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Summary

Standardized Pulmonary Vein Isolation Workflow To Enclose Veins With Contiguous Lesions: The Multicentre VISTAX Trial

Duytschaever M, Vijgen J, De Potter T, Scherr D, Van Herendael H, Knecht S, Kobza R, Berte B, Sandgaard N, Albenque J-P, Szeplaki G, Stevenhagen YJ, Taghji P, Wright M, Macours N, Gupta D

Europace. 2020;22(11):1645-1652.

STUDY QUESTION

What are the safety and effectiveness of a VISITAG SURPOINT™ Module-guided radiofrequency ablation workflow in patients with paroxysmal atrial fibrillation (PAF)?

METHODOLOGY

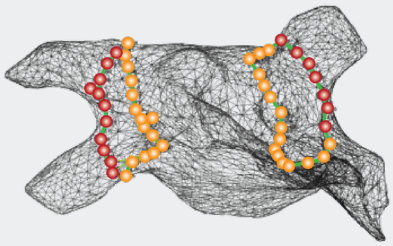
DESIGN:
SINGLE-ARM, MULTICENTER, PROSPECTIVE, NONRANDOMIZED, CLINICAL STUDY

17 EUROPEAN SITES

340 PATIENTS WITH PAF ENROLLED

329 PATIENTS IN EVALUABLE POPULATION

ABLATION SETTINGS



Maximum power:[a] 40 W or 45 W
Contact force range: 4–40 g
Stability range: 2–3 mm
Stability time: 3–5 s
Force over time: 25% > 3 g
Tag radius: 3 mm

VISITAG SURPOINT™ Module Tag Index Targets

- 400 on posterior wall
- 550 on anterior wall
- Intertag distance ≤ 6mm

OUTCOMES

PRIMARY ADVERSE EVENTS

FIRST PASS PULMONARY VEIN ISOLATION (PVI)
(30-min wait and adenosine challenge)

FREEDOM FROM DOCUMENTED ATRIAL ARRHYTHMIA
up to 12 months postablation

RESULTS

ABLATION WITH A STANDARDIZED VISITAG SURPOINT™-GUIDED RADIOFREQUENCY ABLATION WORKFLOW IS ASSOCIATED WITH

3.6% Primary adverse events

90% 12-month freedom from repeat ablation

~90% First-pass PVI by pulmonary vein circle

~90% 12-month freedom from atrial arrhythmia by standard-of-care monitoring

CONCLUSION

The VISTAX study demonstrated **the reproducibility of VISITAG SURPOINT™ Module-guided PAF ablation workflow with high acute first-pass isolation rate, high 12-month freedom from arrhythmia, and low rate of primary adverse events.**

[a]Maximum power was 40 W and 45 W for THERMOCOOL SMARTTOUCH® Catheter and THERMOCOOL SMARTTOUCH® SF Catheter, respectively.

Duytschaever M, Vijgen J, De Potter T, et al. Standardized pulmonary vein isolation workflow to enclose veins with contiguous lesions: The multicentre VISTAX trial. *Europace*. 2020; 22(11):1645-1652.

OBJECTIVE

To evaluate the safety as well as the acute and long-term effectiveness of PVI in patients with PAF using a standardized VISITAG SURPOINT™ Module workflow aiming to enclose the veins with contiguous and optimized RF ablation lesions.

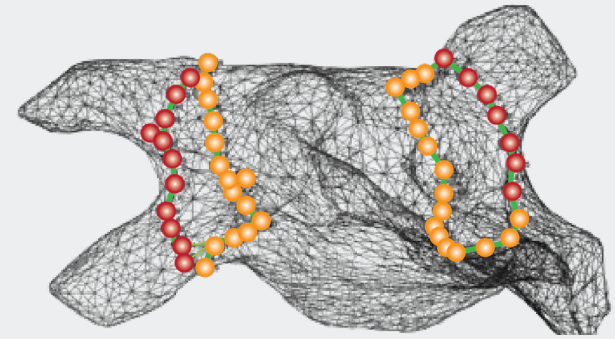
METHODS

Experimental Design

STUDY DESIGN	Single-arm, multicenter, prospective, nonrandomized, clinical study
STUDY PERIOD AND LOCATION	• January 2017 to March 2019 • 17 European sites
SAMPLE SIZE	340 patients with PAF
INTERVENTIONS	RF ablation with THERMOCOOL SMARTTOUCH® Catheter or THERMOCOOL SMARTTOUCH® SF Catheter guided by VISITAG SURPOINT™ Module
PATIENT FOLLOW-UP	3, 6, and 12 months postablation with stringent and standard-of-care monitoring
OUTCOMES	• Incidence of primary adverse events 7 days postablation[a] • Percentage of participants with first pass PV isolation after a 30-minute wait period and adenosine challenge • Freedom from any documented atrial arrhythmia (AF, AT, AFL) with stringent monitoring 3–12 months postablation

Ablation Procedure

VISITAG SURPOINT™ Module Tag Index Targets and ITD by PV Anatomical Location



- 400 on posterior wall
- 550 on anterior wall
- ITD ≤ 6mm

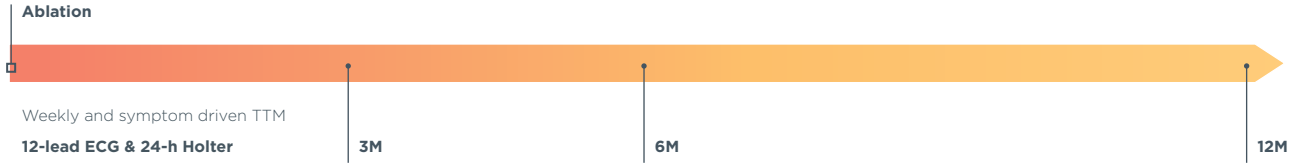
Ablation Parameters

Maximum power:[b] 40 W or 45 W
Contact force range: 4–40 g
Stability range: 2–3 mm
Stability time: 3–5 s
Force over time: 25% > 3 g
Tag radius: 3 mm

PVI Confirmation

- Linear lesions on cavotricuspid isthmus at discretion of operator if AF/AT occurred
- Confirmed by mapping and/or pacing maneuvers

Follow-Up



- Arrhythmia recording was independently adjudicated by a core laboratory.

AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; ECG, electrocardiogram; ITD, intertag distance; PAF, paroxysmal atrial fibrillation; PV, pulmonary vein; PVI, pulmonary vein isolation; RF, radiofrequency; TTM, transtelephonic monitoring.

[a]Primary adverse events included: cardiac tamponade/perforation, myocardial infarction, stroke/cerebrovascular accident, thromboembolism, transient ischemic attack, diaphragmatic paralysis, pneumothorax, heart block, pulmonary edema, pericarditis, and major vascular access complication or bleeding. Death, PV stenosis, and atrioesophageal fistula were considered primary adverse events regardless of the time of occurrence.

[b]Maximum power was 40 W and 45 W for THERMOCOOL SMARTTOUCH® Catheter and THERMOCOOL SMARTTOUCH® SF Catheter, respectively.

RESULTS

Demographics and Procedural Efficiency

PARAMETER	SAFETY POPULATION (N=340)
Age, mean (SD), y	61.3 (10.1)
Male, No. (%)	209 (61.5)
CHA_2DS_2-VASc score, mean (SD) CHA_2DS_2-VASc Score ≥1, No. (%)	1.6 (1.4) 165 (48.5)
LVEF, %, mean (SD)	61.5 (6.9)
Left atrial diameter, mm, mean (SD)	39.1 (5.1)
Medical history, No. (%) • Atrial flutter • Failed I/III AAD at baseline • Hypertension • Coronary disease • Prior thromboembolic events • Type II diabetes	 64 (18.8) 244/331 (73.7) 141/200 (70.5) 34/200 (17.0) 20 (5.9) 22 (6.5)

Pulmonary vein isolation was achieved in 99% of ablation procedures.

Procedural Characteristics of the Evaluable Population (n=329)

Time, mean (SD), minutes	
Overall procedure (including a 30 min waiting period)	156.2 (37.0)
RF application	35.2 (11.1)
Fluoroscopy	7.9 (6.9)

Safety

The overall rate of primary adverse event in the evaluable population was 3.6%.

- **0** — Device-related or device-associated PAEs
- **0** — Cases of atrioesophageal fistula, myocardial infarction, stroke/ cerebrovascular accident, or thromboembolism
- **0** — Cases of transient ischemic attack, pneumothorax, heart block, or PV stenosis

PAE	INCIDENCE NO. (%) (n=329)
Cardiac tamponade/perforation	3 (0.9)
Diaphragmatic paralysis	1 (0.3)
Pericarditis	1 (0.3)
Major vascular access complication/ bleeding Pseudoaneurysm AV communication	 4 (1.2) 1 (0.3)
Pulmonary edema (respiratory insufficiency)	1 (0.3)
Death[a]	1 (0.3)

PAE incidence rate 3.6%, 95% CI 1.9% to 6.3%

AAD, antiarrhythmic drug; AV, arteriovenous; CHA_2DS_2-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; CI, confidence interval; LVEF, left ventricular ejection fraction; PAE, primary adverse event; PV, pulmonary vein; RF, radiofrequency; SD, standard deviation.

[a]A 74-year-old woman died due to acute respiratory distress syndrome at Day 56 after the procedure. The patient had a history of coronary disease and unstable angina, moderate emphysema secondary to sternotomy, and had undergone previous coronary angioplasty and coronary artery bypass graft procedures. The patient developed pneumonia 8 days after ablation, and on Day 27 postprocedure, symptoms of respiratory distress started, and the patient was hospitalized. None of the images of the thorax (including computed tomography scan) taken between Day 8 and 56 were compatible with PV stenosis.

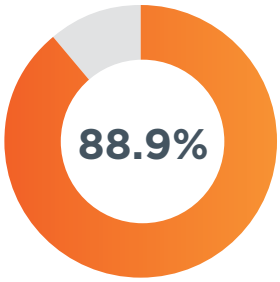
RESULTS

Effectiveness

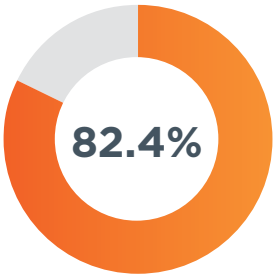
A favorable acute success rate was achieved in the evaluable population.

Primary Acute Effectiveness in the Evaluable Population (n=329):
First-Pass Isolation After a 30-Min Wait Period and Adenosine Challenge

By Pulmonary Vein Circle



By Patient



Kaplan-Meier Analysis of 12-Month Effectiveness in the Evaluable Population (n=329)

78.3% Freedom from atrial arrhythmia by stringent TTM/ECG/Holter monitoring

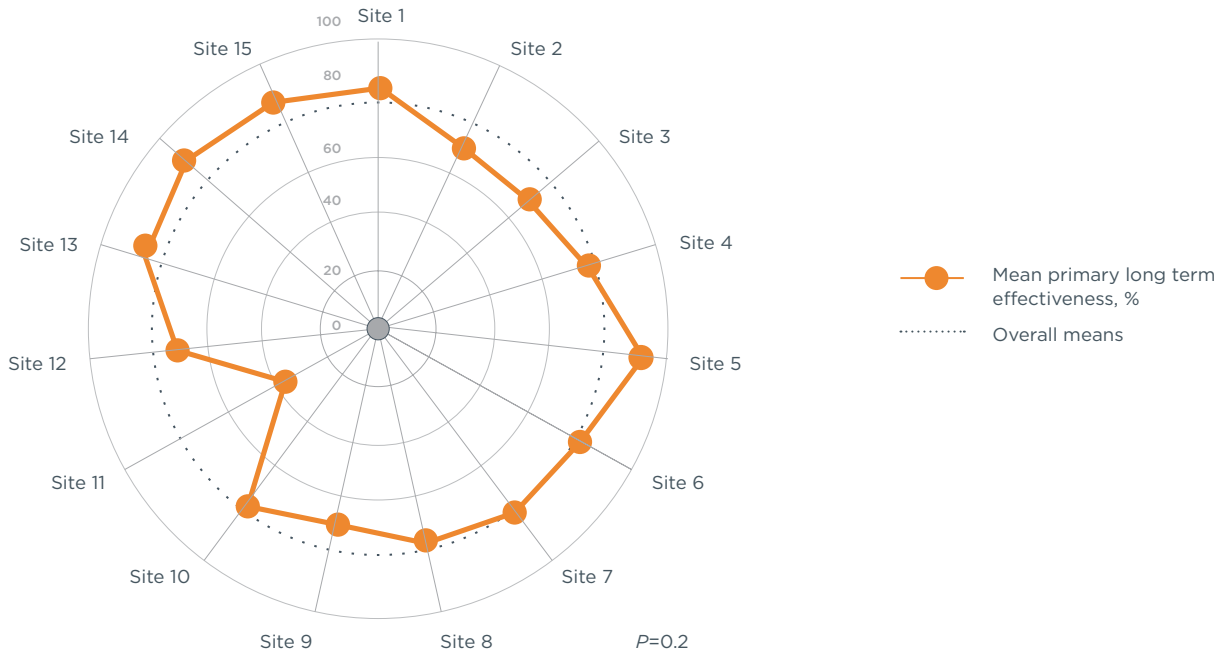
89.4% Freedom from atrial arrhythmia by SOC monitoring

90.4% Estimated freedom from repeat ablation

41.2% Patients with repeat ablations with full isolation of all PV circles

Long-term effectiveness was reproducible across sites.

Long-Term Effectiveness Across Sites

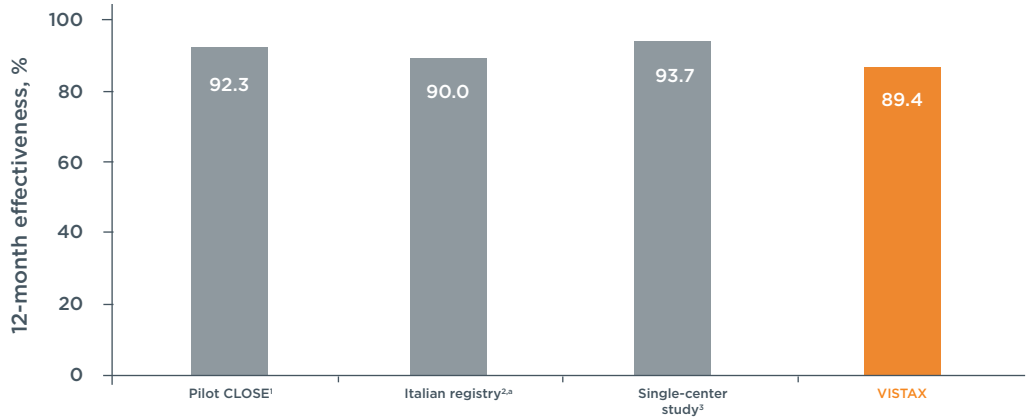


ECG, electrocardiogram; PV, pulmonary vein; SOC, standard of care; TMM, transtelephonic monitoring.

RESULTS

VISTAX Compared With Other Studies Using Optimized Workflow for VISITAG® Module or VISITAG SURPOINT™ Module/Intertag Distance-Guided PVI

VISTAX results confirm prior studies that reported favorable 12M effectiveness by SOC monitoring after PVI with contiguous and optimized lesions.

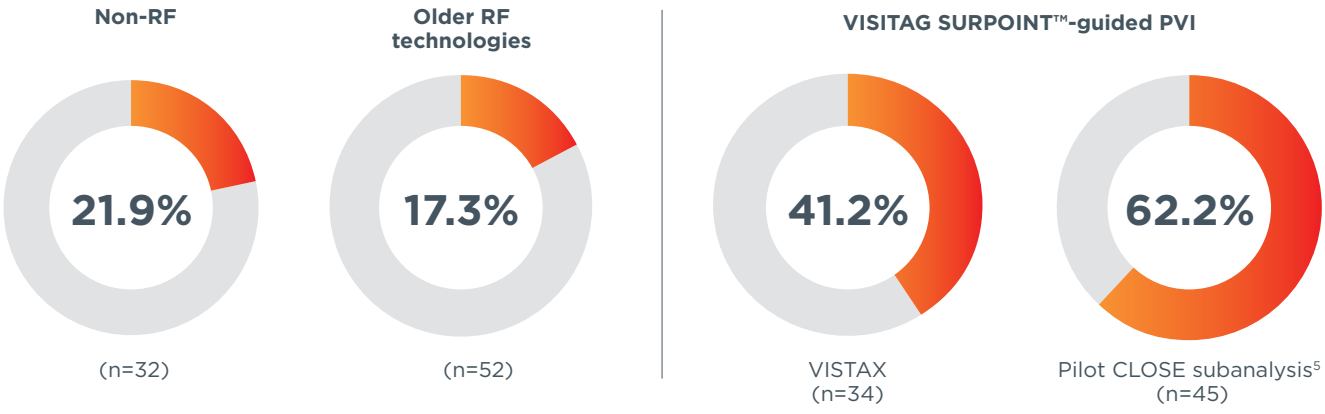


Number of patients	130	157	94	**329**
Number of centers	1	4	1	**17**
Arrhythmia monitoring	ECG at follow-up; 24-h Holter at 3 and 6 months, 7-day Holter at 12 months or in case of symptoms	Clinical assessment of atrial fibrillation recurrence, ECG, and Holter at each follow-up	24-h Holter ECG at each visit; 7-day Holter ECG at 3 and 6 months for asymptomatic or paucisymptomatic patients	**12-lead ECG, 24-h Holter at each follow-up**
Follow-up	1, 3, 6, and 12 months	3, 6, and 12 months	3, 6, and 12 months	**3, 6, and 12 months**

VISTAX patients treated for medically-indicated repeat ablations showed approximately 2× higher PVI durability compared with patients ablated with alternative or older RF technologies.

- VISTAX results confirm the durable PVI observed in prior studies using stable and contiguous lesions.

Patients With 4 Isolated Veins at Repeat Ablation Due to Arrhythmia Recurrence



[a] ECG, electrocardiogram; PVI, pulmonary vein isolation; RF, radiofrequency; SOC, standard of care. Reporting estimated freedom from atrial fibrillation only for the mean follow-up of 12±6 months.

CONCLUSION

The VISTAX study demonstrated the reproducibility of VISITAG SURPOINT™ Module-guided paroxysmal atrial fibrillation ablation workflow with high acute first-pass isolation rate, high 12-month freedom from arrhythmia, and low rate of primary adverse events.

REFERENCES

1. Taghji P, El Haddad M, Phlips T, et al. Evaluation of a strategy aiming to enclose the pulmonary veins with contiguous and optimized radiofrequency lesions in paroxysmal atrial fibrillation: A pilot study. *JACC Clin Electrophysiol*. 2018;4(1):99-108.
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5. De Pooter J, Strisciuglio T, El Haddad M, et al. Pulmonary vein reconnection no longer occurs in the majority of patients after a single pulmonary vein isolation procedure. *JACC Clin Electrophysiol*. 2019;5(3):295-305.

Disclosures

This summary has been written by Biosense Webster (Europe), a division of Johnson & Johnson Medical NV/SA based on the referenced article, and is provided for information purposes only.

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

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