Comparison of the Efficacy and Safety of Pressure-Guided Cryoballoon Ablation with Conventional Cryoballoon Ablation in Patients with Paroxysmal Atrial Fibrillation

Kazuya Yamao
Hitoshi Hachiya
Yasuaki Tsumagari
Satoshi Hara
Yoshikazu Sato
Shigeki Kusa
Yoshito Isaka

Introduction: Pulmonary vein (PV) isolation utilizing a cryoballoon has become one of the standard therapeutic options for atrial fibrillation (AF). Pressure-guided cryoballoon ablation (CBA) may be an alternative method of AF instead of conventional cryoballoon treatment with contrast injection. However, the detailed data about pressure-guided CBA was unclear. We assessed the efficacy and safety of this method.

Methods: We conducted a study to confirm whether pressure-guided CBA was noninferior to conventional CBA in patients with paroxysmal AF. PVI was performed with exclusively one 28-mm second-generation cryoballoon using single 3-minutes freeze technique. Electrical PVI was confirmed with a 20-mm circular mapping catheter in all. Additional touch-up ablation was conducted when electrical PV isolation couldn't be achieved by CB alone. Ultrasound probe was fixed in a headset. As one of the cerebrovascular events, the total microembolic signals (MES) in transcranial doppler during CBA procedure were calculated. A brain MRI was performed the day before and 1 day after the procedure to identify new procedure-related silent strokes. The primary efficacy end point was recurrence of atrial tachycardia. The primary safety end point was cerebrovascular events or serious treatment-related events.

Result: Among a total 207 patients who underwent PV isolation using exclusively 28-mm second generation cryoballoon, 51 patients (24.6%) underwent pressure-guided CBA procedure using the change of PV wedge pressure at the tip of the cryoballoon (Group P). The remaining 156 patients (75.4%) conducted a conventional CBA procedure using contrast injections (Group C). In patient characteristics, aged patients and CHADS2 score were higher in group P than group C. The recurrence of atrial tachycardia among patients was 5 in Group P and 45 in Group C (1-year Kaplan–Meier event rate estimates, 11.0% and 29.9%, respectively, P=0.03). The total MES during CBA procedure were higher in Group C than Group P(P=0.01). However, treatment-related events were comparable between the 2 groups (Group P vs. Group C: silent stroke; 6 vs 37, P=0.07, PV stenosis; 3 vs 3, P=0.16, phrenic nerve injury; 4 vs 6, P=0.27).

Conclusion: In this study, pressure-guided CBA was more useful than conventional CBA with respect to efficacy for the treatment of patients with paroxysmal AF and there was no significant difference between the two methods with regard to overall safety except MES.