

Pulmonary vein isolation using Cryoballoon ablation versus RF ablation using ablation index following the CLOSE protocol: a Prospective Randomized Trial

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Abstract

Background The single procedure success rates of durable pulmonary vein isolation (PVI) for paroxysmal atrial fibrillation (AF) varies between 80 and 90 %. This prospective, randomized study investigated the efficacy of Cryoballoon PVI (CBA) versus pulmonary vein isolation with RF-energy following the CLOSE protocol in terms of single-procedure arrhythmia-free outcome and safety. **Methods and results** A total number of 150 patients undergoing de-novo catheter ablation for paroxysmal AF were randomized to two different treatment arms in a 1:1 fashion. In group-A patients, PVI was performed with the Cryoballoon (Articfront Balloon, Medtronic Inc). The ablation procedure in group B was performed with RF-energy (CARTO 3, Biosense Webster Thermocool STSF), following the CLOSE protocol. During a mean follow-up of 12 ± 4.5 months after a single procedure, 64 (85.33 %) patients of group A were free of arrhythmia recurrence versus 65 (86.67 %) patients in group B (p=ns). A total of 14 patients (group A: 7 (9.33 %) group B: 7 (9.33 %); p=ns) underwent a redo-procedure. No significant difference between both groups was observed in terms of PV recovery (group A: 4 (5.33 %) vs. group B: 3 (4 %); p=ns). Patients of group A showed significantly more AF recurrence during the blanking period of three months (group A: 14 (18.67 %) versus group B: 6 (8 %); p<0.05. **Conclusions** Cryoballoon PVI and PVI using ablation index following the CLOSE protocol are equally efficient in achieving durable PV-isolation. Cryoballoon ablation leads to significantly more AF recurrence during the blanking period.

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