlusion Grade IV:

First Generation Temperature: - **40±4** °C Applications n°: 22

Second Generation Temperature: - 44±5 °C Applications n°: 8

N° Occlusions: 2±1

First Generation Temperature: - **53±10** °C Applications n°: 95

Second Generation Temperature: - **53±6** °C Applications n°: **209**

N° Occlusions: 2±1





RESULTS AF Reversion during CB application. 8/24 patients (33%)

P. V.							
1 st PV LS	2 nd PV LI	3 rd PV RS	4 th PV RI				
3 (12.5%)	2 (8.3%)	2 (8.3%)	1 (4.2%)				

















(Follow-up)

Follow-up started after 3-months Blanking period on medication.

(when all antiarrhythmic drugs were discontinued).

35 patients







(Follow-up)

Closely evaluated via **Transtelephonic** information , and **Holter** monitoring.







(Follow-up)

Follow-up mean duration period.



(range: 7-62 months).



RESULTS



(Follow-up) **6/35** patients (46%) 7 Patients 9 Patients with Structural without Heart Disease. Structural Heart Disease.





RECURRENCES















REDO (Second Procedure)

> **Mean Follow-Up** 21±17 months

(6-56 months) 7 REDO



5

2 Free of On Drugs Medication

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(Follow-up: 35 pts)

Maintain Sinus Rhythm 19/35 Patients (54%)

Without antiarrhythmic drugs.

First procedure

- 2 (10%) First Generation CB
- 17 (90%) Second Generation CB

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6 out of the 19 patients maintaining SR without medication, SR was restored during CB applications.





(Follow-up: 35 Pts)

MAINTAINING SINUS RHYTHM



V

CB/Generation

4 Patients (15.4%) First Generation CB 22 Patients 84.6% Second Generation CB Universidad Europea de Madrid





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All were done with First Generation CB









5 CT patients remain in Sinus Rhythm off drugs:
 1 First Generation CB

□ 4 Second Generation CB (57%)

- **2 CT** pts REDO:
 - I Sinus Rhytm with medication and PV isolated. (First Gen. CB)

□ 1 Sinus Rhythm without medication . (Second Gen. CB).



RESULTS



• SIDE EFFECTS AND COMPLICATIONS:

- ✓ Aphonia: 2 pts (5 %).
 □ 1 First Gen. CB.
 □ 1 Second Gen. CB.
- ✓ Groin Haematoma: 1 (2.5%). (male, 68 years old) (Inadvertent arterial puncture → pseudoaneurysm: surgical repair)
- ✓ Transient Phrenic Nerve Paresia: 4 (10%).
 □ 1 First Gen. CB
 □ 3 Second Gen. CB (7.5%)(*)



RESULTS



SIDE EFFECTS AND COMPLICATIONS:

CB/RSPV/PHRENIC PARESIA

	T °C	Seconds	CB mm.	CB Generation
1	-62	120	28	FIRST
2	-64	123	23	SECOND
3	-68	103	23	SECOND
4	-54	194	23	SECOND





1. CB technique is a **safe** and **useful** tool to treat patients with **persistent long-standing AF**.





2. With a 54% of success rate in terms of MAINTAINING Sinus Rhythm in a medium-long term follow-up WITHOUT medication, after a single procedure.





3. Increasing the success rate to
68.5% after a Second procedure.
And up to 74% when
antiarrhythmic drugs are added.





4. In the majority of patients maintaining Sinus Rhythm (74%) (including REDO+ MEDICATION) the CB/ PVI was achieved with the Second Generation CB (84.6%).





5. Patients who refused REDO (9/25.7%) and continue on Persistent Atrial Fibrillation,
First Generation CB was used at the First Procedure.





6. Second Generation CB is better than First Gen. CB to restored and sustained Sinus Rhythm after PV isolation in patients with persistent long-standing AF (where Bigger antral lesion is needed).





7. Patients without Structural Heart Disease **along with** those who **Sinus Rhythm was restored** during **CB** applications.

Showed the best results.







8. However, the **Main Limitation** of our study might be due to the **small sample size**.

Future larger randomized studies are needed to confirm our findings.