

CRYOBALLOON ISOLATION OF THE PULMONARY VEINS, PROCEDURAL AND LONG-TERM RESULTS IN 346 PATIENTS

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Radiofrequency pulmonary vein isolation (PVI) for treatment of paroxysmal atrial fibrillation (AF) is established. The purpose of this study was to investigate the effectiveness and the safety of a novel cryoballoon device (ArticFront, Cryocath, Montreal, Canada).

Methods

We enrolled 346 patients (pts) with symptomatic, drug refractory paroxysmal (n=293) or persistent (n=53) AF. In all pts, PVI of all targeted PV was the therapeutic aim. The primary endpoints of this study were: 1. acute isolation rate of targeted PV; 2. first recurrence of AF (after a blanking period of 3 months). The secondary endpoints were: 1. occurrence of pulmonary vein stenosis; 2. Occurrence of atrio-esophageal fistula or esophageal injury. Proof of PVI was determined by established criteria with a circumferential mapping catheter. Recurrence of AF was defined according to the HRS guidelines as single episode of documented AF>30 sec during follow-up off drugs. Follow-up was performed on a 3 monthly basis with 7 day Holter ECGs, questionnaire, and event recorder.

Results

1360/1403 PVs (97%) could be isolated with the balloon (1302/1403; 93% or with the balloon in combination with the use of large tip cryoablation catheter (Freezor MAX[®]) (58/1403; 4%). The median total procedure time was 170 (14-195) min, the median of fluoroscopy time was 40 (30-57) min. Ablation with the cryoballoon technique resulted in a maintenance of sinus rhythm without anti-arrhythmic drug treatment in 74% of pts with paroxysmal AF and in 38% of pts with persistent AF. The multivariate Cox-regression model revealed persistent AF and long axis of left atrium > 60mm to be independent predictors for documented recurrence. No PV narrowing occurred. Most frequent complication was a right phrenic nerve palsy observed during ablation at the right superior PV.

Conclusion

Complete isolation of the pulmonary veins with the double lumen cryoballoon is feasible. PVI can be achieved in the vast majority of patients with a limited single balloon approach. In the majority of pts with paroxysmal AF, cryoballoon ablation resulted in a stable sinus rhythm without any drug treatment. In our series, the cryoballoon ablation strategy was less effective in pts with persistent AF.