Changing the Paradigm?
Thrombectomy for Chronic Total Occlusions, In-Stent Restenosis, Acute Deep Vein Thrombosis & Pulmonary Embolism with the Indigo System

George L. Adams, MD, MHS, FACC, FSCAI
Clinical Associate Professor of Medicine
University of North Carolina Health System
Director of Cardiovascular and Peripheral Vascular Research, Rex Healthcare
Raleigh, North Carolina
Disclosure

Speaker name:
George L. Adams, MD, MHS, FACC, FSCAI

I have the following potential conflicts of interest to report:

☒ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest
Thrombus Epidemic

- STEMI: 250,000 Americans per year
- DVT/PE: 300,000 to 600,000 Americans per year
- CVA: 795,000 Americans per year
- Acute Limb Ischemia: 45,000 Americans per year
- Incidence of clinically significant embolization in peripheral arterial interventions is estimated at 1-5%

What are the Tools to Treat Thrombotic Plaque

• Manual Aspiration
• Pharmacologic Thrombolysis (Lytic Catheter)
• Mechanical/Pharmacological Thrombolysis (EKOS)
• Embolic Protection
• **Mechanical Aspiration (Indigo)**
Challenges with Current Thrombosis Treatment

- **Lytics**
  - Extended hospital stays “TPA drip overnight”
  - Risk of bleeding complications

- **Surgery**
  - Blind
  - Perforation or Dissection
  - Distal Embolization
  - Difficult in smaller vessels
Challenges with Current Thrombus Treatment

• Manual Aspiration Catheters
  • Only for softer, acute clot
  • Limited Trackability
  • Smaller lumen

• Mechanical systems
  • High risk of distal emboli
  • Renal Complications
  • Bulky, complicated setup
Indigo System

- Easy-to-use single operator design
- Penumbra MAX Pump delivers almost pure vacuum
- Allows for hands free aspiration
Visualization Under Fluoro

CAT8XTORQ115

CAT8TORQ85

CAT6

CAT5/SEP5

CAT8XTORQ115/SEP8 showing better visualization under fluoro
Range of Sizes to Personalize Care

Guidewire Compatibility

- **.014” - .025”**
  - Can be inserted coaxially through CAT8 for further distal access

- **.014” - .038”**
  - Can be inserted coaxially through CAT8 for further distal access
  - Can be inserted coaxially through CAT5, CAT6 & CAT8 for further distal access
Mechanical Clot Engagement and Extraction

- Separator allows clot engagement and extraction without losing access
- Maximized extraction lumen for efficient clot removal
Aspiration Efficiency

Aspiration Volume (mL in 20 sec)

<table>
<thead>
<tr>
<th></th>
<th>mL /20 sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiojet</td>
<td>3</td>
</tr>
<tr>
<td>CAT3</td>
<td>14</td>
</tr>
<tr>
<td>CAT5</td>
<td>56</td>
</tr>
<tr>
<td>CAT6</td>
<td>90</td>
</tr>
<tr>
<td>CAT8</td>
<td>160</td>
</tr>
</tbody>
</table>
INDIGO Trackability
Larger Sizes & Venous Indication

CAT6

SEP6

SEP8

CAT8
CAT8 XTORQ with SEP
Circumferential Aspiration

STR

TORQ

XTORQ

2.24 mm

15 mm

25.4 mm
Case Study (CTO)

- 58 Y/O Male
- History of hypertension, dyslipidemia and tobacco abuse
- Life limiting claudication < 50 yards
- LLE ABI: 0.5
- Duplex US revealed an SFA occlusion with three vessel outflow
Case Presentation CTO

• What are the characteristics of the plaque? CTO pathology
• What is your approach to cross the lesion? Cross from antegrade, retrograde, transcollateral?
• What devices would you use to cross and treat?
• Would you place a distal protection device?
• Biologic Therapy?
Case Presentation CTO

- 18g CTO wire
- 2x200mm PTA; pilot channel
- Penumbra CAT5 Indigo aspiration
Case Presentation CTO

- 5x150mm PTA
- Penumbra CAT5 Indigo second pass

Post indigo
Case Presentation CTO

- (4) 6x80mm Zilver PTX drug eluting stents
- 5x200mm Post dilatation
In-Stent Restenosis Case
Case Presentation DVT

- 77 Y/O Female
- Whipple procedure for pancreatic cancer
- Septic

Courtesy of: Shahab Toursavadkohi, MD
University of Maryland
Case Presentation DVT

• Concern was that thrombus in the IVC was infection and/or cancer
• IVUS was used to confirm thrombus location

Courtesy of: Shahab Toursavadkohi, MD
University of Maryland
Case Presentation DVT

Pre – Treatment
Treatment

- A 6.5F steerable sheath
- Indigo Cat6/Sep6

*Courtesy of: Shahab Toursavadkohi, MD University of Maryland*
Case Presentation PE

- 70 y/o male
- Acute shortness of breath
- Bilateral PE with Left > Right
- ECG showed significant RV strain
- Mild clot in right PA
- Significant clot in left PA

Courtsey of Corey Teigen, MD
Sanford Health, ND
Case Presentation PE
Pre - Treatment

Courtsey of Corey Teigen, MD
Sanford Health, ND
Treatment

• IJ access
• CAT8/SEP8 thrombectomy was performed in left distal and segmental PA
• Pt. 02 Sat improved from 88% to 94%
• Systolic PA pressure dropped from 50mm Hg to 40mm Hg

Courtsey of Corey Teigen, MD
Sanford Health, ND
Case Presentation PE

Post Treatment
Indigo System
For The Periphery

• Provide endovascular option for clot management
• Safe and simple procedure
• May reduce the need for lytics
• Visualize the clot
Thank You!
Changing the Paradigm? Thrombectomy for Chronic Total Occlusions, In-Stent Restenosis, Acute Deep Vein Thrombosis & Pulmonary Embolism with the Indigo System

George L. Adams, MD, MHS, FACC, FSCAI
Clinical Associate Professor of Medicine
University of North Carolina Health System
Director of Cardiovascular and Peripheral Vascular Research, Rex Healthcare
Raleigh, North Carolina