

## Impact of initial rhythm control with cryoballoon ablation versus drug therapy on atrial fibrillation recurrence and quality of life: results from the Cryo-FIRST study

Pavlovic N.<sup>1</sup>; Kuniss M.<sup>2</sup>; Velagic V.<sup>3</sup>; Hermida JS.<sup>4</sup>; Healey S.<sup>5</sup>; Arena G.<sup>6</sup>; Badenco N.<sup>7</sup>; Meyer C.<sup>8</sup>; Chen J.<sup>9</sup>; Iacopino S.<sup>10</sup>; Anselme F.<sup>11</sup>; Kaplon RE.<sup>12</sup>; Chierchia GB.<sup>13</sup>

<sup>1</sup>University Hospital Sestre Milosrdnice, Zagreb, Croatia

<sup>2</sup>Kerckhoff Heart and Thorax Center, Bad Nauheim, Germany

<sup>3</sup>University Hospital Centre Zagreb, Zagreb, Croatia

<sup>4</sup>University Hospital of Amiens, Amiens, France

<sup>5</sup>Monash Health, Clayton, Australia

<sup>6</sup>Ospedale Apuane, Massa Carrara, Italy

<sup>7</sup>Sorbonne University, Paris, France

<sup>8</sup>University Heart Centre Hamburg, Hamburg, Germany

<sup>9</sup>Haukeland University Hospital, Bergen, Norway

<sup>10</sup>Maria Cecilia Hospital, Cotignola, Italy

<sup>11</sup>CHU de Rouen, Rouen, France

<sup>12</sup>Medtronic, Mounds View, United States of America

<sup>13</sup>UZ Brussel, Jette, Belgium

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**OnBehalf:** The Cryo-FIRST Investigators

**Background:** Cryoballoon ablation (CBA) as a first-line rhythm control strategy is superior to antiarrhythmic drugs (AADs) for preventing atrial arrhythmia recurrence; however, the impact of first-line CBA specifically on atrial fibrillation (AF) recurrence and quality of life (QoL) has not been well characterized.

**Purpose:** To compare AF recurrence and QoL following first-line CBA vs. AAD therapy in patients with paroxysmal AF within the CryoFIRST trial (NCT01803438).

**Methods:** Patients with recurrent symptomatic paroxysmal AF who had not been administered class I or III AAD therapy for >48 hours were enrolled at 18 sites in 9 countries. Patients were randomized (1:1) to CBA or AAD treatment (Class I or III). Subjects were followed by 7-day Holter at 1, 3, 6, 9, and 12 months. Time-to-first AF recurrence outside of a 90-day blanking period was estimated by Kaplan-Meier analysis. QoL was evaluated using the Atrial Fibrillation Effect on Quality of Life (AFEQT) and 36-Item Short Form Health Survey (SF-36) v2 questionnaires.

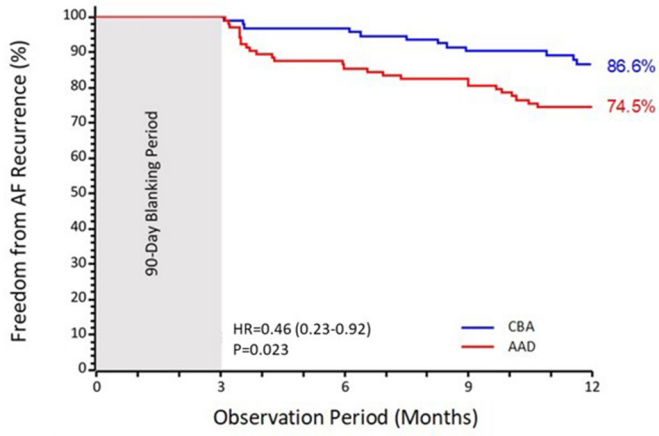
**Results:** Of the 218 randomized subjects, 187 (86%) completed the 12-month follow-up. By intention-to-treat (ITT) analysis, freedom from AF after blanking was achieved in 86.6% in the CBA and 74.5% in the AAD group ( $p = 0.023$ ). There was no difference in the time-to-first serious adverse event between groups. In total, 84.3% of patients in the CBA vs. 75.0% of patients in the AAD arm had a clinically important improvement ( $\geq 5$  points) in the AFEQT summary score. The adjusted mean difference in the AFEQT summary score at 12 months was 9.9 points higher in the CBA group (95% CI: 5.5-14.2;  $P < 0.001$ ). All AFEQT subscale scores were more favorable in the CBA vs. AAD group at 12 months. There were no significant group differences in any of the SF-36 health domain scores at 12 months in the ITT analysis. In the per-protocol analysis, clinically important and significant group differences in favor of CBA were observed at 12 months for 3 of 8 SF-36 health domain scores (physical functioning, general health and social functioning).

**Conclusion:** CBA is superior to AAD for preventing AF recurrence and improving AF-specific QoL in patients with paroxysmal AF.

AFEQT Scores at Baseline and 12 Months

AFEQT Score, Mean $\pm$ Standard Deviation	CBA		AAD		Adjusted Mean Difference at 12 Months (CBA vs. AAD)	p-value
	12 Months	Baseline	12 Months	Baseline		
Baseline						
Daily Activities	65.3 $\pm$ 25.8	87.8 $\pm$ 17.1	61.0 $\pm$ 27.9	76.6 $\pm$ 25.4	8.9 (3.2-14.6)	0.002
Symptoms	59.9 $\pm$ 24.8	88.8 $\pm$ 15.6	58.4 $\pm$ 25.2	80.9 $\pm$ 22.2	7.1 (1.5-12.7)	0.014
Treatment Concern	59.9 $\pm$ 23.1	89.8 $\pm$ 14.0	60.4 $\pm$ 24.5	77.7 $\pm$ 22.2	12.7 (7.9-17.5)	<0.001

AFEQT, Atrial Fibrillation Effect on Quality of Life questionnaire. CBA, cryoballoon ablation. AAD antiarrhythmic drug. Abstract Figure. Freedom From Atrial Fibrillation



No. at Risk	0	3	6	9	12
Cryo-ablation	107	94	90	83	56
Drug therapy	111	104	88	81	43