

Summary

Persistent Atrial Fibrillation Ablation With Contact Force Sensing Catheter: The Prospective Multicenter PRECEPT Trial^{1,2}

1. Mansour M, Calkins H, Osorio J, Pollak SJ, Melby D, Marchlinski FE, Athill CA, Delaughter C, Patel AM, Gentlesk PJ, DeVille B, Macle L, Ellenbogen KA, Dukkipati SR, Reddy VY, Natale A. *JACC Clin Electrophysiol.* 2020;6(8):958-969.
2. PRECEPT IDE G140102.

STUDY QUESTION

What are the safety and effectiveness of radiofrequency ablation in patients with persistent atrial fibrillation treated with the THERMOCOOL SMARTTOUCH® SF Catheter?

METHODOLOGY

DESIGN:

SINGLE ARM, PROSPECTIVE, MULTICENTER, NONRANDOMIZED CLINICAL STUDY



27
CENTERS

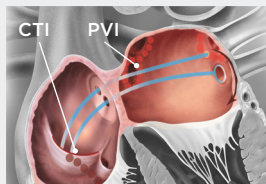
381
PATIENTS

with documented persistent atrial fibrillation <1 year

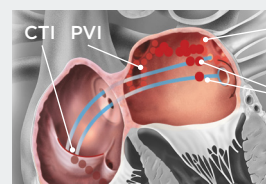
INTERVENTIONS

THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module

Tailored Ablation Strategy^a



PVI Only



or

PVI+

Roof Line

Posterior wall isolation/
substrate modification

OUTCOMES



PRIMARY EFFECTIVENESS
(Freedom from documented AF/AT/AFL and 5 failure modes^b at 15 months)



CLINICAL SUCCESS
(Freedom from symptomatic AF/AT/AFL at 15 months)



PRIMARY ADVERSE EVENTS
(within 7 days of the initial and repeat ablation procedures^c)

RESULTS

TAILORED PVI-ONLY/PVI+ PERSISTENT ATRIAL FIBRILLATION ABLATION WITH THERMOCOOL SMARTTOUCH® SF CATHETER WITH CARTO VISITAG™ MODULE IS ASSOCIATED WITH

61% Primary effectiveness at 15 months

4.7% Rate of primary adverse events at 15 months

80% Clinical success at 15 months

86% Freedom from repeat ablation at 15 months

CONCLUSION

The PRECEPT study demonstrated the clinical safety and effectiveness of persistent atrial fibrillation ablation using contemporary contact-force sensing technologies.

AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; CFAE, complex fractionated atrial electrograms; CTI, cavotricuspid isthmus; PV, pulmonary vein; PVI, pulmonary vein isolation. PVI+, PVI with additional non-PV target ablations allowed per operator's discretion.

^a Substrate modification was allowed in the PVI+ strategy if the patient could not be returned to sinus rhythm by the end of the procedure; this included roof line, non-PV triggers and CFAE.

^b Failure modes included: acute procedural failure, use of nonstudy catheter, repeat procedures, use of new/higher dose antiarrhythmic drug, and surgical ablation.

^c Primary adverse events included: death, atrioesophageal fistula, cardiac tamponade/perforation, myocardial infarction, stroke/cerebrovascular accident, thromboembolism, transient ischemic attack, diaphragmatic paralysis, pneumothorax, heart block, PV stenosis, pulmonary edema, pericarditis, and major vascular access complication or bleeding. PV stenosis and atrioesophageal fistulas occurring more than 7 days after the index procedure were also considered primary adverse events.

¹ Mansour M, Calkins H, Osorio J, et al. Persistent atrial fibrillation ablation with a contact force sensing catheter: the prospective multicenter PRECEPT trial. *JACC Clin Electrophysiol.* 2020;6(8):958-969.

² PRECEPT IDE G140102.

OBJECTIVE

To evaluate the safety and effectiveness of catheter ablation in patients with persistent atrial fibrillation using the contact-force sensing THERMOCOOL SMARTTOUCH® SF Catheter with CARTO VISITAG™ Module.

METHODS

Experimental Design

STUDY DESIGN	Prospective, multicenter, nonrandomized clinical study
STUDY PERIOD AND LOCATION	<ul style="list-style-type: none"> • June 2016 to June 2019 • 27 centers in the United States and Canada
SAMPLE SIZE	<ul style="list-style-type: none"> • 381 patients ≥18 yrs old • Documented persistent atrial fibrillation <1 yr • Nonresponsive or intolerant to ≥ 1 AAD (Class I/III)
PATIENT FOLLOW-UP	Phone follow-up: 7 days Clinical follow-up: 1, 3, 6, 9, 12, and 15 months
PRIMARY ENDPOINT	<ul style="list-style-type: none"> • Primary effectiveness • Incidence of any PAEs occurring within 7 days of the initial and repeat ablation procedures^a
OTHER OUTCOMES	<ul style="list-style-type: none"> • Acute procedural success (entrance block in all PVs) • Clinical success

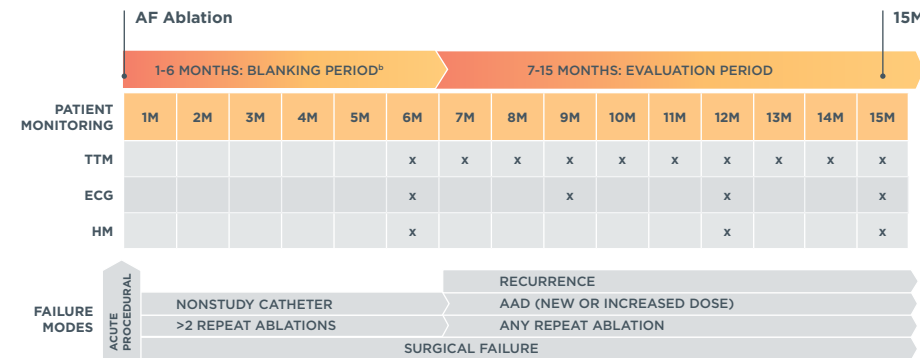
Tailored Ablation Approach

- Isolation of all PVs was required for all patients (PVI only). Additional ablations were allowed (PVI+) per operator's discretion.
- Right atrial cavotricuspid isthmus linear ablation was required in cases of documented typical atrial flutter.

Recommended CARTO VISITAG™ Module Settings

- Location stability: 3 mm
- Minimum time: 3 s
- Force-over-time filter: <50%

Study Design



Primary effectiveness

Freedom from documented AF/AT/AFL recurrence ≥30 s and freedom from prespecified failure modes (see gray bars)

Clinical Success

Freedom from documented **symptomatic** AF/AT/AFL recurrence ≥30 s

AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; CTI, cavotricuspid isthmus; ECG, electrocardiogram; HM, Holter monitoring; PAEs, primary adverse events; PV, pulmonary vein; PVI, pulmonary vein isolation; PVI+, PVI with additional non-PV target ablations allowed per operator's discretion; RF, radiofrequency; TTM, transtelephonic monitoring.

^a PAEs included: death, atrioesophageal fistula, cardiac tamponade/perforation, myocardial infarction, stroke/cerebrovascular accident, thromboembolism, transient ischemic attack, diaphragmatic paralysis, pneumothorax, heart block, PV stenosis, pulmonary edema, pericarditis, and major vascular access complication or bleeding. PV stenosis and atrioesophageal fistulas occurring more than 7 days after the index procedure were also considered PAEs.

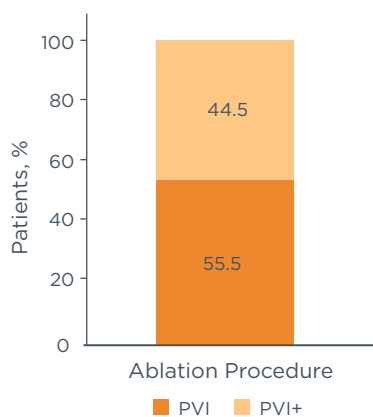
^b The blanking period consisted of a 3-month medication adjustment period followed by a 3-month therapy consolidation period. All symptomatic cardiac episodes were recorded and transmitted via TTM at the time of the event.

RESULTS

Demographics and Procedural Efficiency

PARAMETER	SAFETY POPULATION (n=348)
Age, mean (SD), y	65.4 (8.7)
Male, No. (%)	246 (70.7)
CHA ₂ DS ₂ -VASc score, mean (SD)	2.3 (1.5)
Left atrial dimension, mean (SD), mm	42.4 (5.1)
Left ventricular ejection fraction, mean (SD), %	56.2 (7.2)
Medical history, No. (%)	
• Hypertension	238 (68.4)
• Obstructive sleep apnea	134 (38.5)
• Coronary disease	77 (22.1)
• Symptomatic PsAF duration, mean (SD), month	15.5 (30.2)

Procedural Characteristics (Safety Population, n=348)



Time, mean (SD), minutes

Total procedure	178.0 (71.0)
Ablation	107.7 (48.6)
RF application	55.6 (23.0)
Mapping	15.3 (17.5)
Fluoroscopy	15.3 (16.6)

Safety

The overall rate of primary adverse events was 4.7%, similar to paroxysmal atrial fibrillation studies.^{3,4}

0 — Incidence of death, atriopharyngeal fistula, myocardial infarction, thromboembolism, pneumothorax, heart block, pulmonary vein stenosis, transient ischemic attack

1 — Case each of cerebrovascular accident/stroke, diaphragmatic paralysis

2 — Pericarditis cases

3 — Major vascular access complication/bleeding cases

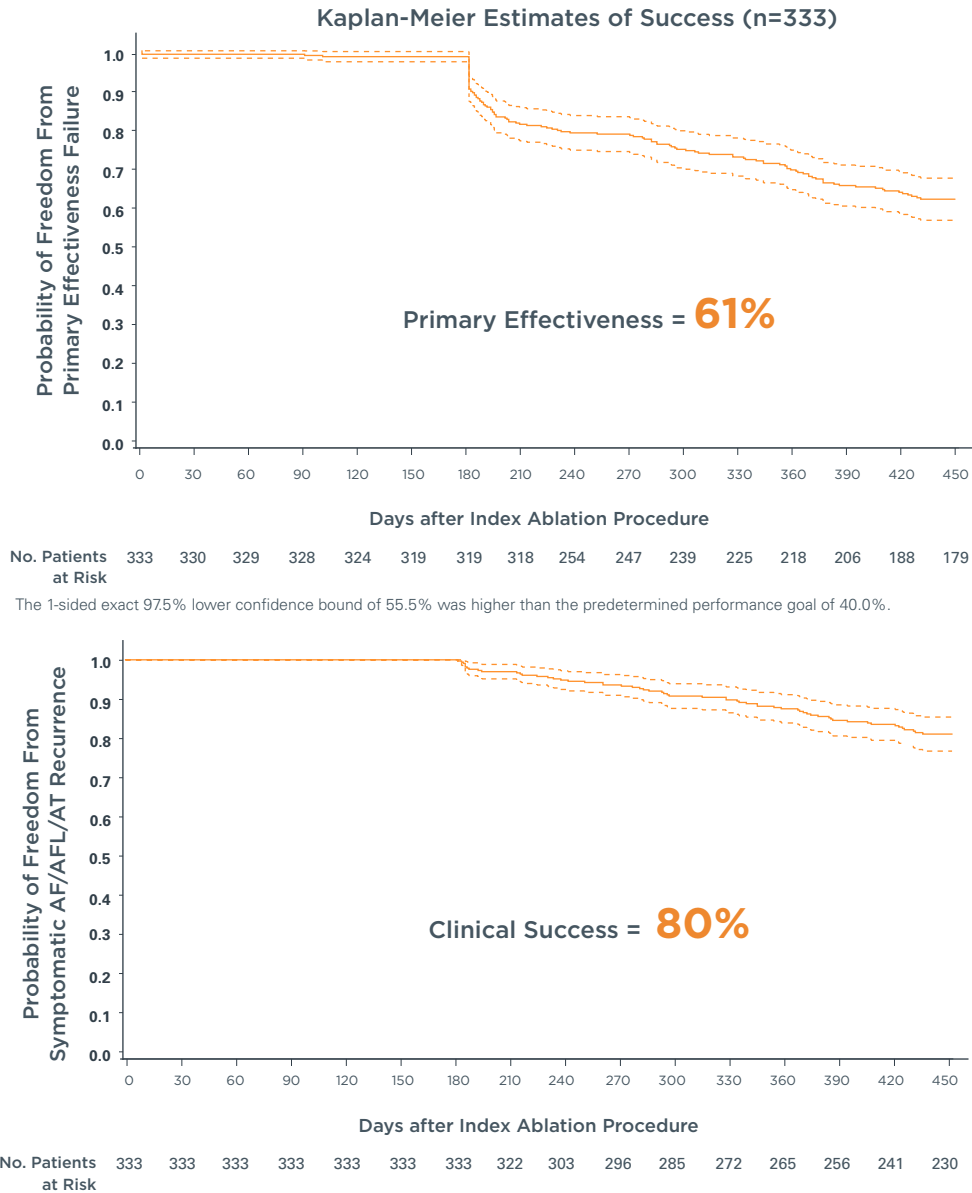
5 — Cases each of cardiac tamponade, pulmonary edema (respiratory insufficiency)

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; PVI, pulmonary vein isolation; PsAF, persistent atrial fibrillation; RF, radiofrequency.

RESULTS

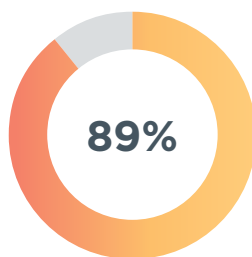
Effectiveness

Utilization of PVI only or PVI+ tailored ablation strategy results in high clinical effectiveness in a broad group of persistent atrial fibrillation patients.

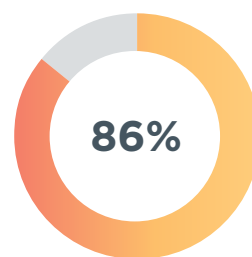


- Kaplan Meier estimates of single procedure freedom from documented AF/AT/AFL recurrence was 64% by all 3 study arrhythmia monitoring methods.

Repeat Ablation



12-Month Freedom From Repeat Ablation



15-Month Freedom From Repeat Ablation

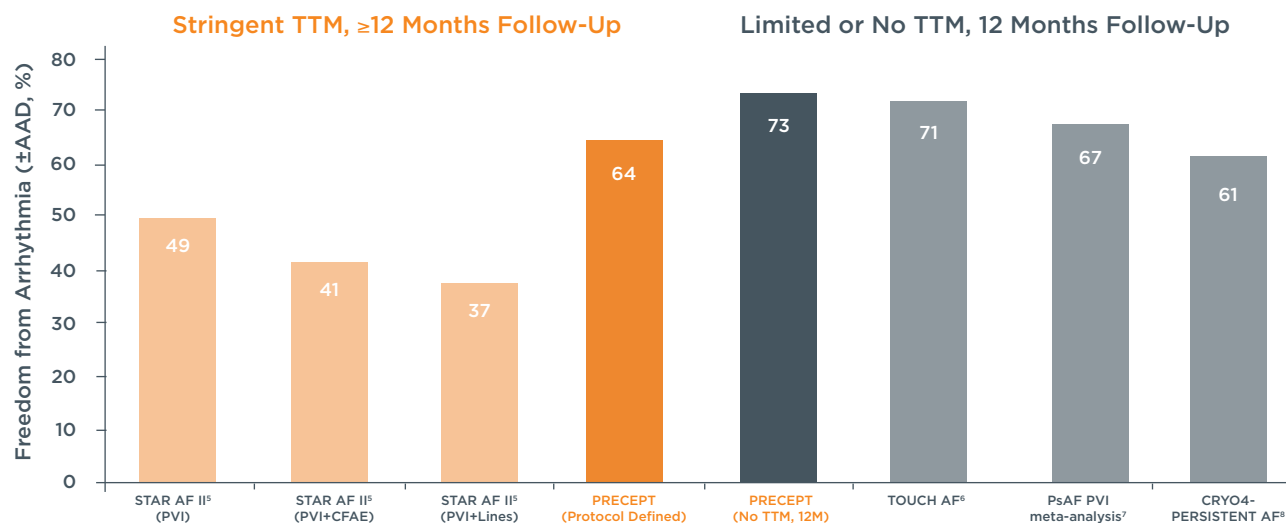
AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia.

RESULTS

PRECEPT Compared With Other Multicenter Persistent Atrial Fibrillation Studies

PRECEPT reported higher freedom from arrhythmia rates than other contemporary clinical studies.

- The single procedure success rate reported for PRECEPT was 64%.
 - Exploratory analysis of single-procedure success rate at 12 months with ECG/Holter monitoring was estimated at 73%.



Ablation Technology	Non-CF RF			CF RF	CF RF	CF RF	Non-CB, Non-CF or CF RF	CB2
12-lead ECG	Yes			Yes	Yes	Yes	Yes	Yes
Arrhythmia Monitoring	24-hr			24-hr	24-hr	48-hr	Mostly 24-h	48-hr
TTM	Stringent			Stringent	None	Limited	Mostly none	None
Follow-Up	3 to 18 months			6 to 15 months	3 to 18 months	3 to 12 months	Mostly 3 to 12 months	3 to 12 months
Repeat Ablation ^a	14 (22%)	67 (26%)	83 (33%)	26/333 (7.8%)	31/333 (9.3%)	21 (17%)	N/A	17 (17%)

CONCLUSION



The PRECEPT study demonstrated the clinical safety and effectiveness of persistent atrial fibrillation ablation using contact-force sensing technologies. The primary adverse events rate was within the range reported in paroxysmal atrial fibrillation studies.

AAD, antiarrhythmic drug; AF, atrial fibrillation; CB, cryoballoon; CB2, second generation cryoballoon; CF, contact force; CFAE, complex fractionated atrial electrograms; ECG, electrocardiogram; PVI, pulmonary vein isolation; TTM, transtelephonic monitoring.

^a Number of patients receiving repeat ablation after the blanking period.

REFERENCES

1. Mansour M, Calkins H, Osorio J, et al. Persistent atrial fibrillation ablation with contact force sensing catheter: The prospective multicenter PRECEPT trial. *JACC Clin Electrophysiol*. 2020;6(8):958-969.
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7. Voskoboynik A, Moskovitch JT, Harel N, Sanders P, Kistler PM, Kalman JM. Revisiting pulmonary vein isolation alone for persistent atrial fibrillation: A systematic review and meta-analysis. *Heart Rhythm*. 2017;14(5):661-667.
8. Boveda S, Metzner A, Nguyen DQ, et al. Single-procedure outcomes and quality-of-life improvement 12 months postcryoballoon ablation in persistent atrial fibrillation: results from the multicenter CRYO4PERSISTENT AF trial. *JACC Clin Electrophysiol*. 2018;4(1):1440-1447.

Disclosure

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