

Toccatà Multi-center Clinical Study: Irrigated RF Ablation Catheter With An Integrated Contact Force Sensor - Long-term Results

Boris Schmidt, MD*, Vivek Y. Reddy, MD**, Andrea Natale, MD***, Dipen Shah, MD****, Nadir Saoudi, MD*****, Claudia Herrera, MD*****, Gerhard Hindricks, MD, PhD*****, Pierre Jais, MD*****, Aude Yulzari*****, Karl-Heinz Kuck, MD, FHRS* and Hendrik Lambert, PhD*****.

Asklepios Klinik St. Georg, Hamburg, Germany*, Mount Sinai School of Medicine, New York City, NY**, Texas Cardiac Arrhythmia Institute, Austin, TX***, Hôpital Universitaire de Genève, Geneva, Switzerland****, Centre Hospitalier Princesse Grace, Monaco, Monaco****, Herzzentrum Bad Krozingen, Bad Krozingen, Germany*****, Herzzentrum Leipzig, Leipzig, Germany*****, Hôpital Haut-Lévêque, Bordeaux, France*****, Endosense SA, Geneva, Switzerland*****

Introduction: Contact force (CF) during catheter ablation is a significant parameter for effective and safe lesion creation. TOCCATA is the first multi-center trial to evaluate the clinical use of real-time tip-to-tissue CF during RF catheter ablation (TactiCath™, Endosense, Switzerland).

Methods: The prospective study had two groups: A) right SVT (RSVT) including Atrial Flutter (AFL), AVNRT and WPW; B) Paroxysmal AF (PAF) indication. CF information was recorded during the entire intervention and related to catheter position during ablation. Serious adverse events (SAE) were analyzed for primary study endpoints at 7 day FU for A and at 3 months for B. Chronic success was assessed by Holter (24h for RSVT and 7-day for AF) at 6 and 12 months post intervention. Re-intervention at any time was counted as a failure.

Results: 76 pts were treated at 8 centers by 21 operators: 42 RSVT (aged 57+/-13 y) and 34 PAF (aged, 60+/-8 y). Target arrhythmia was fully treated with study device in 73 pts (93% RSVT, 100% AF). In 3 pts, isolation line for AFL was completed with non-study device. 1 procedure related SAE (2%) occurred in group A (sinus bradycardia). In group B, 1 device related SAE (3%, tamponade) and 3 procedure related SAE (9%) were reported (stroke, transient sinus arrest, bleeding at groin). 297 ablations were given in A and 1028 in B. CF at ablation showed very high inter- and intra-operator variability. Average CF in A was 13+/-12g (range 1-113g) and in B 17+/- 13g (range 1-163g). Variability of forces applied amongst the 21 operators was significant in AFL ($p < 0.0001$) and in AF ($p < 0.0001$). At 6 months, 33 (85%) RSVT pts and 17 (51%) AF pts were free of arrhythmia. Retreatment was needed for 3 pts in group A and for 5 AF pts. An inverse trend between CF applied at ablation procedures and gaps in PV isolation lines at re-intervention was identified.

Conclusions: Toccatà study demonstrated safe and effective use of TactiCath RF ablation catheter with CF sensor. Real-time CF information showed high variability of CFs during ablation, suggesting room for safer and more effective RF treatment in the future. Full study 12 MFU will be completed in February 2010.