Real life experience with atrial fibrillation cryoballoon ablation: results from a nationwide registry

T. Lubimceva[1], A. Topchyan[2], K. Davtyan[2], E. Artiykhina[3], E. Tarasiyk[4], A. Kosonogov[5], D. Kryzhanovsky[6], S. Korolev[7], G. Kolunin[8], I. Sagitov[9], A. Nechepurenko[10], N. Grachev[11], R. Batalov[12], D. Lebedev[1], E. Mikhaylov[1]

[1]Almazov National Medical Reseach Centre, Saint Petersburg, Russian Federation; [2]National Research Center for Preventive Medicine, Moscow, Russian Federation; [3]AV Vishnevsky Institute of Surgery, Moscow, Russian Federation; [4]Amur State Medical Academy of the Ministry of Health, Blagoveshchensk, Russian Federation; [5]City Clinical Hospital No. 5 of the Nizhegorodskiy District, Nizhniy Novgorod, Russian Federation; [6]26 Hospital, Saint Petersburg, Russian Federation; [7]Federal Scientific and Clinical Centre of Specialized Care and Medical Technology of FMBA of Russia, Moscow, Russian Federation; [8]Tyumen Cardiology Research Center, Tyumen, Russian Federation; [9]Republic Cardiology Centre, Ufa, Russian Federation; [10]Federal Center of Cardiovascular Surgery, Astrakhan, Russian Federation; [11]Primorsky Regional Clinical Hospital„ Vladivostok, Russian Federation; [12]Cardiology Research Institute Tomsk National Research Medical Centre Russian Academy of Sciences, Tomsk, Russian Federation

On behalf of Cryoregistry Russian Team

Funding Acknowledgement: Type of funding source: Public grant(s) – National budget only. Main funding source(s): Government of the Russian Federation

Cryoballoon ablation (CBA) is an effective strategy for AF management. The Russian Cryoballoon Atrial Fibrillation Ablation Registry (NCT03040037) is a prospective observational multicenter national registry that aims to provide real-world efficacy, safety and outcomes of this technology.

Purpose: To evaluate the CBA efficacy, types of adverse events following CBA based on a multicenter nationwide registry.

Materials and methods: A web-based registry platform was developed for prospective data entry. The platform consisted of 8 sections: AF ablation experience, patient and CBA characteristics, periprocedural management, 12-month FU, redo procedures, early and late procedure-related complications. Inclusion criteria were the following: indications for AF catheter ablation, planned CBA, a signed informed consent.

32 ablation centers and 1118 patients (572 males, a mean age 68.3±11.4) were included into the registry. Paroxysmal AF was presented in 722 pts, persistent AF – 350 pts, long standing persistent AF – 46 pts. The main underlying diseases were hypertension, coronary artery disease, chronic heart failure; less commonly - hypertrophic cardiomyopathy and dilated cardiomyopathy. The mean LA diameter was 44.7±11.1 mm, LVEF was 62.6±10.8%. The mean BMI was 32.3±3.5 kg/m^2. Cardioversion prior to CBA was performed in 32.8%. There were different strategies of AF recurrence documentation: ECG, 24-hour ECG monitor, ECG loop recorder implantation.

Results: The mean temperature of cryoablation was –45.7±17.4 C. The mean fluoroscopy time was 23.98 mins. The mean patient procedure duration was 108.46 mins [min 30; max 266]. The combination of RFA and CBA was reported in 9 cases. Periprocedural anticoagulant therapy included: uninterrupted NOACs (535 pts), bridge anticoagulation (365 pts), uninterrupted warfarin (67 pts), anticoagulation initiated only after CBA (151 pts). Transesophageal echo-guided CBA was performed in 126 cases, intracardiac echocardiography-guided CBA was performed in 474 cases. Esophageal temperature was controlled in 16 cases.

A 12-months follow-up was completed in 906 pts (81.0%). Arrhythmia recurrence was documented in 238 cases (21.3%), mainly AF. Elective cardioversions were performed in 39 pts. Redo ablation procedures were performed in 122 cases. There were a wide range of antithrombotic therapy, as well as pts without anticoagulants despite the fact of AF recurrence. There were 35 (3.1%) CBA-related major adverse events. Esophageal damage was found in 3 cases. There were registered 3 deaths (1 – oncology, and 2 due to unknown cause), 1 MI, 3 persistent phrenic nerve dysfunctions, 3 valve dysfunctions.

Conclusion: This nationwide registry represents contemporary safety and efficacy of CBA for AF. A high success rate of the procedure has been shown during 12 months post procedure. Although a total low number of procedure-related complications has been noted, the occurrence of life-threatening adverse events calls for a caution.