A New Implantable Carotid Intraluminal Coil Device (Javelin Vine) To Prevent Embolic Strokes In High Risk Atrial Fibrillation Patients: Device Description And Scientific Rationale

Vivek Y. Reddy, MD
Helmsley Trust Professor of Medicine
Director, Cardiac Arrhythmia Service
The Mount Sinai Hospital
vivek.reddy@mountsinai.org

Disclosures

• Grant support and/or Consultant:
  * I have an equity stake in these companies
• I will be discussing FDA-unapproved and off-label use of catheter devices

A Novel Mechanical Approach to Stroke Prevention
A Permanent Bilateral Common Carotid Filter

• The Device is called "Vine™" (being developed by Javelin Inc.)

Do CCA Filters make clinical sense?
What about the Vertebral Arteries? Emboli Size?

Anterior Circulation Strokes in AF ~80%
Posterior Circulation and Lacunar Strokes ~20% (non-embolic)


Table: Stroke Territory

<table>
<thead>
<tr>
<th>Stroke Territory</th>
<th>AF Population (%) n = 3169</th>
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<tbody>
<tr>
<td>Total Anterior Circulation Infarcts (TACI)</td>
<td>36%</td>
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<tr>
<td>Partial Anterior Circulation Infarcts (PACI)</td>
<td>41%</td>
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<tr>
<td>Lacunar Infarcts (LACI)</td>
<td>13%</td>
</tr>
<tr>
<td>Posterior Circulation Infarcts (POCI)</td>
<td>9%</td>
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A Permanent Common Carotid Filter
Device is Designed for Percutaneous Insertion

The Device Recovers its Shape in the CCA upon Exit from the 24G Needle
Permanent Common Carotid Filter

Addressing Safety & Efficacy Requirements

- "Non-thrombogenic"
- Non-occlusive
- Single puncture
- Stable in pulsatile flow
- retrievable
- Captures emboli > 1.2mm
- Can be crossed by guiding catheter

Pre-Clinical Experience

- Safety studies (30 sheep, 60 implants, 1-7 mo)
  - Safe implant – 60/60 (100%)  
  - Implantation success – 60/64 (94%)
  - No migration – 60/60 (100%)

The Device is Readily Visible by Ultrasound

The Device is Hemocompatible

Options for Pivotal Study(s)

- OAC Alternative in “Contraindicated” AF pts
- Adjunctive to OACs in High-Risk AF pts
- To reduce peri-/post-TAVR related strokes

First-in-Human Clinical Experience

CAPTURE: “Contraindicated” AF Patients

- Clinical Trial Centers in Europe
  - Homolka Hospital, Prague (P. Neuzil / V. Kveder)
  - Antwerp CV Institute, Antwerp (S. Verheye)
  - St. Antonia Ziekenhuis, Nieuwegein (J. Heijden)
  - Hartcentrum OLV Aalst, Aalst (T. de Potter)