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Toccata Multi-Center Clinical Study Using Irrigated Ablation Catheter with Integrated Contact Force Sensor: First Results

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Introduction: During RF irrigated ablation, contact force (CF) is a significant parameter for effective and safe lesion creation. TOCCATA multi-center clinical study evaluates a newly designed open irrigated RF ablation catheter (TactiCath®).

Methods: TOCCATA is a prospective, non-randomized, dual-arm, multi-centre study to evaluate safety and performance of the TactiCath® (Endosense, Geneva, Switzerland) open irrigated RF ablation catheter with integrated force sensor as the study device (SD). Study arms: 1) Right SVT group (RSVT) of 40 patients (pts) with indications of atrial flutter (AFl), AVNRT and WPW, 2) AF group for 30 pts with PAF. Primary endpoint (PrE) is procedure or device related serious Adverse events (SAE) till 7 days follow-up (FU) (RSVT) or 3 months (M) FU (AF). SD was evaluated by operators by rating 13 questions on a 1 (poor)-5 (excellent) scale.

Results: To date, 28 pts were treated with SD.
RSVT: 20pts, 13 male, age 55±14y. Indication was 14 AFl, 5 AVNRT, 2 WPW with underlying disease: hypertension (9), coronary heart disease (3), valvular (2), other arrhythmia (Arrhy) (3), other (2). Target Arrhy was eliminated in 17 pts with the SD, 3 AFl were terminated with a non-SD. Ablation time was 36±32 min (AFl) and 27±17min (WPW + AVNRT). All patients had 7 day FU and 1 SAE non-SD related was reported. Average CF during mapping was 12.6±12.0g and during ablation 14.9±13.8g.
AF: 7 pts, 5 male, age 54±7.5y. Four pts had concomitant Afl. All Pvs were isolated successfully with SD. Ablation time was 86±33 min. One tamponade occurred. Average CF during mapping was 14.9±13.8g and during ablation 16.2±13.0g.
Combined for both groups; operator rated SD performance for steerability was 3.9 ±0.7, for force sensing features 4.0 ±1.0.

Conclusions: First results of TOCCATA indicate that TactiCath SD is an effective device for treatment of RSVT and AF, providing reliable real time CF information during mapping and ablation. Full primary endpoint results will be communicated at full enrolment and FU.

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