Summary

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


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

ABLATION SETTINGS

Maximum power: 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

VISTAX SURPOINT™ Module Tag Index Targets

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

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% First-pass PVI by pulmonary vein circle
90% 12-month freedom from repeat ablation
～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.

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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

<table>
<thead>
<tr>
<th>STUDY DESIGN</th>
<th>Single-arm, multicenter, prospective, nonrandomized, clinical study</th>
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</thead>
</table>
| 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

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.

\(^a\)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 atretosophageal 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

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>SAFETY POPULATION (N=340)</th>
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<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>61.3 (10.1)</td>
</tr>
<tr>
<td>Male, No. (%)</td>
<td>209 (61.5)</td>
</tr>
<tr>
<td>CHA₂DS₂-VASc score, mean (SD)</td>
<td>1.6 (1.4)</td>
</tr>
<tr>
<td>CHA₂DS₂-VASc Score ≥1, No. (%)</td>
<td>165 (48.5)</td>
</tr>
<tr>
<td>LVEF, %, mean (SD)</td>
<td>61.5 (6.9)</td>
</tr>
<tr>
<td>Left atrial diameter, mm, mean (SD)</td>
<td>39.1 (5.1)</td>
</tr>
<tr>
<td>Medical history, No. (%)</td>
<td></td>
</tr>
<tr>
<td>• Atrial flutter</td>
<td>64 (18.8)</td>
</tr>
<tr>
<td>• Failed I/III AAD at baseline</td>
<td>244/331 (73.7)</td>
</tr>
<tr>
<td>• Hypertension</td>
<td>141/200 (70.5)</td>
</tr>
<tr>
<td>• Coronary disease</td>
<td>34/200 (17.0)</td>
</tr>
<tr>
<td>• Prior thromboembolic events</td>
<td>20 (5.9)</td>
</tr>
<tr>
<td>• Type II diabetes</td>
<td>22 (6.5)</td>
</tr>
</tbody>
</table>

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

Procedural Characteristics of the Evaluable Population (n=329)

<table>
<thead>
<tr>
<th>Time, mean (SD), minutes</th>
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<tbody>
<tr>
<td>Overall procedure (including a 30 min waiting period)</td>
</tr>
<tr>
<td>RF application</td>
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<tr>
<td>Fluoroscopy</td>
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</tbody>
</table>

Safety

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

<table>
<thead>
<tr>
<th>PAE</th>
<th>INCIDENCE NO. (%) (n=329)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac tamponade/perforation</td>
<td>3 (0.9)</td>
</tr>
<tr>
<td>Diaphragmatic paralysis</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Pericarditis</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Major vascular access complication/bleeding</td>
<td>4 (1.2)</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>AV communication</td>
<td></td>
</tr>
<tr>
<td>Pulmonary edema (respiratory insufficiency)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Deatha</td>
<td>1 (0.3)</td>
</tr>
</tbody>
</table>

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

AAD, antiarrhythmic drug; AV, arteriovenous; CHA₂DS₂-VASc, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke (or transient ischemic attack) or 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 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

88.9%

By Patient

82.4%

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

90.4%  Estimated freedom from repeat ablation

89.4%  Freedom from atrial arrhythmia by SOC monitoring

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

Long-term effectiveness was reproducible across sites.

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

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

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

<table>
<thead>
<tr>
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<th>Non-RF</th>
<th>Older RF technologies</th>
<th>VISITAG SURPOINT™-guided PVI</th>
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</thead>
<tbody>
<tr>
<td>(n=32)</td>
<td>21.9%</td>
<td>17.3%</td>
<td>41.2%</td>
</tr>
<tr>
<td>(n=52)</td>
<td></td>
<td></td>
<td>62.2%</td>
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<tr>
<td>FIRE AND ICE subanalysis⁴</td>
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ECG, electrocardiogram; PVI, pulmonary vein isolation; RF, radiofrequency; SOC, standard of care.
⁴Reporting 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


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.

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

Manufacturer
Biosense Webster, Inc.
31 Technology Drive, Suite 200
Irvine, California 92618, USA
Tel: +1-909-839-8500

For additional medical information request, please contact: https://www.jnjmedicaldevices.com/en-EMEA/mir