Clinical applications

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Low incidence of major procedure-related adverse events of cryoballoon ablation in real practice: an interim analysis of the Russian national prospective cryoablation registry

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OnBehalf: On Behalf Of the National Cryoballoon Registry Investigators

Background

Cryoballoon ablation (CBA) is an effective strategy for atrial fibrillation (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.

Methods

A specialized Web-based registry platform was developed for prospective data entry. The platform consists of 8 sections: AF ablation clinic experience and operator experience, patient characteristics, CBA procedure characteristics, periprocedural patient management (including drug therapy), 12-moths follow-up with scheduled and unscheduled visits, redo procedure characteristics, early and late procedure-related complications. Patient inclusion criteria were the following: indications for AF catheter ablation, planned CBA, a signed informed consent.

Results

To date thirty-one clinics have joined the Registry, and 830 patients (477 males, a mean age 65.4 ± 11.3 years) were included. The mean BMI was 33.2 ± 3.3 kg/m2. Paroxysmal AF was presented in 688 pts, persistent AF – 111 pts, long standing persistent AF – 31 pts. The main underlying diseases were hypertension (75%), coronary artery disease (11%), chronic heart failure (25%); less commonly - hypertrophic cardiomyopathy (1.4%) and dilated cardiomyopathy (0.7%). The mean LA diameter was 45.4 ± 10.2 mm, and LVEF was 65.4 ± 12.6%.

Periprocedural anticoagulant therapy included: uninterrupted NOACs (313 pts), bridge anticoagulation (327 pts), uninterrupted warfarin (45 pts), anticoagulation initated only after CBA (32 pts). The mean temperature of cryoablation was -44.6 ± 16.3 C. Transesophageal echo-guided CBA was performed in 92 cases , intracardiac echocardiography-guided - in 465 cases. There were 5 (0.6%) cases of hemopericardium, and pericardiocentesis was required in 1 (0.1%) case only. Periprocedural TIA was diagnosed in 1 (0.1%) patient with bridge anticoagulation, no stroke occurred. Transient phrenic nerve injury was detected in 18 (2.1%) patients, persistent palsy – in 1 (0.1%) patient. Two cases of esophageal injury were reported, no surgery was required and healing was reported in both patients. The data collection is ongoing.

Conclusion: We report early results of the ongoing national CBA Registry. There was a low number of major procedure-related adverse events in real clinical practice among centers with different AF ablation experience. Long-term follow up of the included patients will be reported in the future.

Abstract Figure. Antithrombotic therapy and CBA