Safety and Acute Procedural Outcomes using Cryoballoon for Atrial Fibrillation Ablation in Japan: Results from the Cryo AF Global Registry

Ken Okumura
Osamu Inaba
Masahiko Goya
Satoshi Shizuta
Kaoru Okishige
Takashi Kurita
Koichiro Kumagai
Junjiro Koyama
Kunichi Hiroshima
Atsushi Kobori
Masaomi Kimura
Junichi Nitta

Introduction: The Japan PMS Study, and several single center publications have reported patient outcomes using the cryoballoon. However, there are limited publications on a large, prospective, multicenter patient population treated with the Arctic Front Advance cryoballoon Japan.

Methods: The Cryo AF Global Registry (NCT02752737) is a prospective, global, multi-center, observational post-market registry. AF patients 18 years or older with an ablation procedure using the Arctic Front™ Advance Cryoablation Catheter are eligible for this study. The present analysis reports baseline demographics, procedural data, and acute outcomes for all 355 patients with an index ablation procedure among 10 study centers in Japan.

Result: All 355 patients (65 ± 10 years, 35.8% female, CHA2DS2-VASc 2.2 ± 1.5, LAD 38 ± 6 mm) underwent an ablation procedure using exclusively the 28 mm second generation cryoballoon. Focal cryo was used in 4 (1.1%) patients, and focal RF was used in 17 (4.8%) patients to complete PVI. Non-PVI lesions were created in 132 (37.2%) patients. In total, 1,420 pulmonary veins were ablated with a mean of 1.3 ± 0.4 cryoballoon applications and an average ablation duration of 175.1 ± 39.5 seconds. A mean nadir temperature of -48.6 ± 6.6°C was reported. The mean procedure time, LA dwell, and fluoroscopy times were 73.1 ± 25.7 min, 44.8 ± 19.0 min, and 47.4 ± 36.1 minutes, respectively. The mean total lab occupancy time was 134.1 ± 40.8 minutes. An esophageal temperature probe was used during 320 (90.1%) procedures, and CMAP was used to monitor the phrenic nerve in 268 (75.5%) procedures. Dormant conduction testing was completed for 176 (49.6%) patients. Device related adverse events were observed in 8 (2.3%) patients with phrenic nerve injury the most common event and observed in 5 (1.4%) patients. At the time of hospital discharge, 65 (18.3%) of patients were prescribed an antiarrhythmic.

Conclusion: These acute results support cryoballoon PVI ablation as a safe and efficient procedure for treatment of atrial fibrillation patients in Japan.