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### Efficacy of Cryoballoon Ablation. A Comparison Between First- and Second-Generation Balloon Catheters

Atrial fibrillation (AF) is the most common sustained arrhythmia encountered in clinical practice. Clinical trials based on epidemiology data predict that its prevalence will be 2-to-3-fold higher by 2050. (1)

Catheter ablation of paroxysmal or persistent AF is the treatment of choice in refractory and symptomatic patients, according to the current treatment guidelines. However, the procedure is not without complications, which are usually between 2% and 5%, as reported in the literature. (1)

While radiofrequency (RF) is the most widely used energy source, it encounters some limitations, and cryoablation has become an alternative treatment option by offering a safer lesion profile, among other advantages. (2-4) Since 2012, a second-generation balloon catheter has been used whose technological improvement consisted in the addition of 4 refrigerant injectors to the existing ones, and the location of a more distal injection coil within the balloon. (4-6)

However, these technical improvements have not been clinically evaluated in terms of efficacy. The purpose of this article is to compare the safety, efficacy, and success rate of this procedure between first-generation balloon (CB1) and second-generation balloon (CB2) catheters.

This is an observational, retrospective, single-center (Instituto Cardiovascular de Buenos Aires) study, including the first 35 consecutive ablations of paroxysmal AF performed with 28 mm Arctic Front® cryoballoon catheter (Medtronic, Inc.) (CB1), and 35 ablations performed with Arctic Front® Advance cryoballoon catheter (CB2), from November 2013 to December 2014 (Figure 1). It should be pointed out that selection criteria for any of the two catheters were not based on clinical criteria but on availability, since the CB2 catheter has been available in the Argentine market since August 2014.

A total of 70 patients were included in the study; 71.43% in the CB1 group and 73.33% in the CB2 group were men ( $p=0.650$ ). Mean age was  $54.2 \pm 13.42$  years in CB1 and  $52.94 \pm 12.25$  in CB2 ( $p=0.406$ ). All patients had history of documented recurrent paroxys-

**Table 1.** Technical characteristics of the procedure

|                                           | CB1                 | CB2                | p      |
|-------------------------------------------|---------------------|--------------------|--------|
| Number of applications per vein           | $2.27 \pm 0.59$     | $1.11 \pm 0.32$    | 0.01   |
| Mean time to vein disconnection           | $82.08 \pm 15.67$   | $47.02 \pm 9.45$   | 0.0001 |
| Mean temperature reached in each vein, °C | $-38.18 \pm 4.76$   | $-42.44 \pm 4$     | 0.0003 |
| Mean procedure time, min                  | $83.83 \pm 18.34$   | $61 \pm 12.88$     | 0.0001 |
| Fluoroscopy time, min                     | $25.38 \pm 12.22$   | $12.99 \pm 3.58$   | 0.01   |
| Mean fluoroscopy dose, mGy                | $243.43 \pm 142.43$ | $131.73 \pm 90.03$ | 0.002  |
| Complications, %                          | 0                   | 2.85               | 0.307  |

mal AF (PAF) of 2-6 years evolution and refractory to antiarrhythmic treatment. Average CHA2DS2-VASC score was 1 (1-3) for both groups.

No significant differences were found in the left atrial (LA) area, [ $20.10 \pm 3.63$  cm<sup>2</sup> in the CB1 group and  $19.94 \pm 2.98$  cm<sup>2</sup> in the CB2 group ( $p=0.943$ )], or in the ejection fraction [ $59.94 \pm 4.17$  in CB1 and  $60.26 \pm 2.85$  in CB2 ( $p=0.719$ )].

Immediate success rate was 100% for both groups, and the number of applications per vein was  $2.27 \pm 0.59$  in the CB1 group and  $1.11 \pm 0.32$  ( $p=0.01$ ) in CB2 group. Mean time to vein disconnection was  $82.08 \pm 15.67$  seconds in the CB1 group and  $47.02 \pm 9.45$  seconds ( $p=0.0001$ ) in the CB2 group. Mean temperature in the CB1 group was  $-38.18 \pm 4.76$  °C, and  $-42.44 \pm 4.05$  °C ( $p=0.0003$ ) in the CB2 group.

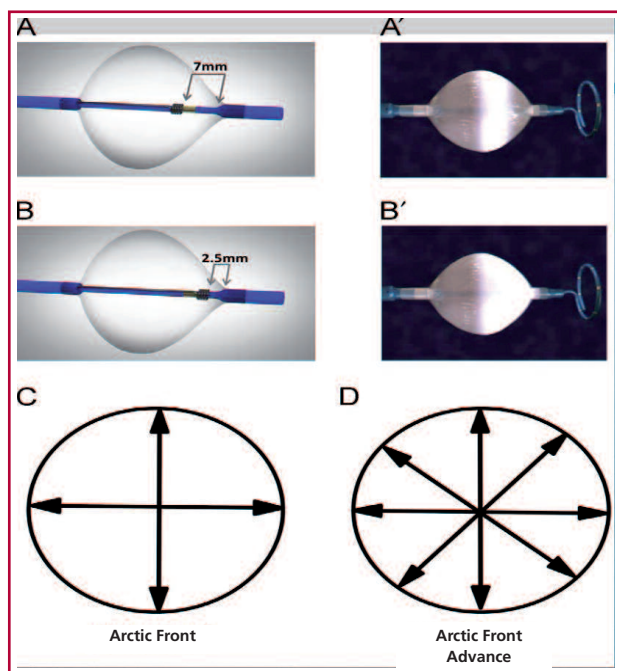
Procedure time was  $83.83 \pm 18.34$  min in the CB1 group and  $61 \pm 12.88$  min ( $p=0.0001$ ) in the CB2 group; fluoroscopy duration was  $25.38 \pm 12.22$  minutes for the CB1 group and  $12.99 \pm 3.58$  min ( $p=0.01$ ) for the CB2 group; fluoroscopy dose was  $243.43 \pm 142.43$  MGy and  $131.73 \pm 90.03$  mGy respectively ( $p=0.002$ ).

As for the safety of the procedure, the CB1 group did not have phrenic nerve paralysis, while there was one case of phrenic paralysis in the CB2 group which reversed one month after ablation ( $p = 0.307$ ).

Patients with over 6-month follow-up after the procedure were included in this study. Follow-up included all 70 patients; mean follow up was  $11.95 \pm 3.79$  months and recurrence rate was 24.75% for the CB1 group, and  $10.07 \pm 3.67$  months and 14.28 % for the CB2 group ( $p=0.477$ ).

Radiofrequency ablation is currently the most widely used method for the effective treatment of AF; however, success rate and limitations to RF ablation have been properly described by our study team and in the literature.

Today, cryoablation is being used as an option to



**Fig. 1.** A, C & A'. First-generation balloon with a more distal injection coil within the balloon and four refrigerant injectors, resulting in the cooling of the balloon at mid level.

B, D & B'. Second-generation balloon with a more distal injection coil within the balloon and eight refrigerant injectors, covering a wider freezing balloon surface area including its distal half.

RF ablation for pulmonary vein isolation. (2-4)

It is important to point out that, in our center, cryoablation was performed with different power catheters: the first 35 cases were treated with CB1 catheters, while CB2 catheters were used for the remaining 35 cases.

We understand that CB2 is more effective than CB1, because although vein isolation was achieved with both in 100% of cases, CB2 required fewer vein applications per patient, less time to reach the same goal, and achieved lower temperatures than CB1.

Cryoablation is associated with significantly shorter procedure times than those required by RF. In our initial experience, mean procedure times was  $78.03 \pm 19.84$  min, (3) similar to those reported by other authors. (4-6) Results analyzed by subgroups showed a significant difference between both groups in favor of CB2 over CB1; the same occurred with time and fluoroscopy dose.

In our initial experience, AF-free rate was 80.73%, with a mean follow-up of  $10.20 \pm 3.83$  months, (3) similar to that reported in the current literature. (4, 6) When results were analyzed by subgroups, a tendency in favor of CB2 (85.72%) over CB1 (75.25%) was observed, but the difference was not significant ( $p=0.477$ ). These results could reach statistical significance with a larger number of patients.

We believe that cryoablation is a safe procedure; phrenic nerve paralysis is its most common complication, but it is usually transitory and reverses 24 hours after the procedure. Only a few persist after 12 months.

In this series, the rate of complications was 1% (1 patient), (3) due to phrenic paralysis that reverted within the first month, lower than the rate reported in the current literature. (4, 5) Phrenic paralysis occurred only in the CB2 group, and the difference was not significant ( $p=0.307$ ).

The limitations of the study were its retrospective nature and the fact that it was single-center study, in which procedures were carried out by two different operators. Another aspect to be considered is that at first, when cryoballoon isolation of pulmonary veins began to be implemented, the only balloon available was the first generation one (the second generation balloon was implemented later), so that results could have been influenced by the learning curve. Lastly, we should mention that patient follow-up was higher for the CB1 group than for the CB2 group, a fact that might have influenced the AF-free rate.

In conclusion, cryoablation with CB2 proved to be as efficient as with CB1, but with shorter duration of the procedure and lower radiology dose. The safety profile is still favorable for CB1, with non-significant tendency.

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