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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Disclosure
None Conflict Of Interest
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.
INTRODUCTION

Clinical success rate published around 70-80% in terms of maintenance of sinus rhythm (1-4), in a short-medium-term follow-up.

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.
INTRODUCTION

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 - 66%
- Second Generation CB - 84%

INTRODUCTION

First study report

One-year Clinical outcome 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)

INTRODUCTION

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 analyzed the acute results and the medium-long term follow-up of our patients suffering (AF) and initially treated with the CB.
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 $4\pm3$ years (2-11).
• All Patients were previously treated with antiarrhythmic drugs
  • ββ: 33 patients (82.5%)
  • Class III: 3 patients (7.5%)
  • Class 1C: 28 patients (70%)
  • ββ+ 1C: 25 patients (62.5%)
Patients with Structural Heart Disease 7 (17.5%)

- 2 HOCM (5%)
- 2 Chronic Ischemic Heart 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 assess PV anatomy.
METHODS

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

Morphological and structural **LA/PV** and **LV** data.

<table>
<thead>
<tr>
<th></th>
<th>Without structural heart disease</th>
<th>With structural heart disease</th>
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<tbody>
<tr>
<td></td>
<td><strong>(33 patients)</strong></td>
<td><strong>(7 patients)</strong></td>
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<tr>
<td><strong>Diameters (mm)</strong></td>
<td><strong>LA</strong> 40±4 (33-49)</td>
<td><strong>LA</strong> 43±5 (34-48)</td>
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<tr>
<td></td>
<td><strong>PV</strong> 21±5 (14-30)</td>
<td><strong>PV</strong> 18±5 (14-28)</td>
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<td><strong>LCT</strong> 28±2 (25-30)</td>
<td><strong>LCT</strong> 27</td>
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<td></td>
<td><strong>LVEF</strong> 68%±6</td>
<td><strong>LVEF</strong> 63%±5</td>
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<tr>
<td></td>
<td><strong>LA/AREA (cm²)</strong> 24±5 (14-36)</td>
<td><strong>LA/AREA (cm²)</strong> 28±3 (24-33)</td>
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<tr>
<td><strong>AP</strong></td>
<td></td>
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<tr>
<td><strong>SI</strong></td>
<td>54±8 (42-70)</td>
<td>60±4 (55-65)</td>
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<tr>
<td></td>
<td>22±4 (9-32)</td>
<td>22±5 (16-32)</td>
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<td></td>
<td>31±3 (30-35)</td>
<td>30</td>
</tr>
<tr>
<td><strong>LAT</strong></td>
<td>46±7 (41-66)</td>
<td>50±7 (43-60)</td>
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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 Physiology

Was monitored in all cases during RPV/CB applications

By pacing SVC (2000mS Cl)

- Intermitten fluoroscopy.
- Tactile feedback placing the operator’s hand on the patient’s abdomen.
Before CB, Electrical Cardioversion (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)
• 153 PV and 7 Common Trunks (CT) were treated with the CB.
• Bidireccional Block was demonstrated in 146 PV (96%)
RESULTS

Occlusion applications CB

153 PV/ 7 CT

Occlusion Grade III:

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

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

Occlusion Grade IV:

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

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

Nº Occlusions:  2±1

Nº Occlusions:  2±1
RESULTS

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

<table>
<thead>
<tr>
<th>P. V.</th>
<th>1ˢᵗ PV LS</th>
<th>2ⁿᵈ PV LI</th>
<th>3ʳᵈ PV RS</th>
<th>4ᵗʰ PV RI</th>
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<tbody>
<tr>
<td></td>
<td>3 (12.5%)</td>
<td>2 (8.3%)</td>
<td>2 (8.3%)</td>
<td>1 (4.2%)</td>
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</table>

LSPV

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

(when all antiarrhythmic drugs were discontinued).

35 patients
Closely evaluated via Transtelephonic information, and Holter monitoring.
Results

Follow-up mean duration period.

- 2.5 years
  (range: 7-62 months).
RESULTS

(Follow-up)

RECURRENCES

16/35 patients (46%)

- 7 Patients with Structural Heart Disease.
- 9 Patients without Structural Heart Disease.
RESULTS

RECURRENTS

after
First Procedure

16 patients

Medication added

9 Persistent AF (Refuse REDO)

(Including All 7 patients with SHD)

Sinus Rhythm

7 REDO
RESULTS

RECURRENTS

Second Procedure (REDO)

7 patients (44%)

5
PV
reconducted

New CB PVI

2
All PV
disconnected
(First Gen. CB)
At First
procedure.

1
First Gen. CB

4
Second Gen. CB
RESULTS

REDO
(Second Procedure)

Mean Follow-Up

21±17 months
(6-56 months)

7 REDO

Remain/ SR

5 Free of Drugs

2 On Medication
RESULTS

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

(Follow-up: 35 Pts)

MAINTAINING SINUS RHYTHM

26 Patients

CB /Generation

4 Patients (15.4%) First Generation CB

22 Patients 84.6% Second Generation CB
RESULTS

CB Generation

9 Recurrence patients (Refuse REDO)

PERSISTENT AF

All were done with First Generation CB
RESULTS

Common Trunks (CT)

- 5 CT patients remain in **Sinus Rhythm** off drugs:
  - 1 First Generation CB
  - 4 Second Generation CB (57%)

- 2 CT pts REDO:
  - 1 **Sinus Rhythm 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:**

<table>
<thead>
<tr>
<th>CB/RSPV/PHRENIC PARESIA</th>
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<tr>
<td><strong>T °C</strong></td>
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<tr>
<td>-----------</td>
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<tr>
<td>1</td>
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CONCLUSIONS

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.