

SUMMARY

Gains in Paroxysmal Atrial Fibrillation Ablation Using a Standardized Workflow to Optimize Contact Force Technologies

Osorio J, Hunter TD, Bubien RS, Rajendra A, Arciniegas J, Morales G

J Atr Fibrillation. 2018;11(4):2097

STUDY QUESTION

How do the procedural efficiency and long-term clinical outcomes obtained with a real-world standardized workflow for paroxysmal atrial fibrillation (PAF) ablation with the THERMOCOOL SMARTTOUCH® Catheter (ST) and the CARTO VISITAG™ Module (VS) compare with results of other technologies?

METHODOLOGY

DESIGN: SINGLE CENTER, RETROSPECTIVE, REAL-WORLD COHORT STUDY IN THE UNITED STATES



32 Patients in THERMOCOOL™ SF Catheter (SF) cohort

232 Patients in ST cohort

59 Patients in cryoablation (CA) cohort

ABLATION SETTINGS:

Standardized ST workflow

VS setting: location stability 2.5 mm max range; time ≥ 4 sec, force over time ≥ 10 g, $\geq 50\%$ of time

Power: 40 W

Contact force target: 10–20 g

OUTCOMES

PRIMARY OUTCOME



Overall procedure and fluoroscopy times

OTHER OUTCOMES



Safety



Freedom from recurrent atrial arrhythmia (AF, atrial tachycardia, atrial flutter) at 12 months

RESULTS

ABLATION WITH THE ST CATHETER WITH A HIGHLY STANDARDIZED VS ABLATION WORKFLOW IS ASSOCIATED WITH

The shortest procedure and fluoroscopy times, the lowest radiation exposure, and the lowest reablation rates among the 3 cohorts.



- Procedure time (min): **ST**, 81.9; **SF**, 92.2; **CA**, 93.6
- Fluoroscopy time (min): **ST**, 0.2; **SF**, 1.5; **CA**, 12.4
- Radiation dose (mGy): **ST**, 9.5; **SF**, 247.7; **CA**, 676.4
- Product limit survival estimates of repeat procedures at 1 year (%): **ST**, 6.5; **SF**, 15.6; **CA**, 13.7

Similar safety profile



Acute procedure related serious complications (%):
ST, 3.9; **SF**, 6.3; **CA**, 1.7

CONCLUSION

PAF ablation using a **standardized ST and VS workflow** resulted in **low procedure and fluoroscopy times, minimal fluoroscopy exposure**, and long-term **freedom from reablations**.

OBJECTIVE

To evaluate a real-world standardized workflow for PAF ablation with the THERMOCOOL SMARTTOUCH® Catheter and the CARTO VISITAG™ Module to enhance procedural efficiency and long-term clinical outcomes compared with prior technologies.

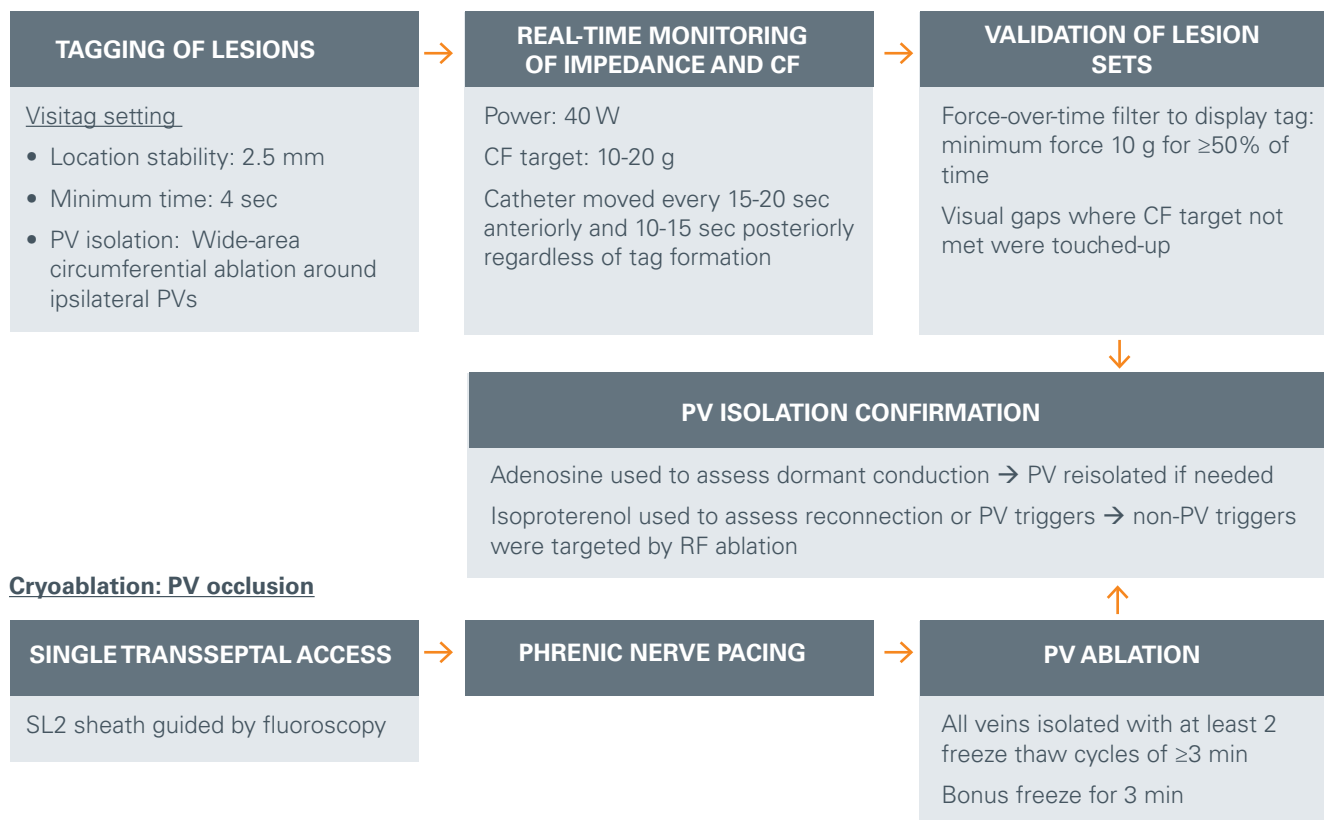
METHODS

Experimental Design

STUDY DESIGN	Single center, retrospective, real-world cohort study
STUDY PERIOD AND LOCATION	<ul style="list-style-type: none"> July 2013 to June 2016 High-volume catheter ablation center in the United States (2 operators)
SAMPLE SIZE	<ul style="list-style-type: none"> 323 patients with de novo ablations for PAF
INTERVENTIONS	<ul style="list-style-type: none"> RF ablation <ul style="list-style-type: none"> THERMOCOOL™ SF Catheter guided by CARTO VISITAG™ Module (July 2013 to March 2014) THERMOCOOL SMARTTOUCH® Catheter guided by CARTO VISITAG™ Module (April 2014 onward) Cryoablation <ul style="list-style-type: none"> Arctic Front Advance™ cardiac cryoablation catheter
PATIENT FOLLOW-UP	<ul style="list-style-type: none"> 3, 6, and 12 months postablation
PRIMARY ENDPOINT	<ul style="list-style-type: none"> Total procedure time Fluoroscopy duration and dose
OTHER OUTCOMES	<ul style="list-style-type: none"> Serious procedure related complications Freedom from repeat ablation Freedom from recurrent atrial arrhythmia (AF/AT/AFL) 12-months postablation

Ablation Procedure

ST/SF



AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; CF, contact force; PAF, paroxysmal atrial fibrillation; PV, pulmonary vein; RF, radiofrequency; SF, THERMOCOOL™ SF Catheter; ST, THERMOCOOL SMARTTOUCH® Catheter.

RESULTS



Demographics

Baseline patient characteristics were similar across all 3 cohorts.

PARAMETER	SF (n=32)	ST (n=232)	CA (n=59)
Age, mean (SD), y	63.8 (11.5)	62.9 (10.9)	63.7 (12.6)
Male, No. (%)	17 (53.1)	128 (55.2)	16 (27.1)
Left atrial size, mean (SD), cm	3.8 (0.7)	3.9 (0.8)	3.9 (0.7)
LVEF, No. (%)			
≤44%	5 (15.6)	23 (9.9)	1 (1.7)
45–54%	4 (12.5)	25 (10.8)	9 (15.3)
≥55%	15 (46.9)	116 (50.0)	35 (59.3)
Unknown	8 (25.5)	68 (29.3)	14 (23.7)
CHA ₂ DS ₂ -VASc Score, No. (%)			
0	0 (0.0)	17 (7.3)	2 (3.4)
1	6 (18.8)	52 (22.4)	11 (18.6)
2	9 (28.1)	58 (25.0)	11 (18.6)
3	6 (18.8)	49 (21.1)	10 (17.0)
4	8 (25.0)	30 (12.9)	13 (22.0)
5	1 (3.1)	18 (7.8)	6 (10.2)
6	2 (6.3)	5 (2.2)	5 (8.5)
7	0 (0.0)	3 (1.3)	1 (1.7)
CHA ₂ DS ₂ -VASc Score, mean	1.4	1.3	1.4
Preablation medication, No. (%)			
Antiarrhythmic drugs	23 (71.9)	145 (62.5)	50 (84.8)
β-blockers	18 (56.3)	131 (56.5)	24 (40.7)



Safety

Acute procedure complications were infrequent and similar between cohorts.

SF	1 - Pericardial effusion (treatment required) 1 - Stroke (with complete resolution)
ST	6 - Effusion or cardiac tamponade 1 - Vascular access requiring blood transfusion 2 - Transient cardiovascular event symptoms (treatment not required)
CA	1 - Pericardial effusion (treatment required)

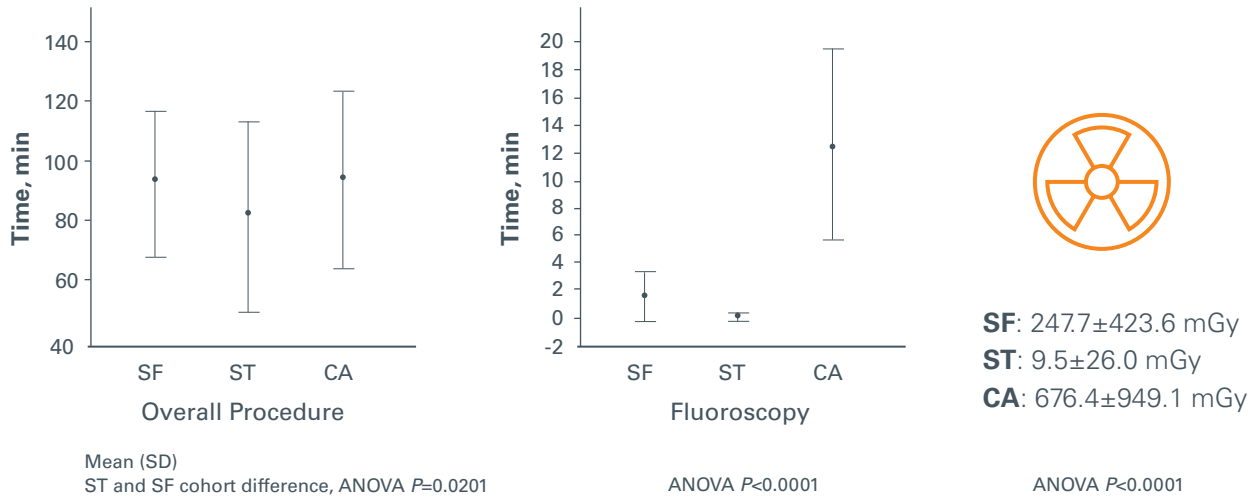
$P=0.53$

CA, cryoablation; CHA₂DS₂-VASc, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke (or transient ischemic attack/thromboembolism), vascular disease, age 65–74 years, sex category; LVEF, left ventricular ejection fraction; PAF, paroxysmal atrial fibrillation; SD, standard deviation; SF, THERMOCOOL™ SF Catheter; ST, THERMOCOOL SMARTTOUCH® Catheter.

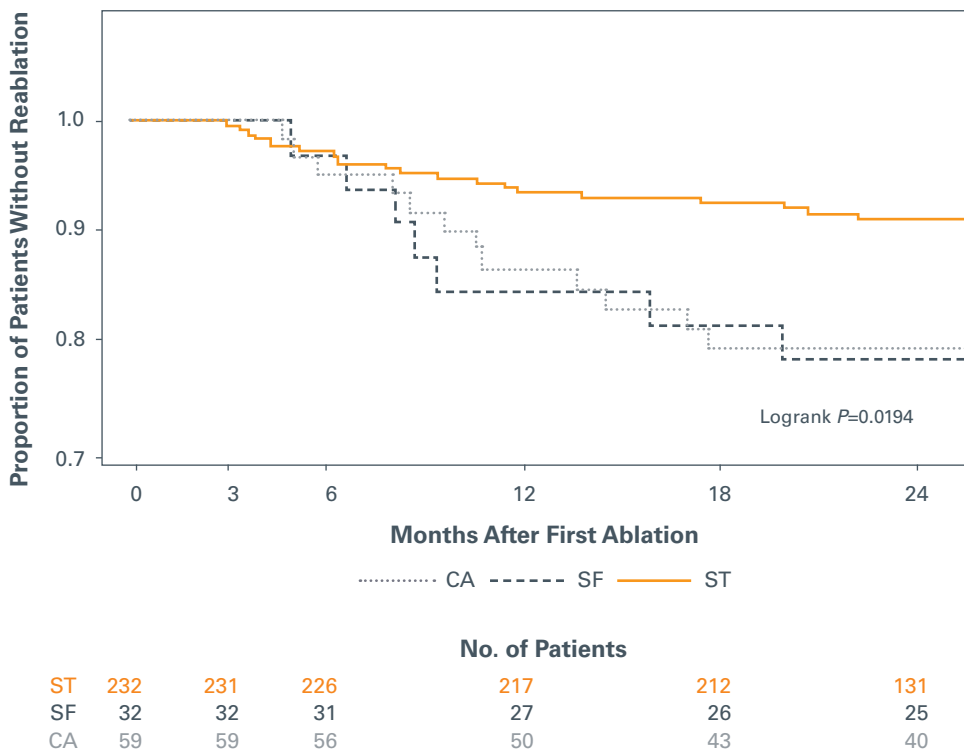
RESULTS

Procedural Efficiency

Mean procedure times were similar between the SF and CA cohorts and 10 minutes shorter with ST, leading to significant reductions in fluoroscopy time and radiation dose.



Kaplan-Meier survival analysis showed that ST ablation was associated with a significant reduction in repeat procedure rates.



This figure has been adapted from the original article.

CONCLUSION

Atrial fibrillation ablation using a standardized THERMOCOOL SMARTTOUCH® Catheter and CARTO VISITAG™ Module workflow resulted in low procedure and fluoroscopy times, minimum radiation exposure, and higher long-term freedom from reablations in patients with paroxysmal atrial fibrillation, without compromising procedural safety.

REFERENCES

Osorio J, Hunter TD, Bubien RS, Rajendra A, Arciniegas J, Morales G. Gains in paroxysmal atrial fibrillation ablation using a standardized workflow to optimize contact force technologies. *J Atr Fibrillation*. 2018;11(4):2097.

Third party trademarks used herein are trademarks of their respective owners.

Important information: Prior to use, refer to the instructions for use supplied with the device for indications, contraindications, side effects, warnings and precautions.

This publication is not intended for distribution outside of the EMEA region.

EC Representative | Biosense Webster
A Division of Johnson & Johnson Medical NV/SA
Leonardo da Vincilaan 15 | 1831 Diegem, Belgium
Tel: +32-2-7463-401 | Fax: +32-2-7463-403

For additional medical information request, please contact: bwimedinfo@its.jnj.com