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Novel temperature guided irrigated ablation catheter: reproducibility of procedural efficiencies and acute success to isolate the pulmonary veins from two multicenter, feasibility studies

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Background/Introduction: The novel catheter with 6 thermocouples for real-time temperature monitoring during irrigated radiofrequency ablation was designed to potentially enhance safety and effectiveness of the Smart Touch Surround Flow (STSF) catheter by incorporating real-time temperature sensing. A supplementary, novel algorithm was developed to modulate power to maintain target temperature during high power/short duration ablation (90W, 4s).

Purpose: This sub-analysis was performed to examine consistency and reproducibility of the procedural efficiencies and acute success of the novel catheter with optimized temperature control and microelectrodes in treating paroxysmal atrial fibrillation (PAF) across multiple sites from two initial feasibility studies, in standard (QMODE) and high power/short duration (QMODE+) temperature-control ablation modes.

Methods: The QDOT-MICRO (QMODE, NCT02944968; N=42) and QDOT-FAST (QMODE+, NCT03459196; N=52) studies were both prospective, non-randomized multi-center, clinical investigations completed across 6 and 7 centers, respectively, in Europe. Procedural efficiencies and acute success (PVI via entrance block) was examined across sites within the study.

Results: In the QDOT-MICRO study, median procedure time (105–155 min), RF ablation time (27.7–39.5 min), and fluoroscopy times (2.2–8 min) during QMODE ablation were similar across the 6 sites. In QMODE+ ablation, median procedure time, RF ablation time, and fluoroscopy times all fall within (84–134 min), (4.8–9.7 min) and (1.1–9.6 min), respectively, across the 7 sites. Fluid delivery by the study catheter was low in both studies: QDOT-MICRO 547±278mL (mean ± SD); QDOT-FAST 382±299. mL (mean ± SD); which is 39.1 and 57.4% lower, respectively, than reported in the SMART SF trial. Esophageal temperature probe was used in the majority of patients (30/42 for QDOT MICRO and 51/52 for QDOT-FAST). Acute PVI was successful in 100% of patients in both studies with no deaths or unanticipated AEs.

Conclusion(s): In both feasibility studies, procedural efficiencies were reproducible across study sites in both QMODE and QMODE+, with 100% acute success and good safety outcomes. Efficiencies are likely to improve with further experience. These results need to be confirmed in larger trials.