A multicenter study of the need of additional freezing for cryoballoon ablation in patients with atrial fibrillation: The AD-Balloon study.

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Abstract: Pulmonary vein isolation (PVI) is a cornerstone of catheter ablation in patients with paroxysmal atrial fibrillation (PAF), and balloon-based ablation has been recently performed worldwide. Ablation using the second-generation cryoballoon (CB2) (Arctic Front Advance(TM), Medtronic, MN, USA) is useful for PVI; however, there is some debate concerning the optimal freezing time and number of cycles after PVI is achieved.

The AD-Balloon study was designed as a prospective, multicenter, randomized clinical trial to evaluate the optimal strategy (freezing cycles) of CB2 ablation (UMIN Clinical Trials Registry UMIN000020130). The main objective of this study is to investigate the need for an additional freezing cycle after PVI in patients treated with CB2 ablation. Patients will be randomly assigned in a 1:1 ratio to treatment with additional freezing (AD group) or without additional freezing (non-AD group). In the AD group, 3 min of additional freezing time will be applied in all pulmonary veins after PVI is confirmed at the previous freezing cycle. In the non-AD group, no additional freezing will be applied in all pulmonary veins after PVI is confirmed. The primary endpoint of this study is the occurrence of atrial tachyarrhythmias within a 1-year follow-up period. We will enroll 110 consecutive patients with PAF. We will also investigate the usefulness of delayed-enhancement magnetic resonance imaging to assess the ablation lesions caused by CB2 ablation.

The results of this study are currently under investigation.

The AD-Balloon study would assess the need for an additional freezing cycle after PVI is achieved. Our findings may contribute to further improvement of the CB2 ablation procedure.

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