SMART SF STUDY RESULTS

OBJECTIVE

To evaluate the outcomes of radiofrequency ablation with the THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module in patients with symptomatic, drug-refractory paroxysmal atrial fibrillation.

METHODOLOGY

DESIGN: SINGLE ARM. OPEN LABEL PROSPECTIVE, MULTICENTER, NONRANDOMIZED CLINICAL STUDY

165 — **SYMPTOMATIC, DRUG-REFRACTORY PAROXYSMAL AF PATIENTS**
(mean age 62.7 yrs; male 57.9%, Caucasian 97%)

17 — **US CENTERS**

INTERVENTIONS

Circumferential PVI with THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module

OUTCOMES

ACUTE EFFECTIVENESS
(Confirmation of entrance block in all PVs)

ACUTE SAFETY
(Primary AEs 1-week postablation)[a]

12-MONTH EFFECTIVENESS
(Freedom from documented AF/AT/AFL based on electrocardiographic data)[b]

RESULTS

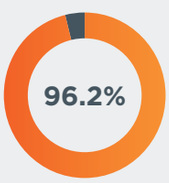
PROCEDURAL EFFICIENCY

181 min — Procedure Time

104 min — Ablation Time

19 min — Fluoroscopy Time

ACUTE EFFECTIVENESS



ACUTE SAFETY

2.5% — PRIMARY AE RATE

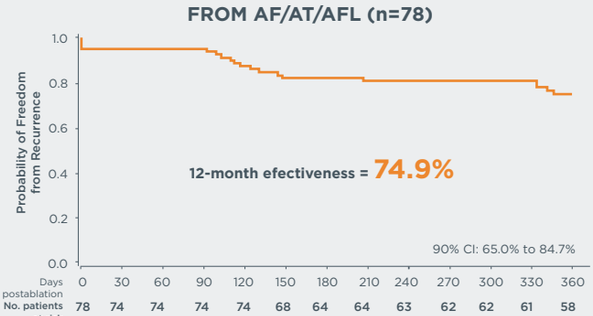
0 — Cases of deaths, atrioesophageal fistula, myocardial infarction, stroke, cerebrovascular accident, diaphragmatic paralysis, pneumothorax

1 — Case each thromboembolism, transient ischaemic attack

0 — Cases of heart block, PV stenosis, pulmonary edema, peridarditis, major vascular access complication/bleeding

2 — Cases of cardiac tamponade/performation

KAPLAN-MEIER 12-MONTH FREEDOM FROM AF/AT/AFL (n=78)



FACTORS ASSOCIATED WITH 12-MONTH FAILURE

Class I AAD history
($P \leq 0.05$)

Female sex
(OR=3, 95% CI: 0.79 to 11.27)

Additional month of AF history increased failure odds by 1%

CONCLUSION

The SMART SF study demonstrated the safety and effectiveness of ablation with the THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module in patients with symptomatic, drug-refractory paroxysmal atrial fibrillation ablation.

AAD, antiarrhythmic drug; AE, adverse events; AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; PV, pulmonary vein; PVI, pulmonary vein isolation.

[a] Incidences of atrioesophageal fistula or PV stenosis reported >1 week postablation were also considered primary adverse events.

[b] Effectiveness evaluation was based on electrocardiogram, telemetry strip, and 48-h Holter monitor collected at the 6-to-9- and 12-month visits. 12-month effectiveness success also required freedom from acute procedural failures and freedom from repeat ablation.

THERMOCOOL® Navigation Catheters are indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® 3 Systems (excluding NAVISTAR™ RMT THERMOCOOL™ Catheter).
The CARTO VISITAG™ Module provides access to data collected during the application of RF energy. The data does not indicate the effectiveness of RF energy application. CARTO VISITAG™ Module settings are user defined based on the user's clinical experience and medical judgment. Biosense Webster, Inc. does not recommend any settings for the CARTO VISITAG™ Module.
Important information: Prior to use, refer to the instructions for use supplied with the device for indications, contraindications, side effects, warnings and precautions. Caution: US law restricts this device to sale by or on the order of a physician.

Chinitz LA, Melby DP, Marchlinski FE, et al. Safety and efficiency of porous-tip contact-force catheter for drug-refractory symptomatic paroxysmal atrial fibrillation ablation: Results from the SMART SF trial. *Europace*. 2018;20(FI_3):f392-f400.

Natale A, Monir G, Patel AM, et al. Long-term safety and effectiveness of paroxysmal atrial fibrillation ablation using a porous tip contact force-sensing catheter from the SMART SF trial. J *Interv Card Electrophysiol*. 2020 May 27. doi: 10.1007/s10840-020-00780-4. Online ahead of print.

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