Endovascular Revascularization Devices

Dorris Luong, NP
Interventional Neuroradiology
Redwood City Kaiser
Objectives

- Identify the different causes of ischemic strokes
- Know what is Interventional Neuroradiology
- Be familiar with the latest advancements in endovascular devices for the treatment of ischemic stroke
- Understand that there are possible device associated complications
“OH, MY GOD! THAT’S NOT THE BACKSTROKE! THIS FLY IS HAVING AN ACTUAL STROKE!”
Types of Strokes

**STROKE**

- **Hemorrhagic**
  - 15-20%

- **Ischemic**
  - 80-85%

- **Subarachnoid Hemorrhage**
  - ~6-8%

- **Intracerebral Hemorrhage**
  - ~10-15%
Ischemic stroke: Classification
(Based on the Trial of Org 10172 in Acute Stroke Treatment (TOAST criteria))

- **Large artery atherosclerosis**—infarction in the perfusion territory of an extracranial or intracranial artery within >50% stenosis, and no other likely cause of stroke
- **Cardioembolism**—infarction in the presence of at least 1 cardiac condition strongly associated with stroke, such as atrial fibrillation
- **Stroke of other determined etiology**—cerebral infarction caused by vasculitis, arterial dissection, and hypercoagulable states
- **Stroke of undetermined etiology**—infarction in the setting of 2 or more different potential etiologies, no potential etiology despite complete diagnostic evaluation, or an incomplete evaluation
Neurological Interventional Radiology (NIR or Neuro IR or INR)

- Endovascular treatment is a medical imaging technique used to visualize the inside of blood vessels of the body. This is done by injecting a radio-opaque contrast agent into the blood vessel and imaging using X-ray based techniques such as fluoroscopy.
Intra-Arterial tissue Plasminogen Activator (tPA)

- Available in neurointerventional radiology and pharmacy
- Reconstituted by radiology RN
- Administered by Neurointerventional Radiologist
- tPA used intra-arterially can be more effective than IV tPA in its ability to recanalize major intracranial arterial occlusions
- Intra-arterial tPA can be administered up to 6 - 12 hours as per the operating physician
- Complications with IA tPA?

RWC Kaiser Policies and Procedures - INR-Medication Preparation-Intra Arterial (IA) Tissue Plasminogen Activator (tPA) Management for Acute Ischemic Stroke INS.09.06
The right middle cerebral artery before and after IA tPA
Merci Retriever System

- Corkscrew-shaped products designed to remove blood clots from large vessels within the neurovasculature
- Use for patients presenting within 8 hours of stroke symptom onset
- There are currently ten Merci Retrievers available to match vessel size
- The Merci Retriever was first cleared for human use in 2004 by the FDA
- Since 2004, the Merci Retriever has been used in more than 14,000+ patients throughout the world including the United States, Europe, Australia, Singapore and Canada.
- Complications with the Merci Retriever System?
Penumbra System

- Indicated for use within 8 hours of stroke symptom onset
- FDA approved in 1/2008
- Uses a reperfusion catheter in parallel with a separator component and an aspiration source to achieve separation of the thrombus and subsequent aspiration of the occlusion from the vessel
- Complications with the Penumbra System
Penumbra System
Solitaire Flow Restoration Device

- Approved by the FDA in March 2012
- Made by Covidien
- A self-expanding, stent-like design, and once inserted into a blocked artery using a thin catheter tube, it compresses and traps the clot. The clot is then removed by withdrawing the device, reopening the blocked blood vessel.
- Complications with the Solitaire?
SWIFT (SOLITAIRe™ FR. With the Intention for Thrombectomy) Trial

- Covidien sponsored the SWIFT trial comparing the Solitaire vs. Merci Retriever
- The trial enrolled 113 stroke patients at 18 hospitals in the United States between February 2010 and February 2011.
- The patients were randomly assigned to undergo clot removal with either the Solitaire Flow Restoration device or the Merci Retriever within 8 hours of stroke onset.
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Solitaire (n=58)</th>
<th>Merci (n=53)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recanalization with no symptomatic ICH</td>
<td>68.5%</td>
<td>24.1%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Good neurological outcome at 90 days</td>
<td>58.2%</td>
<td>33.3%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Use of rescue therapy</td>
<td>20.7%</td>
<td>43.6%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mortality at 90 days</td>
<td>1.7%</td>
<td>38.2%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Symptomatic ICH</td>
<td>1.7%</td>
<td>10.9%</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Any ICH</td>
<td>17.2%</td>
<td>38.2%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Device-related serious adverse events</td>
<td>8.6%</td>
<td>16.4%</td>
<td>0.26</td>
</tr>
<tr>
<td>Procedure-related serious adverse events</td>
<td>13.8%</td>
<td>16.4%</td>
<td>0.80</td>
</tr>
<tr>
<td>Device fracture</td>
<td>3.4%</td>
<td>0</td>
<td>0.50</td>
</tr>
</tbody>
</table>
Trevo Pro

• FDA approved in early 8/2012
• Made by Concentric Medical which made the Merci Retriever. This company has now been acquired by Stryker.
• Trevo 2 trial randomized 178 individuals following an acute ischemic stroke to treatment with either the Trevo Pro or the Merci Retriever
• Complications with the Trevo Pro?
Trevo 2 trial Results

<table>
<thead>
<tr>
<th></th>
<th>Trevo</th>
<th>Merci</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>76</td>
<td>54</td>
</tr>
<tr>
<td>Revascularization rate</td>
<td>86.4%</td>
<td>60%</td>
</tr>
<tr>
<td>Patient with mRS of ≤ 2</td>
<td>40%</td>
<td>21.8%</td>
</tr>
</tbody>
</table>

- Other measures of performance also strongly favored the Trevo Pro Retriever, including improvement in the National Institutes of Health Stroke Scale (NIHSS) and shorter hospital stays.
End Result with Trevo Pro
Conclusion

Previously doctors had limited treatment options with acute ischemic stroke if patients were beyond the three-hour window. Now with revolutionary advancements in technology, there are a number of endovascular devices for revascularization of occluded vessels. However, all revascularization devices are limited by the experience of the operator and the quality of the equipment used.
Early microscope
Questions ?