Double Filtration During CAS Improves Outcomes

The Novel Paladin Balloon With An Integrated Filter Helps To Do This

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Financial Disclosures

Contego Medical: Founder
Medtronic: SMAB, Speakers Bureau
Boston Scientific: Drug Eluting Steering Committee, Consultant
Spectranetics: Consultant

While CAS Results are steadily Improving

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Stroke Remains the Achilles Heal of Carotid Artery Stenting

Access Stenting Post-Procedure

When Do Strokes Occur During Carotid Artery Stenting?

Maximal Risk Of Stroke is during Post-Dilation
Why Do Strokes Occur Despite EPD use?
- Pore Size (100-250 microns)
- Filter Malapposition
  - Improper Sizing
  - Shape Mismatch
  - Patient Movement
- Overwhelming Debris Burden

Hypothesis

- Problem: Risk of stroke is maximal during the post-dilation phase
- Solution: Increase protection during the post-dilation phase

Double Filtration – Symptomatic LICA

Double Filtration

- 221 Non-consecutive Patients
- 2 Centers, Prospective, Non-Randomized
- Double Filtration using a variety of primary filters and stents
- FilterWire used for all secondary filter
- 30 Day Neurological Death, Stroke, MI

Double Filtration: Procedural and 30 day Results

<table>
<thead>
<tr>
<th>Event</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedural Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>0.48%</td>
</tr>
<tr>
<td>Neurological Death</td>
<td>0</td>
<td>0%</td>
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<tr>
<td><strong>30-Day Events</strong></td>
<td></td>
<td></td>
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<td>Myocardial Infarction</td>
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<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Total Neurological Death/Stroke/MI</strong></td>
<td>2</td>
<td>0.96%</td>
</tr>
</tbody>
</table>

Filter Analysis

- 36 Paired Filters Sent to Pathology
- Debris noted in BOTH filters in ALL 36 cases
Limitations of Double Filtration using Two Separate Filters

- Cost of an extra filter
- Extra time require to deploy a second filter
- 36% of patients with insufficient landing zone for a second filter

PALADIN® Carotid Post-Dilation Balloon with Integrated Embolic Protection

First filter with ability to adjust size to suit patient anatomy

PALADIN® Balloon Post-Dilation

PALADIN® Balloon Post-Dilation

Capture Efficiency Testing

Data on file: Contego Medical LLC

PALADIN® Balloon Post-Dilation

Paladin: Data

- Vigorous testing porcine model
- Excellent performance during FIM
- CE Mark and commercially available in EU
- Registry and MRI Data will be presented at LINC 2016
- Randomized trial planned with an MRI endpoint
**Key Points**

- There remains a risk of stroke during carotid artery stenting.
- The majority of the risk is at the time of post-dilation.
- Double filtration appears to reduce this risk of stroke.
- Integrated Embolic Protection Platform will allow an expanded role for embolic protection in all vascular beds.