PRISM Trial

Retrospective Case Review of Technical Success Using the Penumbra and Indigo Systems for Mechanical Thrombectomy in the Periphery

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:

- [x] 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%

Dormandy, J. Semin Vasc Surg.1999 Jun; 12(2):148-53.
www.cdc.gov

Penumbra Indigo® System

- Trackable aspiration system
  - Continuous Vacuum Pump
  - Catheter (3F to 8F)
  - Separator
- Can be used to treat occlusive thrombi/emboli.
- Extensively validated for use in neurovascular interventions

Palaniswami, M., & Yan, B. (2015). Mechanical Thrombectomy Is Now the Gold Standard for Acute Ischemic Stroke: Implications for Routine Clinical Practice. *Interventional neurology*, *4*(1-2), 18-29.

PRISM Trial: Study Design

- 83 patients enrolled
- Retrospective, single-arm, multicenter trial (5 Sites)
- Mechanical thrombo-embolectomy using the Penumbra Indigo® System was performed in cases of:
  - *Acute peripheral and visceral arterial ischemia*
  - *Distal emboli*
  - *Failed thrombolysis*
  - *In-Stent Restenosis*

Number of patients	83
Age (years) [mean ± SD]	68.7 ± 12.8
Female	40.2%
Target vessel location	
Brachial	1.2%
Superior Messenteric	3.6%
Renal	2.4%
External Iliac	1.2%
Common Femoral	1.2%
Profunda Femoris	6.0%
Superficial femoral	27.7%
Popliteal	32.5%
Anterior Tibial	6.0%
Peroneal	7.2%
Posterior Tibial (2 TP trunk)	8.4%
Other	2.4%

Study Metrics

Treatment modality	
Penumbra used frontline	53% (44/83)
Penumbra after thrombolytics	24.1% (20/83)
Penumbra after other mechanical thrombectomy	13.3% (11/83)
Penumbra after both thrombolytics + mechanical	9.6% (8/83)

Median time from symptom onset to procedure	5.0 days [IQR 2.0 - 23.0]

Results: Effectiveness

Primary Endpoint = TIMI 2-3 Revascularization (N=83)

	Pre-procedure and/or post thrombolytic	Post Penumbra/Indigo System alone	Final angiographic outcome*
TIMI 0-1	97.5%	12.2%	3.7%
Successful Revascularization (TIMI 2-3)	2.5%	87.8%	96.3%
Complete reperfusion (TIMI 3)	0%	51.2%	76.5%

⁺TIMI score pre-Penumbra was not obtained in four cases
*TIMI score post-Penumbra was not obtained in two cases

Results: Safety

Type of adverse event	N of patients (%)
Serious adverse event*	10 (12.0%)
Device-related procedural event[1]	1 (1.2%)

[1]Distal embolization occurred in one patient post Viabahn stent placement. Unclear if related to device. The event was resolved at the end of the procedure, with TIMI III flow restoration and no clinical sequelae.

**17 SAEs were observed in 10 patients. . None were classified as related to the study device.*

Summary

- Simple and Easy to use system
- Can be used in a variety of clinical settings (different vessel sizes, and pathology of lesion)
- The Penumbra Indigo is a safe and effective strategy for mechanical thrombectomy
- Future studies focused on peripheral arterial outcome data using the Penumbra mechanical thorombectomy system need to be performed.

Thank You!

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