Individualized Cryoballoon Energy pulmonary vein isolation guided by real Time pulmonary vein recordings, the randomized "ICE–T" Trial

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Background

Second generation cryoballoon (CB) pulmonary vein isolation (PVI) is highly effective in the treatment of paroxysmal atrial fibrillation (PAF). However, the ideal energy dosing strategy remains unclear. We aimed to investigate the clinical effect of an individualized energy dosing strategy based on time to PV isolation (TTI).

Purpose of the study

To prospectively study safety and efficacy of individualized PVI using the second-generation CB guided by real time PV recordings.

Methods

This single center, prospective, randomized pilot study utilized the simplified single big CB procedure. Two groups were defined: group A: acute PVI (TTI<75s) then *no* bonus freeze, group B: acute PVI then *one empiric* bonus freeze regardless of TTI. CB freeze duration was set to 240s. The primary endpoint was single procedure sinus rhythm (SR) after 12 months (blanking period: 3 months). Secondary endpoints included procedural data, complications and biomarker release.

Results

Between May 2013 and January 2015 a total of 100 PAF patients were randomized. Baseline patients` characteristics were not different between both groups. The primary endpoint was identical in both groups (82% vs. 82%). Total procedure time and fluoroscopy exposure was significantly shorter in group A vs. B (70±20min vs. 89±21min, p<0.001) (10.6min±3.9 vs. 12.7±5.5min, p=0.03). In the overall population, average TTI was significantly shorter in patients without recurrent atrial tachyarryhtmia (ATa). In multivariate analysis, a short TTI was the only independent predictor of freedom from recurrent ATa. In trend, more complications occurred in group B vs. A (persistent phrenic nerve injury (PNI): n=1 vs. n=0) (transient PNI: n=5, vs. n=2) (esophageal lesions: n=3 vs. n=1). No death, stroke, cardiac tamponade or AE fistula occurred. Postablation Troponin T levels (ng/l) were not different (group B: 1219±509 vs. goup A: 1035±402 (p=ns) whereas increased LDH release (U/l) was observed in group B: 282±57 vs. 259±47 (p=0.038).

Conclusion

The individualized CB PVI strategy allows faster AF ablation without impacting the favorable clinical outcome. A short TTI appears to predict freedom from recurrent ATa.