Novel cryo-balloon ablation technology for pulmonary vein isolation in patients with atrial fibrillation: preliminary experience from a multicenter clinical practice

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Background: Complete electrical pulmonary vein isolation (PVI) by cryo-balloon approach is a well-established ablation strategy of atrial fibrillation (AF). Recently, a new cryoablation system (POLARx) with unique features has been made available for clinical use. To date, no data exist on procedural characteristics of this system in a multicentric clinical practice.

Purpose: We aimed to characterize the initial experience of this technology in the Italian clinical practice.

Methods: Consecutive patients (pts) undergoing AF ablation from the CHARISMA registry at 5 Italian centres were included. Protocol-directed cryoablation was delivered for 180 sec or 240 sec according to operator's preference for isolation achieved in ≤60 sec, or 240 sec if isolation occurred >60 sec or when time to isolation (TTI) was not available. The ablation endpoint was PV isolation as assessed by entrance and exit block.

Results: Two-hundred sixty-two cryoapplications from 49 pts (194 PVs) were analyzed. PVI was achieved with cryoablation only in all pts. The mean number of freeze applications per pt was 5.3 ± 1.5 (1.3 ± 0.6 for LIPV, LSPV and RSPV, 1.6 ± 1.3 for RIPV), with 143 (73.7%) PVs treated in a single-shot fashion (38, 19.6% with 2 shots; 13, 6.7% with more than 2 shots). Sixteen (33%) pts were treated with a single freeze to each of the PVs. The mean nadir temperature was -55.5 ± 6.9 °C and was colder than -50°C in 83% of the PVs. TTI information was evaluable in 120 (46%) cryoapplications with a median TTI of 47 [32-75] sec (median temperature at TTI = -49 [-53 to -42] °C). The mean time to target -40 °C (TTT) was 30.1 ± 6.9 sec with a TTT < 60 sec achieved in 99.2% of the cryoapplications; the mean thaw time to 0 °C was 18.6 ± 5.8 sec (thaw time >15 sec in 70.3% of the cryoapplications). The mean PV occlusion grade (rank 1-4) was 3.6 ± 0.6 (grade 2 in 5.2% of the cases, grade 3 in 25.6% and grade 4 in 69.2%). No complications were observed at 30 days post-procedure.

Conclusion: In this first multicentric experience in a clinical practice setting, the novel cryo-balloon system proved to be safe and effective and resulted in a high proportion of successful single-freeze isolation. Cooling parameters seem to be slightly different from reference cryo-balloon technology.