Novel cryoballoon ablation system for single shot pulmonary vein isolation: The prospective ICE-AGE-X Study

Tilz RRT; Meyer-Saraei RMS; Vogler JV.; Fink TF.; Sciacca VS.; Kirstein BK.; Delgado Lopez LDL; Phan HLP; Traub AT.; Keelani AK.; Kuck KHK; Eitel CE.; Heeger CH.

University of Luebeck, Medical clinic II, Luebeck, Germany

Funding Acknowledgements: Type of funding sources: None.

Background: The arctic front cryoballon (AF-CB) provides effective and durable pulmonary vein isolation (PVI) associated with encouraging clinical outcome data. The POLARx cryoballoon incorporates unique features which may translate into improved efficacy and safety.

Purpose: To assess efficacy and safety of the novel POLARx cryoballoon in comparison to the fourth generation arctic front cryoballon (AF-CB4).

Methods: Twenty-five consecutive patients with paroxysmal or persistent atrial fibrillation (AF) were prospectively enrolled, underwent POLARx based PVI (POLARx group) and were compared to 25 consecutive patients treated with the fourth generation AF-CB (AF-CB4 group).

Results: A total of 100 (POLARx) and 97 (AF-CB4) pulmonary veins (PV) were identified and all PVs were successfully isolated utilizing the POLARx and AF-CB4, respectively. A significant difference regarding the mean minimal cryoballoon temperatures reached using the AF-CB4 and POLARx (-50 ± 6°C vs. -57 ± 7°C, $p = 0.004$) was observed. Real-time PVI was visualized in 81% of POLARx patients and 42% of AF-CB4 patients ($p < 0.001$). Despite a certain learning curve utilizing the POLARx a trend towards shorter median procedure time (POLARx: 45 (39, 53) minutes vs. AF-CB4: 55 (50, 60) minutes ($p = 0.062$) was found. No differences were observed for periprocedural complications.

Conclusions: The novel POLARx showed similar safety and efficacy compared to the AF-CB4. A higher rate of real-time electrical PV recordings and significantly lower balloon temperatures were observed using the POLARx as compared to AF-CB4.