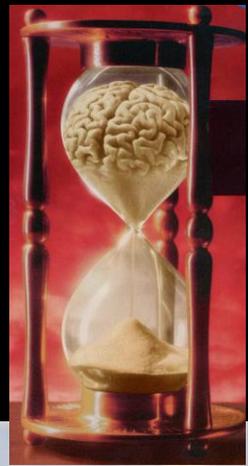


# Endovascular Treatment of Stroke, Present and Future



Ajay K. Wakhloo, MD PhD FAHA

Professor of Radiology, Neurology and Neurosurgery,

Division Neuroimaging and Intervention & The New England Center for Stroke Research

Departments of Radiology, Neurology and Neurosurgery,

University of Massachusetts Medical School



# DISCLOSURES

- Stryker Neurovascular (Consultant)
- Codman J&J (Consultant)
- InNeuroco (Stockholder, CMO)
- Pulsar (Bridge loan)
- Medtronic (Stockholder)
- Philips (MAB, Research Grant, Equipment support)
- Postgraduate Course Harvard Medical School (Speaker)
- Baptist Hospital, Miami, Florida (Speaker)
- NIH (R01 NS45753-01A1; 1R21EB007767-02; 5R01 NS045753-02; 1R21NS061132-01A1; 1R01NS091552-01A1)

# Stroke in USA

- Stroke is the third cause of death and leading cause of disability in the United States
- 800,000 new or recurrent stroke per year
  - Approximately 87% ischemic
  - 40% due to large vessel occlusions
- Every 45 seconds someone in the U.S. has a stroke
- 160,000 fatal per year
- Stroke cost estimated at \$62.7 billion in 2007
- iv t-PA only approved treatment of acute ischemic stroke within 3 h after symptom onset and approved in the US, Canada, Australia, and European Union
- April 1998 – March 1999 out of 14,295 inpatient with acute stroke, only 1.7% received t-PA (National Project of the US Centers for Medicare and Medicaid Service)
- 5-year recurrence rate for stroke 24-42%

# The Economist

FEBRUARY 27TH - MARCH 4TH 2016

INDONESIA: A SPECIAL REPORT

Brexit: a threat to the West

Unjamming megacities

Why Apple is right

Hieronymus Bosch, painter of fear

# Really?



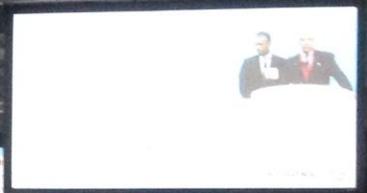
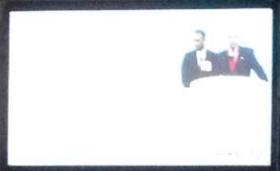
LET'S MAKE AMERICA GREAT AGAIN

887890M ###NUT0###SCH 5-0161T 02466 F55  
#09U06087600 0# Feb 04 17  
#0911-04720  
#2710-1180

# Successful Randomized Stroke Trials (2015)

- MR CLEAN
- ESCAPE
- EXTEND-IA
- SWIFT PRIME
- REVASCAT





## ORIGINAL ARTICLE

## Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection

B.C.V. Campbell, P.J. Mitchell, T.J. Kleinig, H.M. Dewey, L. Churilov, N. Yassi, B. Yan, R.J. Dowling, M.W. Parsons, T.J. Oxley, T.Y. Wu, M. Brooks, M.A. Simpson, F. Miteff, C.R. Levi, M. Krause, T.J. Harrington, K.C. Faulder, B.S. Steinfort, M. Priglinger, T. Ang, R. Scroop, P.A. Barber, B. McGuinness, T. Wijeratne, T.G. Phan, W. Chong, R.V. Chandra, C.F. Bladin, M. Badve, H. Rice, L. de Villiers, H. Ma, P.M. Desmond, G.A. Donnan, and S.M. Davis, for the EXTEND-IA Investigators\*

## ORIGINAL ARTICLE

## Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke

M. Goyal, A.M. Demchuk, B.K. Menon, M. Eesa, J.L. Rempel, J. Thornton, D. Roy, T.G. Jovin, R.A. Willinsky, B.L. Sapkota, D. Dowlathshahi, D.F. Frei, N.R. Kamal, W.J. Montanera, A.Y. Poppe, K.J. Ryckborst, F.L. Silver, A. Shuaib, D. Tampieri, D. Williams, O.Y. Bang, B.W. Baxter, P.A. Burns, H. Choe, J.-H. Heo, C.A. Holmstedt, B. Jankowitz, M. Kelly, G. Linares, J.L. Mandzia, J. Shankar, S.-I. Sohn, R.H. Swartz, P.A. Barber, S.B. Coutts, E.E. Smith, W.F. Morrish, A. Weill, S. Subramaniam, A.P. Mitha, J.H. Wong, M.W. Lowerison, T.T. Sajobi, and M.D. Hill for the ESCAPE Trial Investigators\*

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JANUARY 1, 2015

VOL. 372 NO. 1

## A Randomized Trial of Intraarterial Treatment of Ischemic Stroke

O.A. Berkhemer, P.S.S. Fransen, D. Beumer, L.A. van den Berg, H.F. Lingsma, A.J. Yoo, W.J. S.P.J. Nederkoorn, M.J.H. Wermer, M.A.A. van Waldervee, J. Staals, J. Hofmeijer, J.A. G.J. Lycklama à Nijeholt, J. Boiten, P.A. Brouwer, B.J. Emmer, S.F. de Bruijn, L.C. van Dijk, E.J. van Dijk, J. de Vries, P.L.M. de Kort, W.J.J. van Rooij, J.S.P. van den Berg, B.A.A.M. van't R.J. Dallinga, M.C. Visser, J.C.J. Bot, P.C. Vroomen, O. Eshghi, T.H.C.M.L. Schreuder, R.J. A.V. Tielbeek, H.M. den Hertog, D.G. Gerrits, R.M. van den Berg-Vos, G.B. Karas, E.W. S.H.A. Marquering, M.E.S. Sprengers, S.F.M. Jenniskens, L.F.M. Beenen, R. van den Berg, W.H. van Zwam, Y.B.W.E.M. Roos, A. van der Lugt, R.J. van Oostenbrugge, C.B.L.M. Majo for the MR CLEAN Investigators\*

## Protocols

## Solitaire™ with the Intention for Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke (SWIFT PRIME) trial: protocol for a randomized, controlled, multicenter study comparing the Solitaire revascularization device with IV tPA with IV tPA alone in acute ischemic stroke

Jeffrey L. Saver<sup>1\*</sup>, Mayank Goyal<sup>2,3</sup>, Alain Bonafe<sup>4</sup>, Hans-Christoph Diener<sup>5</sup>, Elad I. Levy<sup>6</sup>, Vitor M. Pereira<sup>7</sup>, Gregory W. Albers<sup>8</sup>, Christophe Cognard<sup>9</sup>, David J. Cohen<sup>10</sup>, Werner Hacke<sup>11</sup>, Olav Jansen<sup>12</sup>, Tudor G. Jovin<sup>13</sup>, Heinrich P. Mattle<sup>14</sup>, Raul G. Nogueira<sup>15</sup>, Adnan H. Siddiqui<sup>16</sup>, Dileep R. Yavagal<sup>17</sup>, Thomas G. Devlin<sup>18</sup>, Demetrius K. Lopes<sup>19</sup>, Vivek Reddy<sup>13</sup>, Richard du Mesnil de Rochemont<sup>20</sup>, Reza Jahan<sup>21</sup>, and for the SWIFT PRIME Investigators

# Stroke Program at UMASS

- Education (Stroke Center)
- Initial (Stroke Center)
- Arrival (Stroke Center)
- Activation (Stroke Center, ED, Stroke  
Neurology, Stroke  
technicians)
- Assessment (Stroke Center)
- Advanced (Stroke Center, MRI)
- Advance to (Stroke Center, Thrombectomy)

Goal: time to  
needle <30 min  
currently ~60min

# Time matters

- Overall rate of successful revascularization in Solitaire-treated patients (mTICI 2b/3): 77% (236/306)
- Rate of independence significantly increased with improved mTICI ( $p=0.01$  for trend)

mTICI	0-1	2a	2b	3
mRS 0-2 - n (%)	8/21 (38%)	25/49 (51%)	62/117 (53%)	77/119 (65%)

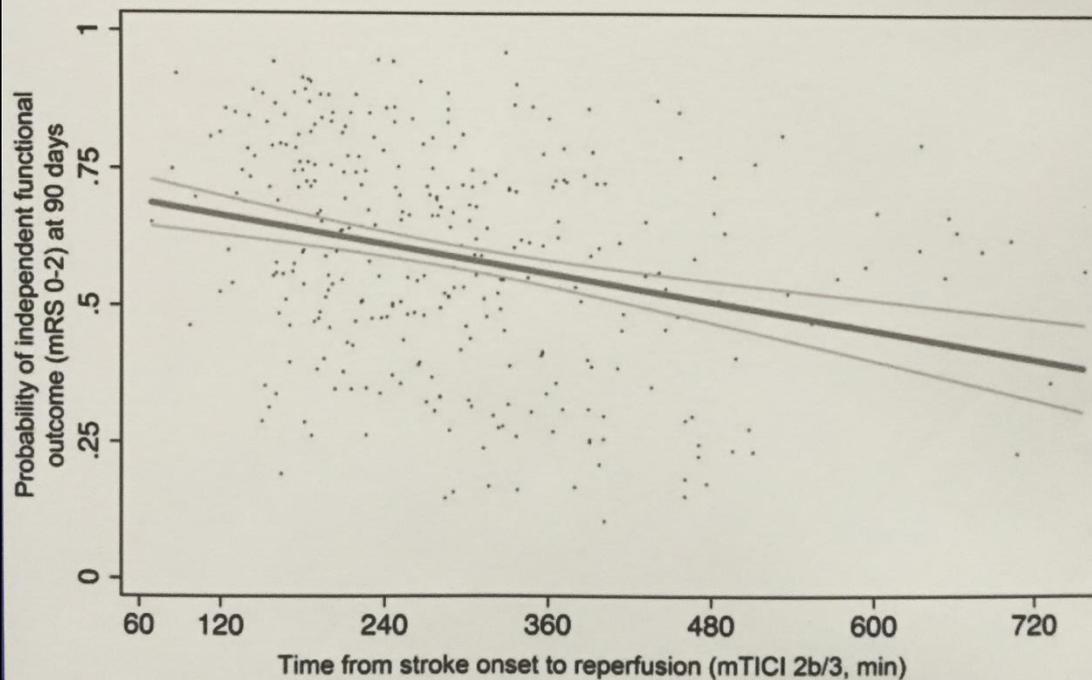


Figure 3: Rate of independence significantly decreased with increased time to reperfusion (OR 0.99 per minute,  $p=0.011$ ) 1% decline in mRS 0-2 per 23 minute delay,  $p=0.01$  for trend effect likely reduced by imaging selection for good collateral/mismatch imaging patterns

# Development of Stroke Centers

*Acute Stroke Care and Stroke Prevention via Clinical Training in the following areas:*

- Neurorehabilitation
- Echocardiography
- Sonology, Telemetry, Holter Monitoring (Ultrasound, TCD)
- Neuroradiology
- Neuropathology
- Varied Research Opportunities
- State of the Art Neuroradiology & Neurointervention
- Vascular Neurology Emergency Care
- Neurocritical Care
- Stroke Prevention Clinic

Program: University of Massachusetts



**Susanne Muehlschlegel, MD**  
Neurocritical Care & Treatment,  
Transcranial Doppler, Research



**Shashi Nanjundaswamy, MD**  
Clinical Trials, Acute  
Stroke Care & Prevention



**Muhammed Ramzan, MD**  
Acute Stroke Care &  
Prevention



**Jane Morris, MD**  
Clinical Trials, Acute  
Stroke Care & Prevention



**David Paydarfar, MD**  
Stroke-related Autonomic  
Dysfunction



**Wiley Hall, MD**  
Neurocritical Care &  
Telemedicine



**Ajay Wakhloo, MD**  
Neurointerventional  
Radiology & Prevention



**Marc Fisher, MD**  
Animal Modeling  
Research



**Majaz Moonis, MD, FAAN**  
Clinical Trials &  
Stroke Outcomes  
Research

Formation of a team at UMASS

> 60 people involvement at various levels including administration, MBAs, physicians, PA, NP, technologist

Goal:  
Duplication of STEMI project UMASS



# Market Size and Development

J.P.Morgan

North America Equity Research  
13 October 2015

**Table 1: Stent Retriever Trials That Didn't Include Modern Endpoints or Patient Selection**

	<b>SWIFT 2012</b>	<b>TREVO 2012</b>	<b>STAR 2012</b>	<b>NASA Registry 2013</b>
Number of Patients	89	88	202	354
TICI 2b/3 (Partial and Complete Revascularization)	76%	68%	85%	73%
Puncture to Revascularization	-	-	-	50 min
Symptomatic Intracranial Hemorrhage	8.6%	9.0%	7.5%	-
Modified Rankin Score $\leq 2$ at 90 Days	36%	40%	55%	42%

Source: Turk et al. Journal of NeuroInterventional Surgery 2014

**Table 2: Stent Retriever Trials with Modern Endpoints and Patient Selection Compared to MULTI MERCI**

	<b>MULTI MERCI 2005</b>	<b>MR CLEAN 2014</b>	<b>ESCAPE 2015</b>	<b>SWIFT PRIME 2015</b>	<b>EXTEND IA 2015</b>
Device	Merci	Mostly Stent Retriever	Mostly Stent Retriever	Solitaire FR	Solitaire FR
% Stent Retrievers	100%	82%	86%	100%	100%
Number of Patients	81	233	165	98	35
Trial Completion	Completed	Completed	Stopped Early	Stopped Early	Stopped Early
Average ASPECTS Score	-	9 (7-10)	9 (8-10)	9 (7-10)	-
TICI 2b/3 (Partial and Complete Revascularization)	70%	59%	72%	88%	86%
TICI 3 (Complete Revascularization)	14%	24%	-	69%	48%
Puncture to Revascularization	91 min	-	33 min	29 min	43 min
Symptomatic Intracranial Hemorrhage	8.0%	7.7%	3.6%	1.0%	0.0%
Modified Rankin Score $\leq 2$ at 90 Days	27%	33%	53%	60%	72%

Source: Smit et al. *Stroke* 2005; Berkhemer et al. *NEJM* 2015; Goyal et al. *NEJM* 2015; Jahan et al. *NEJM* 2015; Campbell et al. *NEJM* 2015

**Table 5: J.P. Morgan US Stroke Market Model**

	2014	2015E	2016E	2017E	2018E	2019E	2020E
US Stroke Patients	795,000	818,850	843,416	868,718	894,780	921,623	949,272
% Ischemic	87%	87%	87%	87%	87%	87%	87%
US Ischemic Stroke Patients	691,650	712,400	733,771	755,785	778,458	801,812	825,866
% Large Vessel Strokes	43%	43%	43%	43%	43%	43%	43%
US Large Vessel Strokes	297,410	306,332	315,522	324,987	334,737	344,779	355,122
% Treatable with Salvageable Tissue	50%	50%	50%	50%	50%	50%	50%
US Ischemic Stroke Patients with ELVO	148,705	153,166	157,761	162,494	167,369	172,390	177,561
% of US Ischemic ELVO Patients Treated	7.9%	11.5%	13.8%	17.3%	21.0%	25.0%	28.5%
<b>US Ischemic ELVO Patients Treated</b>	<b>11,750</b>	<b>17,616</b>	<b>21,695</b>	<b>28,033</b>	<b>35,150</b>	<b>43,100</b>	<b>50,608</b>

**Table 6: J.P. Morgan European Stroke Market Model**

	2014	2015E	2016E	2017E	2018E	2019E	2020E
Total EU Stroke Patients	800,000	800,000	800,000	800,000	800,000	800,000	800,000
% Ischemic	85%	85%	85%	85%	85%	85%	85%
EU Ischemic Stroke Patients	680,000	680,000	680,000	680,000	680,000	680,000	680,000
% Large Vessel Strokes	40%	40%	40%	40%	40%	40%	40%
EU Large Vessel Strokes	272,000	272,000	272,000	272,000	272,000	272,000	272,000
% Treatable with Salvageable Tissue	50%	50%	50%	50%	50%	50%	50%
EU Ischemic Stroke Patients with ELVO	136,000	136,000	136,000	136,000	136,000	136,000	136,000
% of EU Ischemic ELVO Patients Treated	7.5%	15.0%	21.0%	27.5%	34.0%	41.0%	48.0%
<b>EU Ischemic ELVO Patients Treated</b>	<b>10,250</b>	<b>20,450</b>	<b>28,610</b>	<b>37,450</b>	<b>46,290</b>	<b>55,810</b>	<b>65,330</b>

**Table 7: US Stroke Market Shares**

	2014	2015E	2016E	2017E	2018E	2019E	2020E
<b><u>US Aspiration Catheter Sales</u></b>							
Penumbra	35.3	50.8	59.3	72.2	85.1	98.9	109.8
Other	2.5	6.0	10.9	18.6	29.1	41.4	55.3
<b>Total US Sales</b>	<b>\$37.8</b>	<b>\$56.8</b>	<b>\$70.1</b>	<b>\$90.8</b>	<b>\$114.2</b>	<b>\$140.3</b>	<b>\$165.1</b>
Penumbra	94%	90%	85%	80%	75%	71%	67%
Other	6%	11%	16%	21%	26%	30%	34%
<b><u>US Stent Retriever Sales</u></b>							
Medtronic	41.0	60.0	69.4	81.1	91.9	101.4	106.8
Stryker	22.1	33.5	39.6	48.8	58.5	68.3	76.3
Penumbra	0.0	0.0	0.0	2.7	6.3	10.8	15.9
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total US Sales</b>	<b>\$63.1</b>	<b>\$93.5</b>	<b>\$109.0</b>	<b>\$132.6</b>	<b>\$156.7</b>	<b>\$180.5</b>	<b>\$199.1</b>
Medtronic	65%	64%	64%	61%	59%	56%	54%
Stryker	35%	36%	36%	37%	37%	38%	38%
Penumbra	0%	0%	0%	2%	4%	6%	8%
Other	0%	0%	0%	0%	0%	0%	0%
<b><u>Total US Stroke Market</u></b>							
Penumbra	35.3	50.8	59.3	74.9	91.3	109.7	125.7
Medtronic	41.0	60.0	69.4	81.1	91.9	101.4	106.8
Stryker	22.1	33.5	39.6	48.8	58.5	68.3	76.3
Other	2.5	6.0	10.9	18.6	29.1	41.4	55.3
<b>US Stroke Market</b>	<b>\$100.9</b>	<b>\$150.3</b>	<b>\$179.1</b>	<b>\$223.5</b>	<b>\$270.8</b>	<b>\$320.8</b>	<b>\$364.1</b>
Penumbra	35%	34%	33%	34%	34%	34%	35%
Medtronic	41%	40%	39%	36%	34%	32%	29%
Stryker	22%	22%	22%	22%	22%	21%	21%
Other	2%	4%	6%	8%	11%	13%	15%

**Table 8: OUS Stroke Market Shares**

	2014	2015E	2016E	2017E	2018E	2019E	2020E
<b><u>OUS Aspiration Catheter Sales</u></b>							
Penumbra	32.0	46.3	55.4	63.9	72.4	80.0	86.9
Other	10.0	12.1	19.4	28.5	38.9	51.2	66.0
<b>Total US Sales</b>	<b>\$42.0</b>	<b>\$58.5</b>	<b>\$74.8</b>	<b>\$92.4</b>	<b>\$111.3</b>	<b>\$131.2</b>	<b>\$152.9</b>
Penumbra	76%	79%	74%	69%	65%	61%	57%
Other	24%	21%	26%	31%	35%	39%	43%
<b><u>OUS Stent Retriever Sales</u></b>							
Medtronic	39.0	51.9	63.3	74.2	84.3	93.4	101.8
Stryker	22.1	33.5	42.3	51.3	60.0	68.7	77.2
Penumbra	0.0	0.4	1.4	2.8	4.4	6.2	8.3
Other	32.5	41.7	50.9	59.7	67.5	74.7	81.2
<b>Total US Sales</b>	<b>\$93.6</b>	<b>\$127.5</b>	<b>\$157.9</b>	<b>\$188.0</b>	<b>\$216.2</b>	<b>\$243.1</b>	<b>\$268.5</b>
Medtronic	42%	41%	40%	39%	39%	38%	38%
Stryker	24%	26%	27%	27%	28%	28%	29%
Penumbra	0%	0%	1%	2%	2%	3%	3%
Other	35%	33%	32%	32%	31%	31%	30%
<b><u>Total OUS Stroke Market</u></b>							
Penumbra	32.0	46.7	56.8	66.8	76.7	86.2	95.1
Medtronic	39.0	51.9	63.3	74.2	84.3	93.4	101.8
Stryker	22.1	33.5	42.3	51.3	60.0	68.7	77.2
Other	42.5	53.9	70.3	88.1	106.4	125.9	147.2
<b>OUS Stroke Market</b>	<b>\$135.6</b>	<b>\$186.0</b>	<b>\$232.7</b>	<b>\$280.4</b>	<b>\$327.4</b>	<b>\$374.3</b>	<b>\$421.3</b>
Penumbra	24%	25%	24%	24%	23%	23%	23%
Medtronic	29%	28%	27%	26%	26%	25%	24%
Stryker	16%	18%	18%	18%	18%	18%	18%
Other	31%	29%	30%	31%	32%	34%	35%

# STAIR IX

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

## Acute Stroke Trials: Advancing Design, Regulation and Implementation

October 5-6, 2015  
Bethesda Marriott Hotel  
Bethesda, Maryland

### 1. Consensus Statement on Imaging Selection and Outcomes in Acute Stroke Reperfusion Clinical Trials

Steven J. Warach, Marie Luby, Gregory W. Albers, et al. for the STAIR IX Consortium

### 2. STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE - The Next Generation of Endovascular Trials

Tudor G. Jovin<sup>1</sup>, MD, Gregory W. Albers<sup>2</sup>, MD, David S. Liebeskind<sup>3</sup>, MD for the STAIR IX Consortium

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The Stroke Imaging Repository (STIR) Consortium  
The Foundation of the American Society of Neuroradiology

thestair.org

Organized &  
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The Stroke  
Group

In the MR CLEAN trial, the key imaging findings included a

1) clear benefit of endovascular therapy for NCCT ASPECTS scores of 5-10

2) good and moderate collateral score was also associated with a large benefit of endovascular therapy

3) Perfusion CT (PCT) mismatch (CBV and MTT thresholds) predicted functional outcome, the relative treatment effect in patients with and without mismatch was similar.

4) The use of an ischemic core volume  $>70\text{mL}$  on PCT criterion did identify a group of patients with very low rates of independent outcome (1/13 [8%])

# Proposed imaging methods for patient selection

TRAIT	Proposed imaging methods
Artery occlusion	<ul style="list-style-type: none"><li>• CTA</li><li>• MRA</li><li>• Catheter angiography</li></ul>
Core	<ul style="list-style-type: none"><li>• ASPECTS on NCCT</li><li>• Volume of severely decreased CBV or CBF from PCT</li><li>• Volume of acute DWI lesion from MRI</li></ul>
Mismatch	<ul style="list-style-type: none"><li>• Volume of perfusion lesion (by PCT, MRP or ASL) to core volume</li></ul>
Cerebral collaterals	<ul style="list-style-type: none"><li>• CTA source images</li><li>• Single- or multiphasic CTA</li><li>• Contrast-enhanced MRA</li><li>• Catheter angiography</li></ul>

# I. Imaging Selection

## 1. Non contrast CT (NCCT) ASPECTS \*

0-4 poor outcome

> 6 good outcome

>70 mL ischemic core volume

predict low rate of independent  
outcome (<10% mRS 0-2)

Orbito-meatal line

FOV 240mm

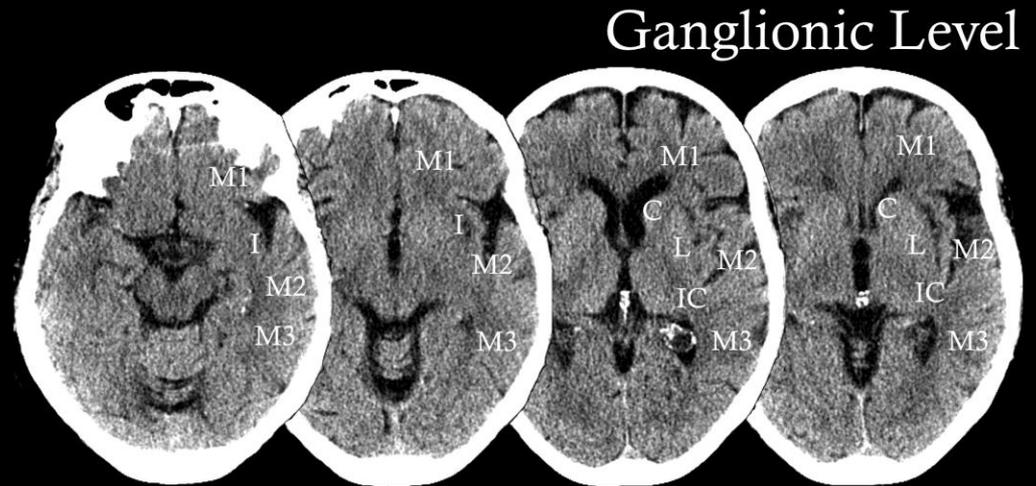
KV 140

mAS 450

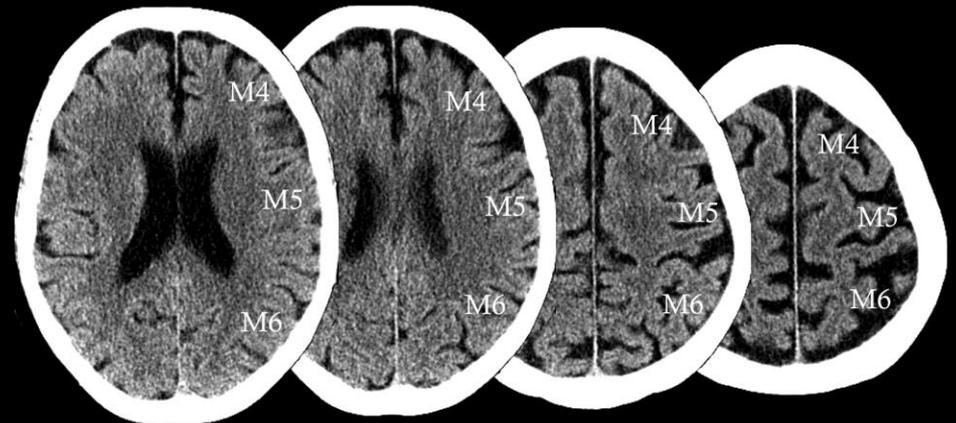
Collimation 1x50

Slice thickness 5mm

Window setting cerebrum and bone



\* Alberta Stroke Program Early CT Score



Supraganglionic Level

# I. Imaging Selection

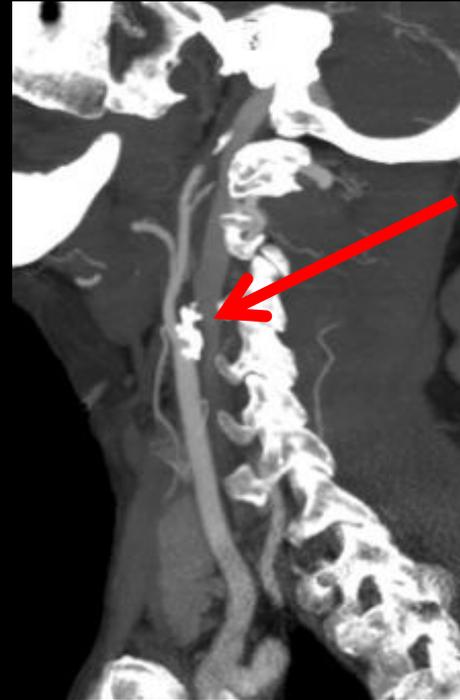
## 2. CT-Angiography (multiphase)

### Extracranial

occlusion (CAS)  
tortuosity  
selection of access products

### Intracranial

occlusion site  
occlusion length  
plaque characteristics  
collaterals  
(poor, moderate, good)

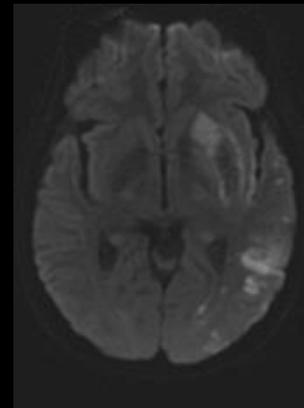


extracranial  
R ICA occlusion



## 3. Role of MRI/DWI/FLAIR

posterior circulation  
delayed treatment (>6 hrs)  
CT questionable  
MRI availability



# I. Imaging Selection

## 4. Role of collaterals

poor  
moderate  
excellent

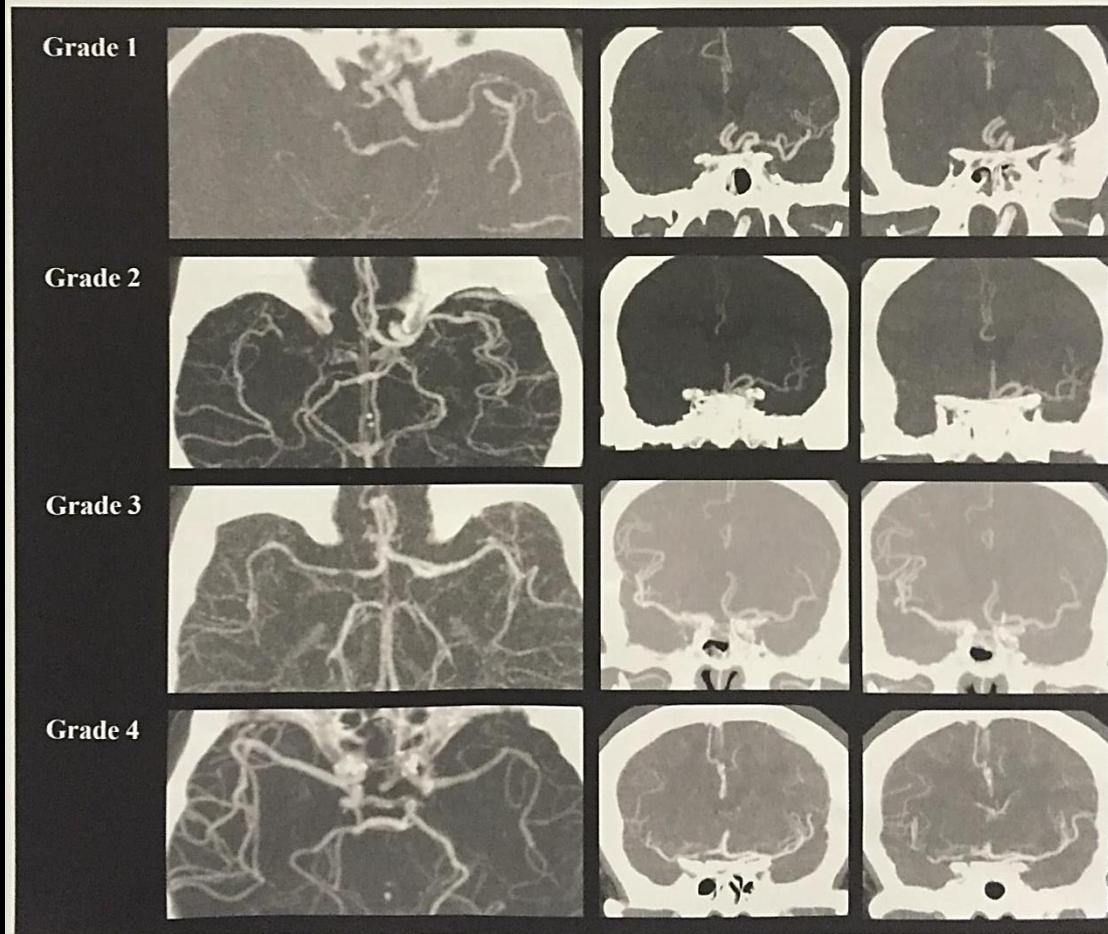
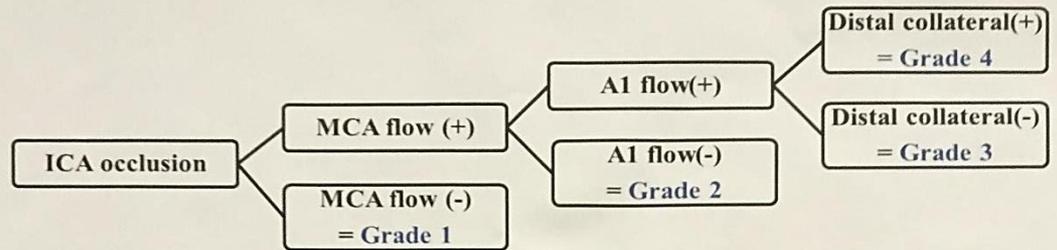


Figure1. Collateral grades system assessed by CTA in ICA occlusion

# Paradigm shift related to Collaterals

- IMS 3: every **30 min** delay in reperfusion is associated with a **10% relative reduction** in probability of good clinical outcome (mRS 0-2, Khatri et al.)
- REVASCAT: **5% reduction for every 30 min** delay (Tudor et al.)



# I. Imaging Selection

## 5. CT-Perfusion

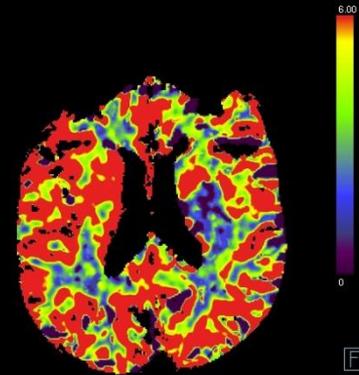
Cerebral Blood Volume (CBV)

Cerebral Blood Flow (CBF)

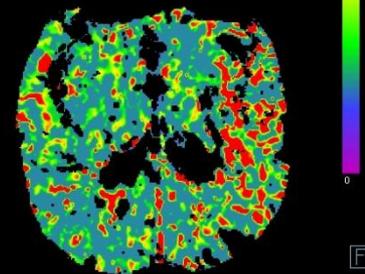
Mean Transit Time (MTT)

Time to Peak (TTP)

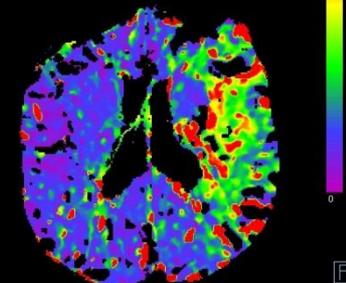
Time to Drain (TTD)



CBV



MTT



TTD

# Stroke CBV

## Case #11

Female, 78 y/o

NIHSS: 20

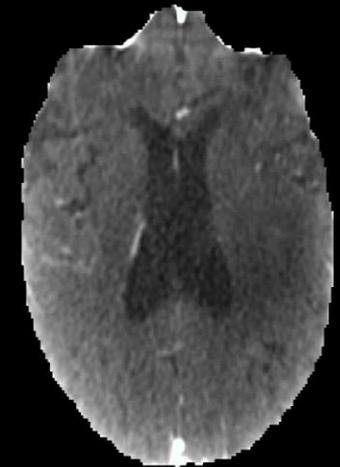
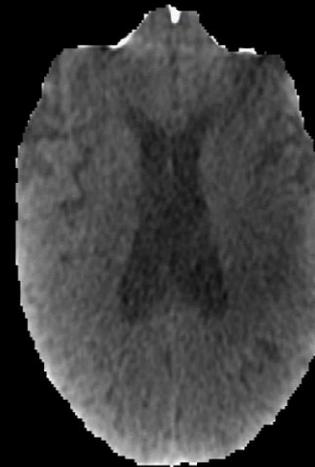
Left MCA mid-distal M2-segment

i.v. TPA

Thrombectomy/aspiration (TICI 3)

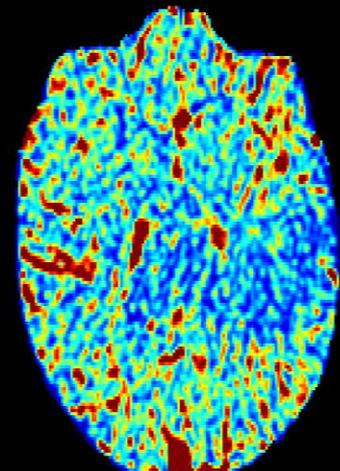
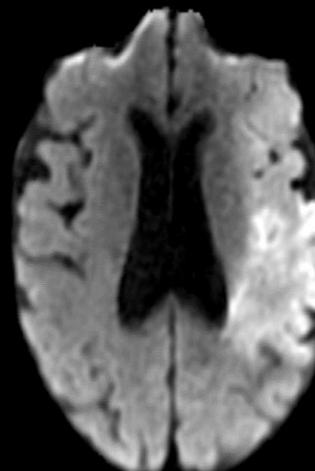
XperCT  
no contrast

XperCT  
with contrast



Pre-treatment MRI  
DWI

XperCT  
CBV

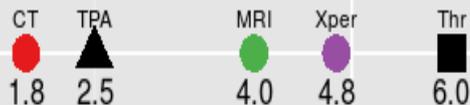


### Imaging

- CT
- CT+Perfusion
- MRI
- XperCT-CBV

### Treatment

- ▲ IV-TPA
- Thrombectomy



Time since LKW (hours)

# Stroke

## CBV

### Case #21

Female, 37 y/o

NIHSS: 21

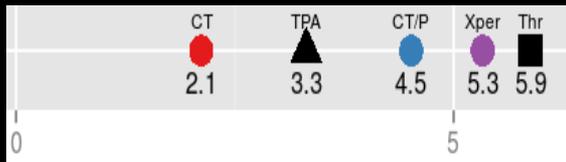
ASPECTS: 6-7/10

Mismatch CBV-CBF on CT Perfusion

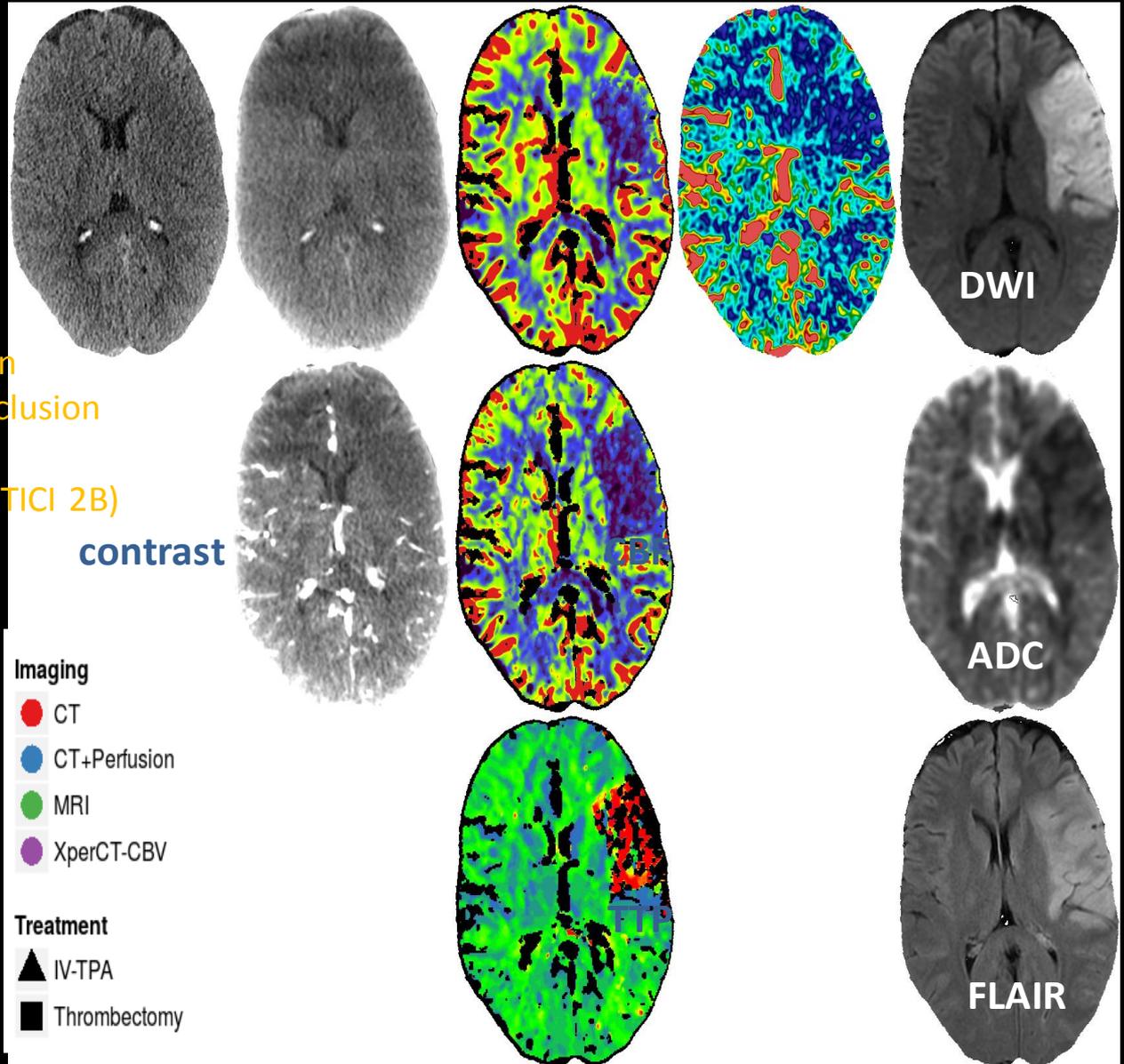
Left M2/MCA superior division occlusion

i.v. TPA

2-pass thrombectomy/aspiration (TICI 2B)



Head CT    XperCT    CT Perfusion    XperCT    MRI  
no contrast no contrast    CBV    CBV    follow-up



# II. Anesthesia

## 1. Conscious Sedation

Cooperative patients  
Non-dominant hemisphere

## 2. MAC

Not cooperative patient  
Dominant hemisphere  
Posterior circulation

## 3. GA Intracranial

Not cooperative patient  
Dominant hemisphere  
Posterior circulation  
Large infarct

Blood pressure control (systol >  
160 mm Hg until revasc)

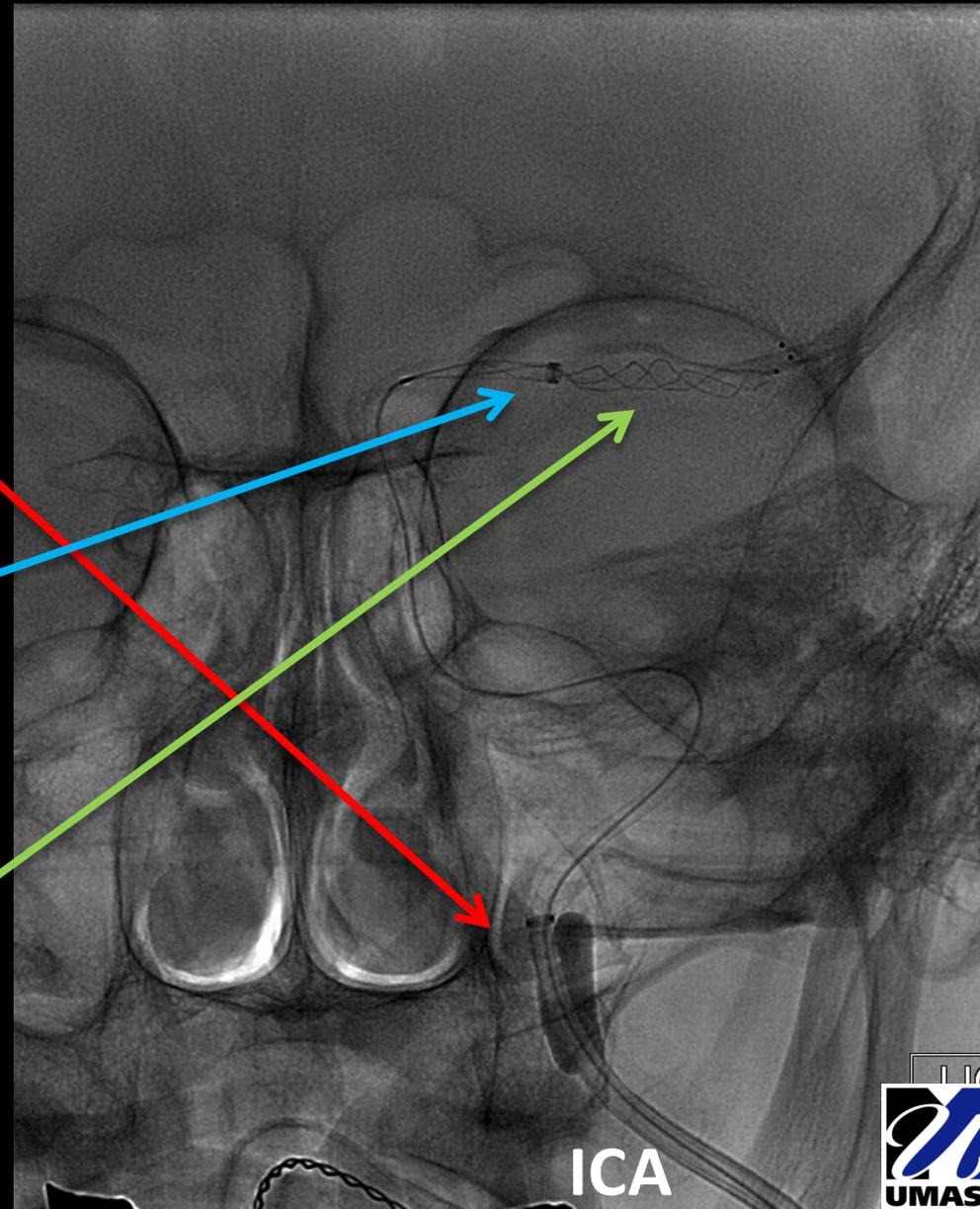
A-line generally not needed

Airways protection

NG tube for antiplatelets if needed

# III. Technology and IV. Techniques

1. Femoral Access 8 F Sheath
2. 8 F Balloon Guide Catheter
3. 6 F Intermediate catheter for suction
4. Microcatheter over microwire
5. Thrombectomy device



## II. Solitaire/Trevo mechanical Thrombectomy Device Selection

# Stent-like clot retriever

VASCULAR

Technique and Application

## RETRIEVABLE CLOSED CELL INTRACRANIAL STENT FOR FOREIGN BODY AND CLOT REMOVAL

**Ajay K. Wakhloo, M.D., Ph.D.**

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Neurosurgery, and Neurology,  
University of Massachusetts  
Medical School,  
Worcester, Massachusetts

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Department of Radiology,  
University of Massachusetts  
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**Reprint requests:**

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Departments of Radiology, Neurology,  
and Neurological Surgery,  
University of Massachusetts  
Medical School,  
55 Lake Avenue North,  
Worcester, MA 02481.  
Email: wakhlooA@ummhc.org

**OBJECTIVE:** To assess the technical feasibility of using a retrievable, closed cell intracranial stent delivered through a microcatheter for safe removal of foreign bodies or clot.

**METHODS:** In vitro and in vivo testing were performed to demonstrate the feasibility of using retrievable intracranial stents for foreign body or clot removal. In vitro testing was performed in an anatomically correct silicone vascular replica by partially deploying the stent around a coil, then retracting the stent into the microcatheter to trap the coil. Withdrawal of the stent delivery system into the guide catheter resulted in coil removal. Subsequently, the technique was evaluated in a porcine model of intracranial aneurysms, wherein both fresh clot and herniated coils were extracted from the carotid arteries.

**RESULTS:** In these experimental procedures, both herniated coils and fresh clot were safely and easily removed from the in vitro and in vivo models. No periprocedural adverse events were observed.

**CONCLUSION:** These in vitro and in vivo studies suggest the potential use of retrievable stents for the removal of foreign bodies or clot from the intracranial circulation.

**KEY WORDS:** Aneurysm, Angiography, Clot, Coil, Endovascular treatment, Retrieval, Stent, Stroke

# Stent-like systems dedicated to remove clots

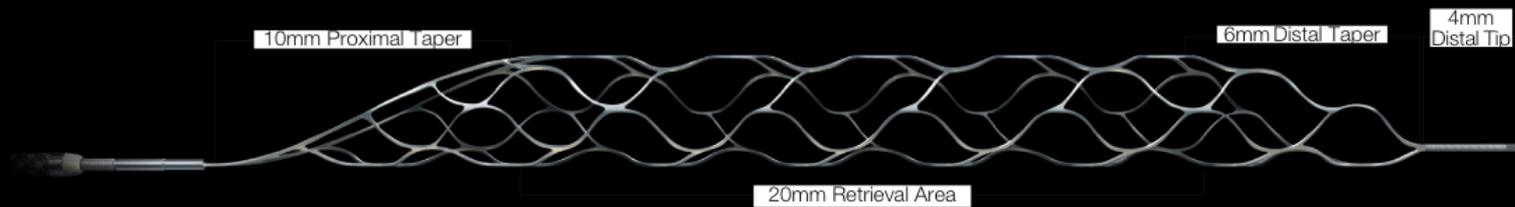


Image courtesy of Stryker Neurovascular  
By Concentric Medical  
"Never Parting" Retrieval System Ltd

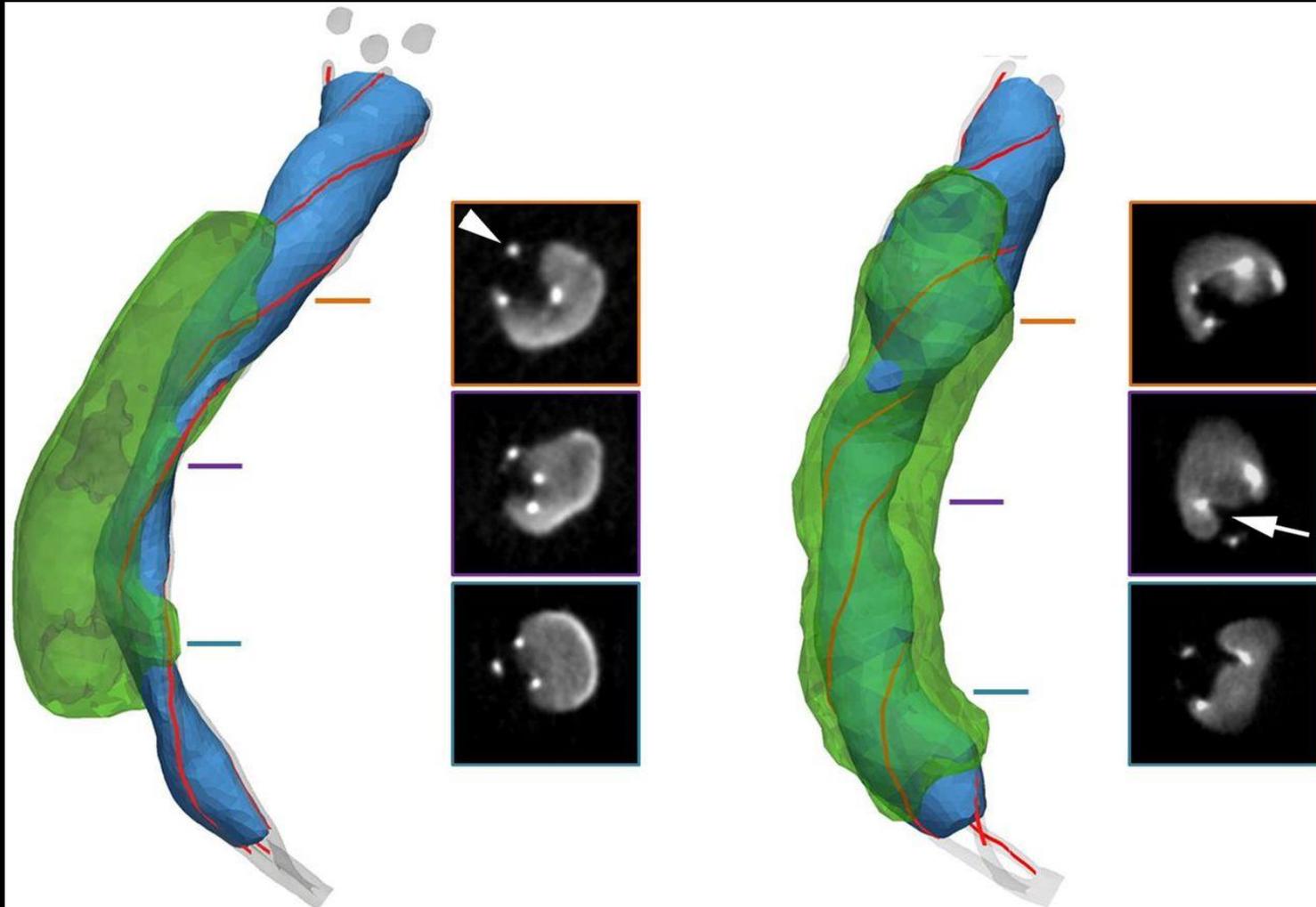
**Trevo® Retriever  
Design**



**Traditional Stent  
Design**



**Representative cases in a hard clot model with different Trevo deployment techniques (left, straight unsheathing; right, initial unsheathing followed by pushing the device and spontaneous retraction of the microcatheter).**



# VasoCT

## Clot Integration Factor

### Related publications:

van der Marel et al.,  
“Quantitative assessment  
of device-clot interaction  
for stent retriever  
thrombectomy”, *J  
Neurointerv Surg* (2016; *in  
press*)

### Conference presentations:

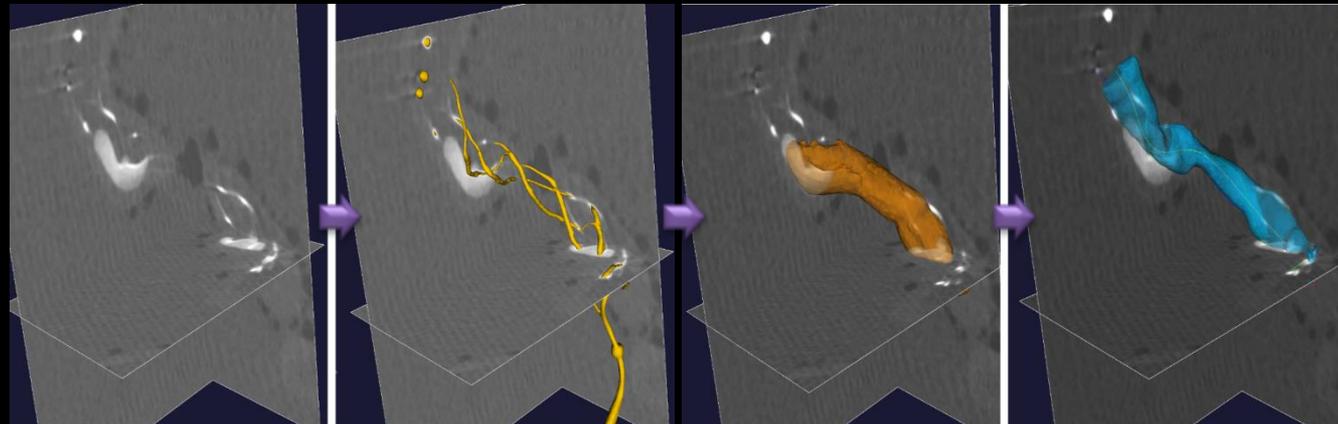
“Clot Integration Factor For In-  
Vitro Quantification Of Stent-  
Retriever Configuration Using  
Cone-beam CT”; *International  
Stroke Conference*; February  
2016 (poster)

“Clot Integration Factor for in-  
vitro quantification of stent-  
retriever configuration using  
cone-beam CT”; *Summer  
Biomechanics, Bioengineering,  
and Biotransport Conference*;  
July 2016 (abstract submitted)

Three marker wires  
Segmented clot  
Intersection device-  
clot



$$\text{Clot Integration Factor} = \frac{\text{Volume of Clot-Device Intersection}}{\text{Volume of Clot}}$$



High-resolution  
reconstruction of  
cone-beam CT image

Extraction of visible  
marker wires

Segmentation of the  
contrast-enriched  
clot

Determination of the  
inner volume of the  
stent-retriever

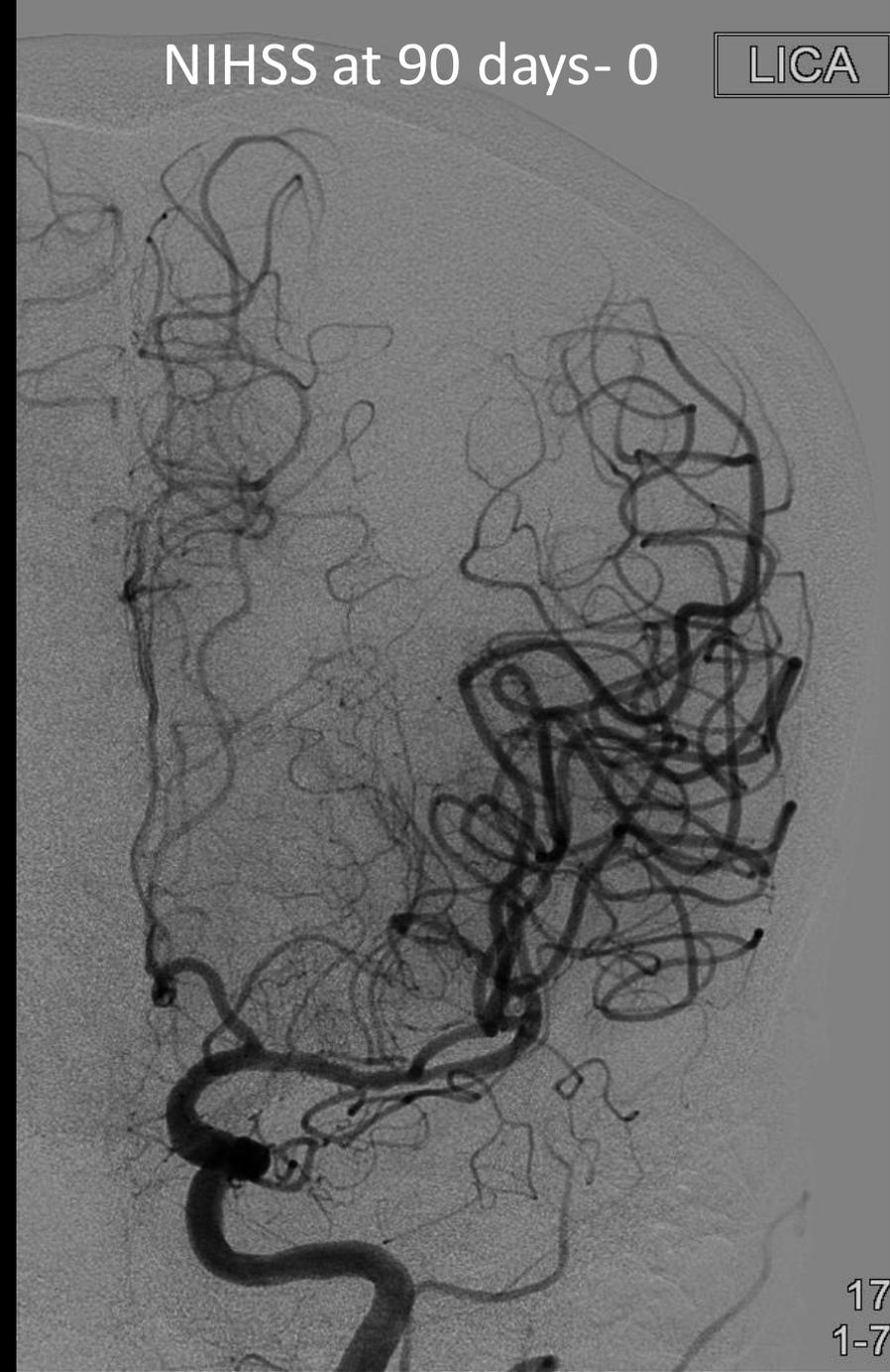
75 year old patient with NIHSS  
of 21.

LICA



NIHSS at 90 days- 0

LICA



17  
1-7



Patient Selection

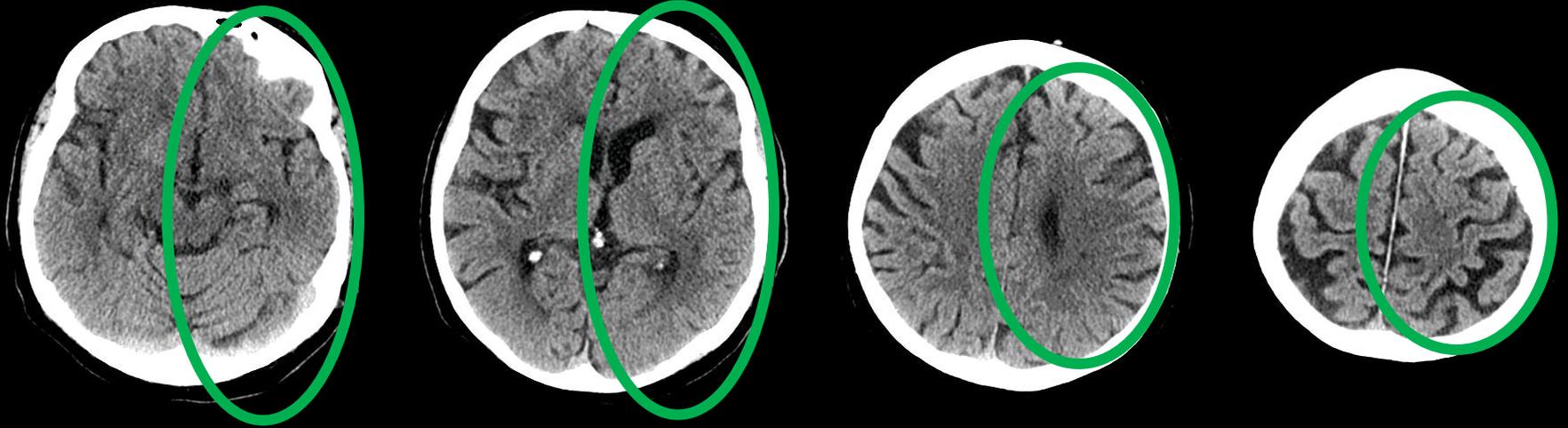
Two Subjects

Clinical Decision Making

# Subject # D.S.

- 91 y o f
- Previous history of exertional dyspnea, HTN, HLD, DM, remote history of smoking mRS=1
- Acute onset of aphasia, right facial droop and right hemiparesis
- At ED new onset of A-Fib
- NIHSS 23

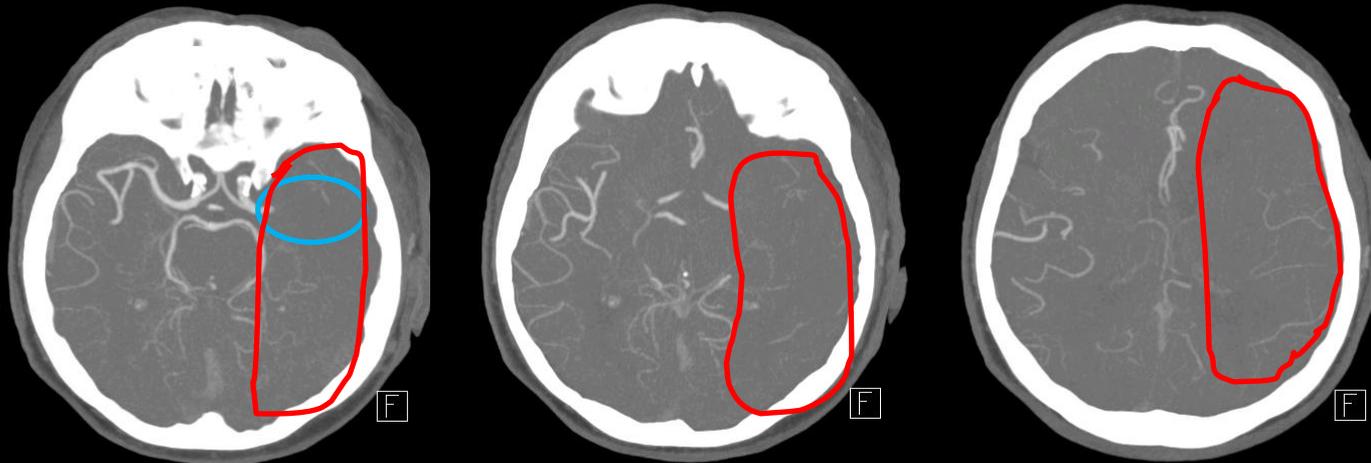
# Imaging



ASPECTS >7

CTA left M1 occlusion

Modest collaterals

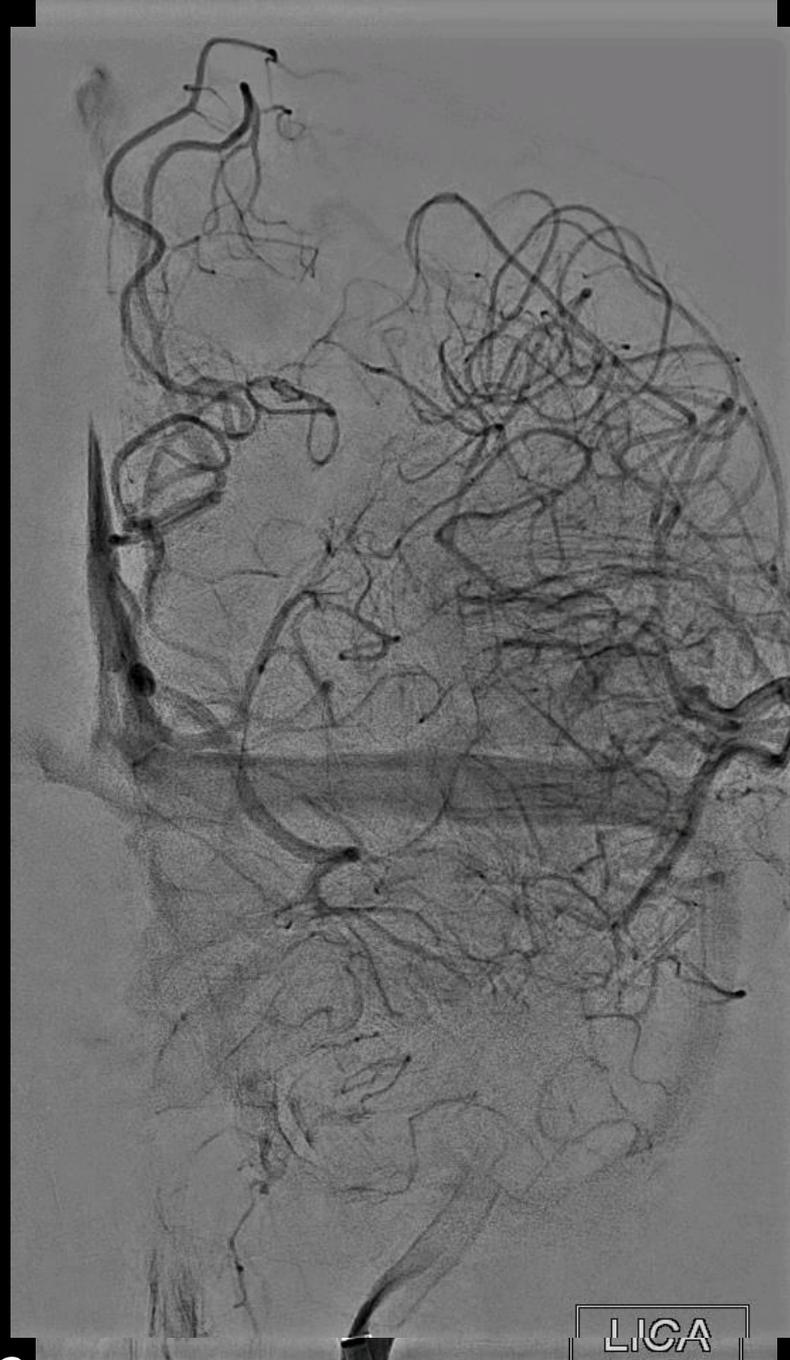
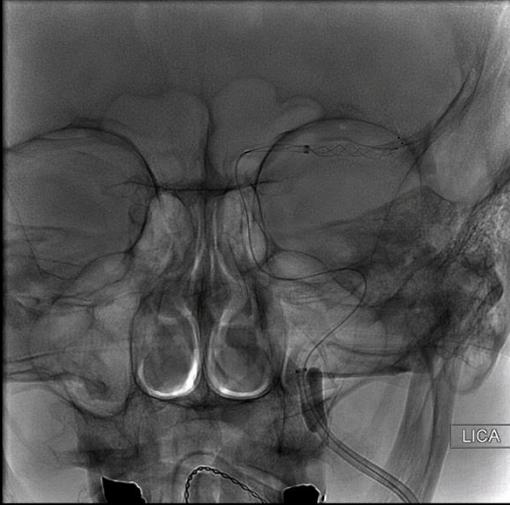


# Treatment

8 F Femoral sheath  
Flowgate 8 F BGC  
ARC 6 F IC catheter  
Trevor 4x20mm , 1 pass



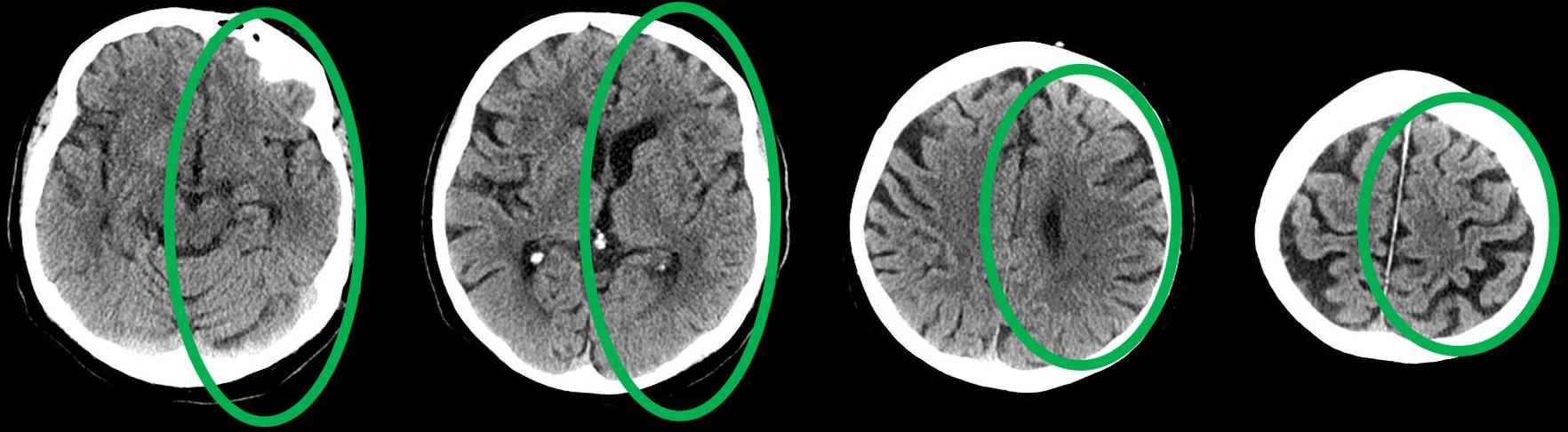
# Treatment



8 F Femoral sheath  
Flowgate 8 F BGC  
ARC 6 IC catheter  
Trevo 4x20mm , 1 pass  
TICI 3

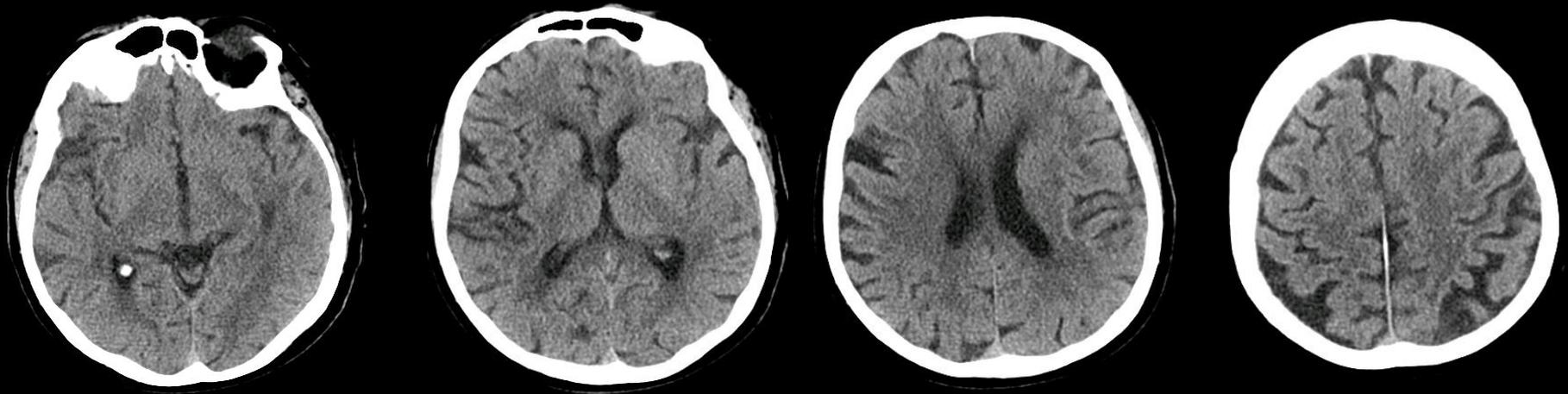
Outcome at 24 hrs: NIHSS 3

# Imaging – Outcome following Thrombectomy



ASPECTS >7 pre treatment

Outcome at 24 hrs: NIHSS 3

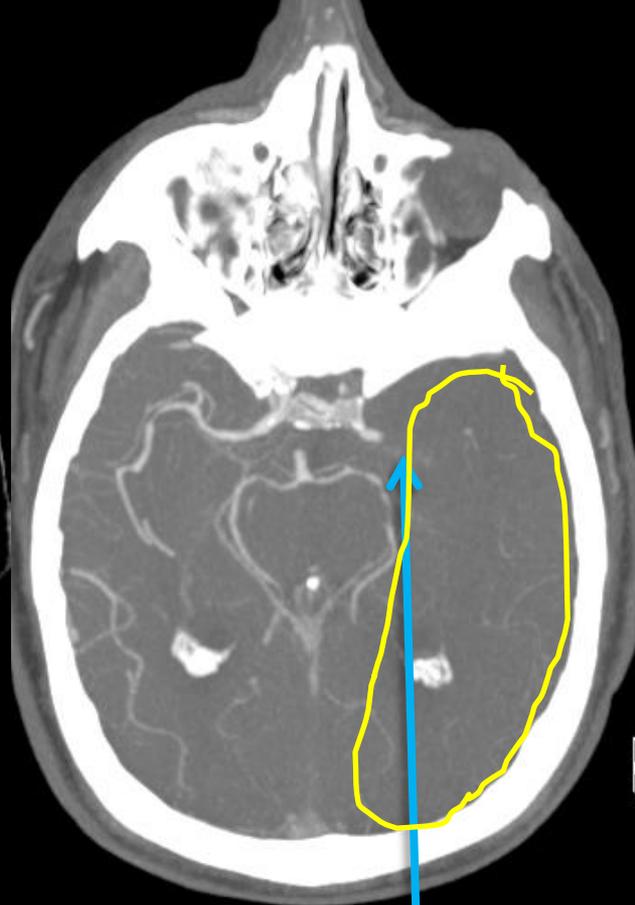


24-hr Follow-up Study

# Subject # J.J.

- 83 y o m
- Early dementia mRS=1
- Acute onset of dysarthria, right facial droop and right hemiparesis
- At outside facility iv t-PA and transferred to UMASS
- NIHSS 28

# Imaging



ASPECTS < 4  
CTA left M1 occlusion  
L ICA occlusion  
Poor collaterals

No intervention

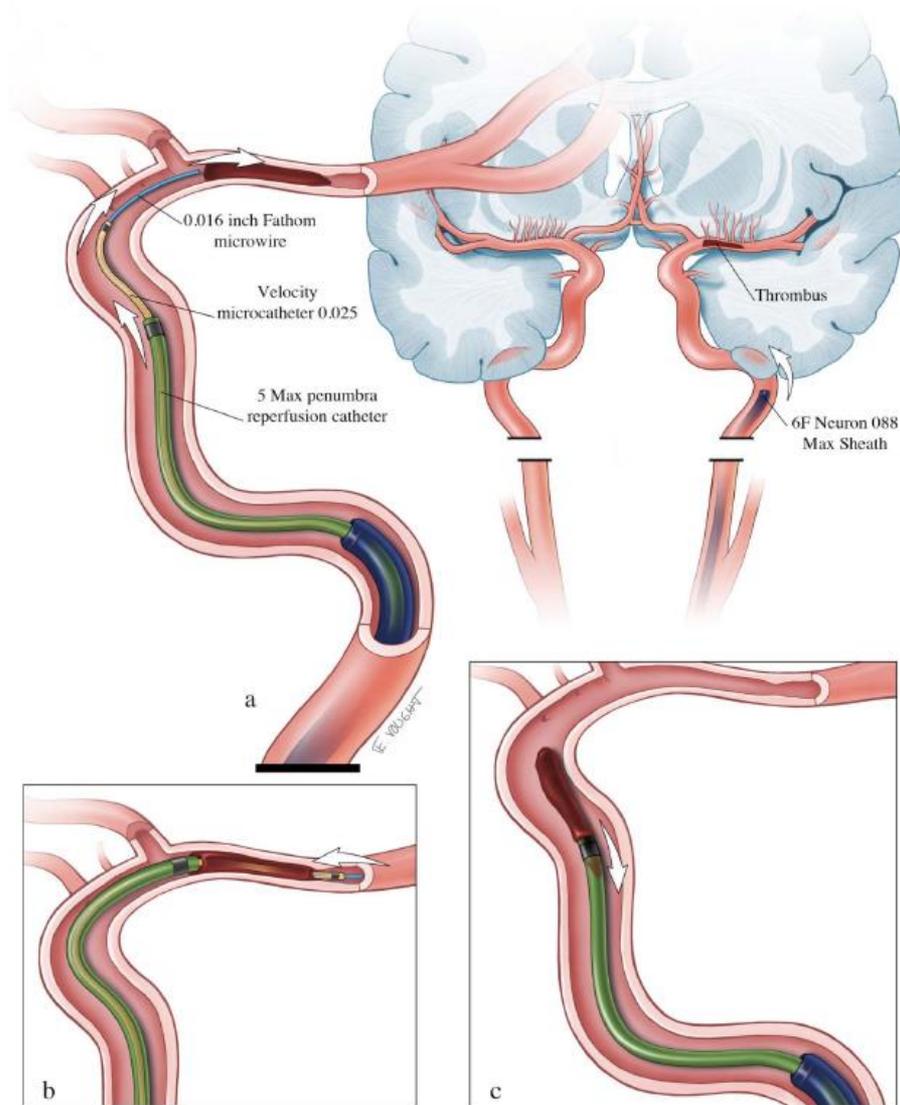
# Evolution of Newer Endovascular Techniques we have adapted

## Few Examples

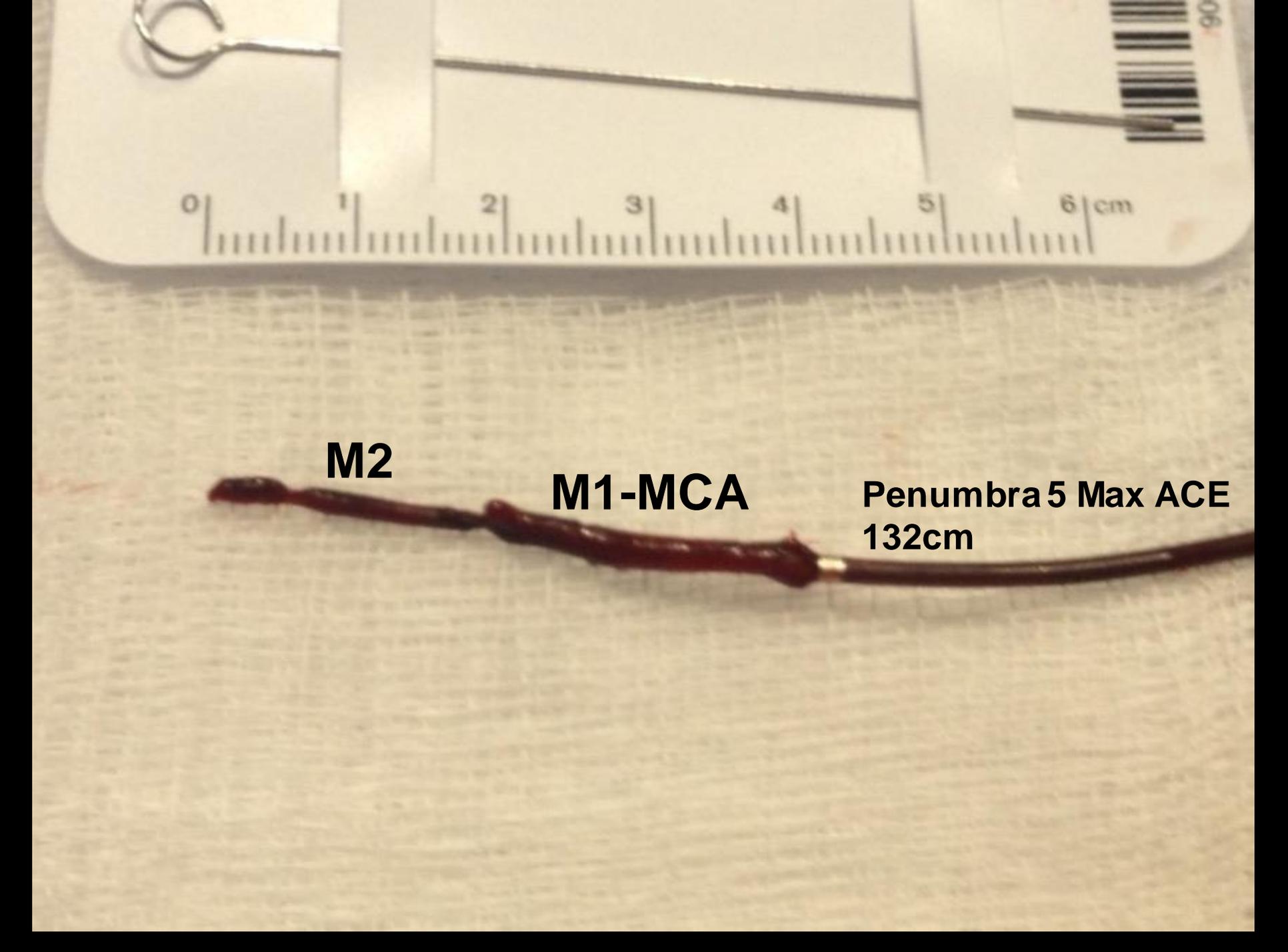
ORIGINAL RESEARCH

## Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy

Aquilla S Turk,<sup>1</sup> Alex Spiotta,<sup>2</sup> Don Frei,<sup>3</sup> J Mocco,<sup>4</sup> Blaise Baxter,<sup>5</sup> David Fiorella,<sup>6</sup>  
Adnan Siddiqui,<sup>7</sup> Maxim Mokin,<sup>7</sup> Michael Dewan,<sup>4</sup> Henry Woo,<sup>6</sup> Raymond Turner,<sup>2</sup>  
Harris Hawk,<sup>1</sup> Amrendra Miranpuri,<sup>1</sup> Imran Chaudry<sup>1</sup>



**Figure 1** Illustration of the ADAPT technique in a middle cerebral artery clot. (A) The Neuron Max guide catheter is positioned as far distally as possible in the supplying internal carotid artery. Through this a 5 Max reperfusion catheter is advanced over a Velocity microcatheter with a 0.016 inch Fathom wire. (B) The Fathom wire and Velocity microcatheter are advanced through and distal to the thrombus to provide stable support for the 5Max to be advanced to the face of the thrombus. (C) Aspiration is applied to the 5 Max until aspiration becomes occlusive and the 5 Max is then removed while maintaining aspiration to ensure the clot remains engaged in the catheter tip.



**M2**

**M1-MCA**

**Penumbra 5 Max ACE  
132cm**

# ARTS (ACE-Retriever Technique for Stroke)

Initial Clinical Experience

# Method

We report a retrospectively collected clinical data utilizing a new recanalization technique based on **combined large lumen aspiration catheter and partially resheathed stent retrievers** for thrombectomy (ARTS: ACE-Retriever Technique for Stroke)

Puri AS et al. SNIS 2015

Chueh JY, Wakhloo AK, Gounis MJ. Effectiveness of mechanical endovascular thrombectomy in a model system of cerebrovascular occlusion. AJNR Am J Neuroradiol 2012;33:1998–2003

## BGC in cervical ICA

Microcatheter past the clot

Advance intermediate catheter proximal to clot over MC

Deploy SR with initial unsheathing and then pushing at the level of the clot

Timer on

Strip micro after 2-3 minutes

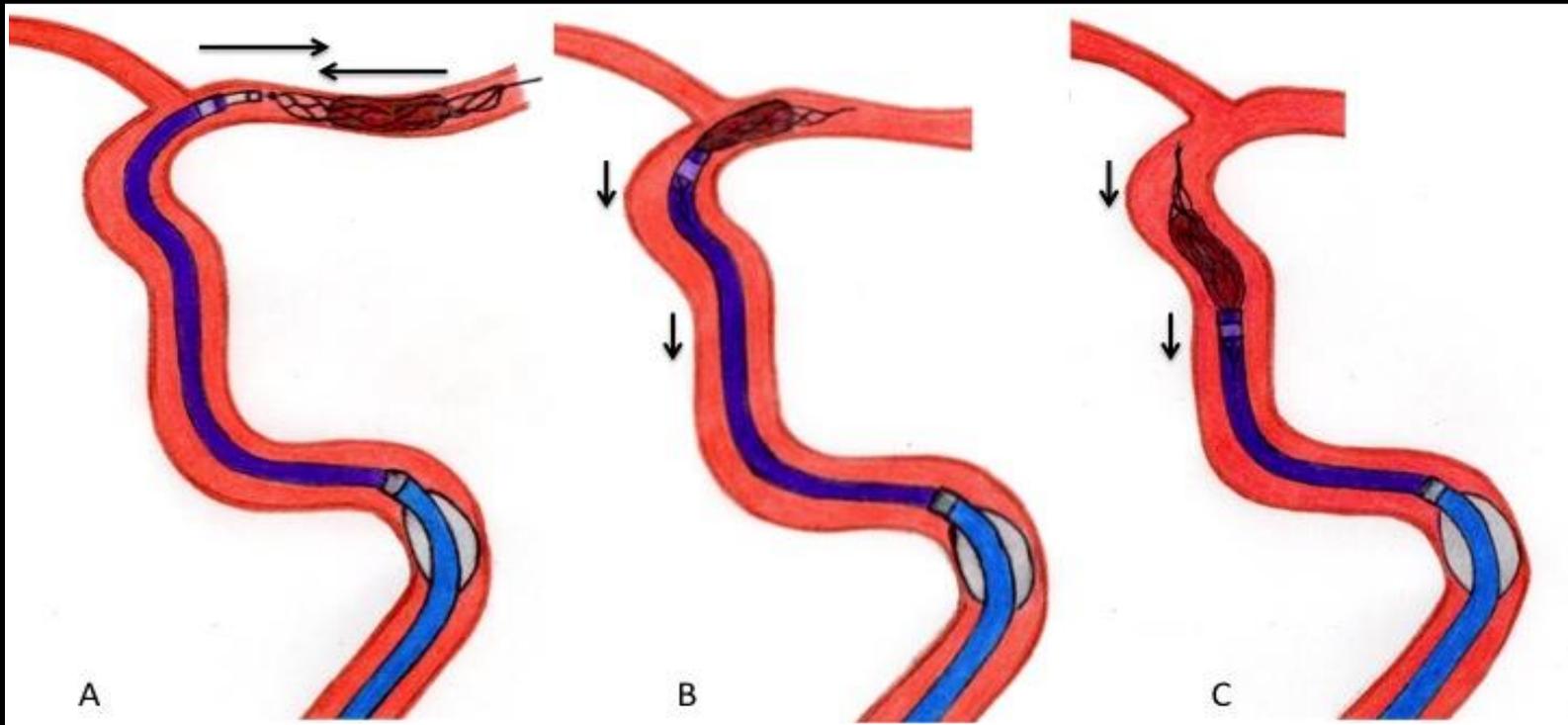
Inflate BGC then connect IGC to aspiration pump (at 4-5 min)

At 4-5 min-Retract SR into IGC till resistance

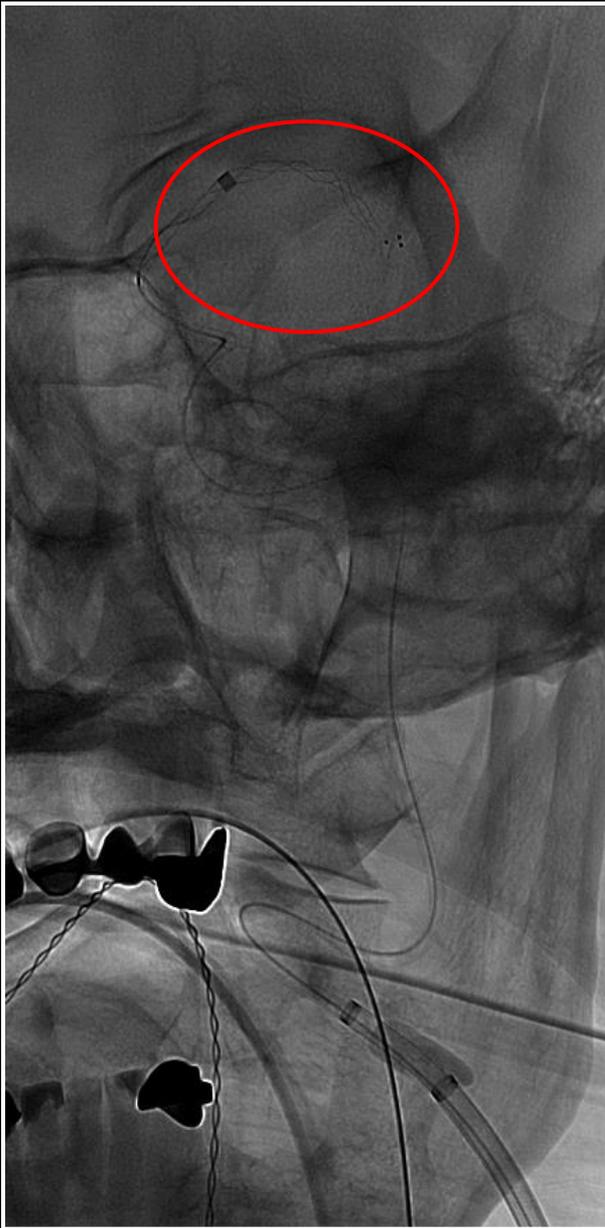
Lock and pull IGC-SR as single assembly under constant aspiration

Aspirate from BGC, deflate BGC and aspirate again (VacLok<sup>®</sup> syringe)

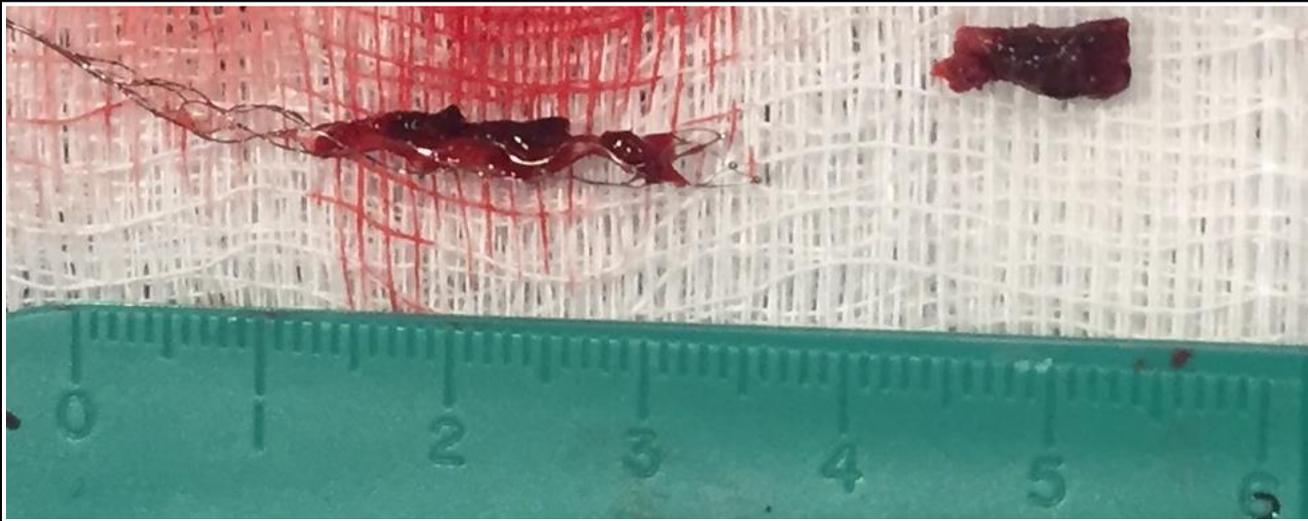
# ARTS & Balloon Guiding Catheter



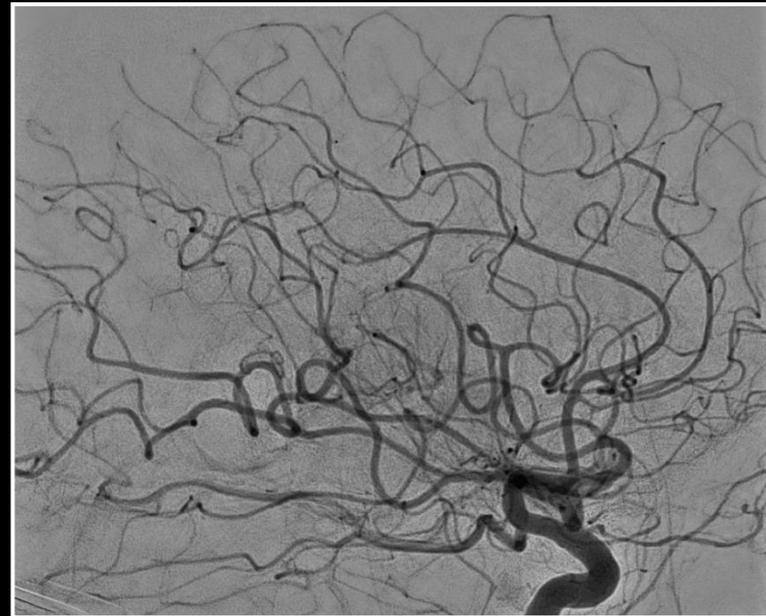
ARTS Illustration



ARTS & Balloon Guiding Catheter



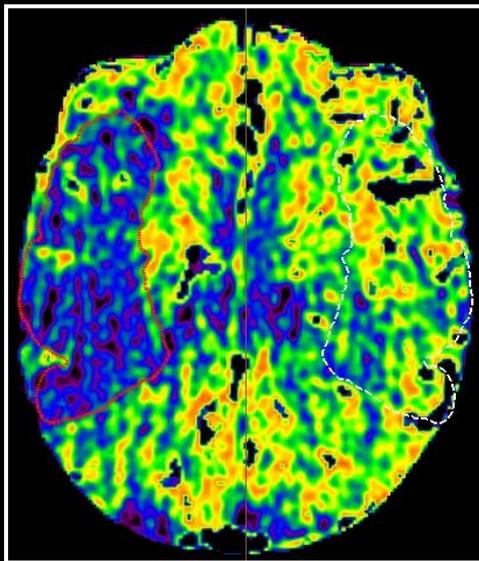
Post-ARTS Clot Removal



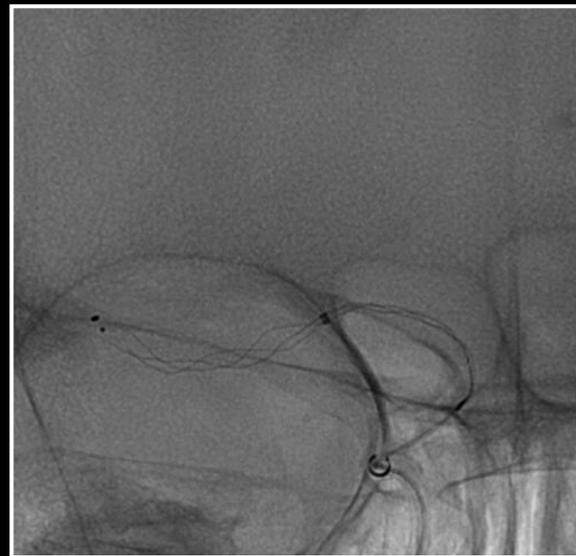
Post-procedural Angiography (TICI 3 recanalization)



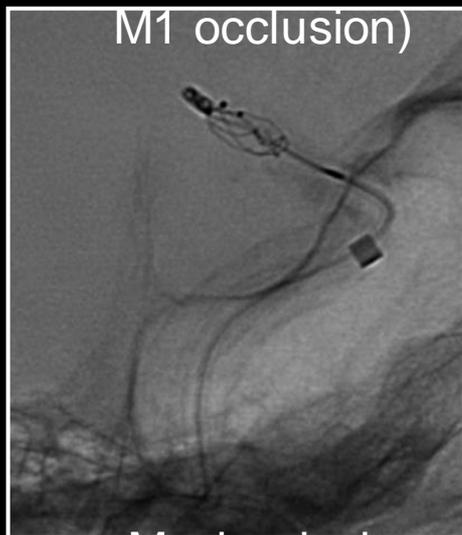
Pre-procedural  
Angiogram  
(distal right MCA  
M1 occlusion)



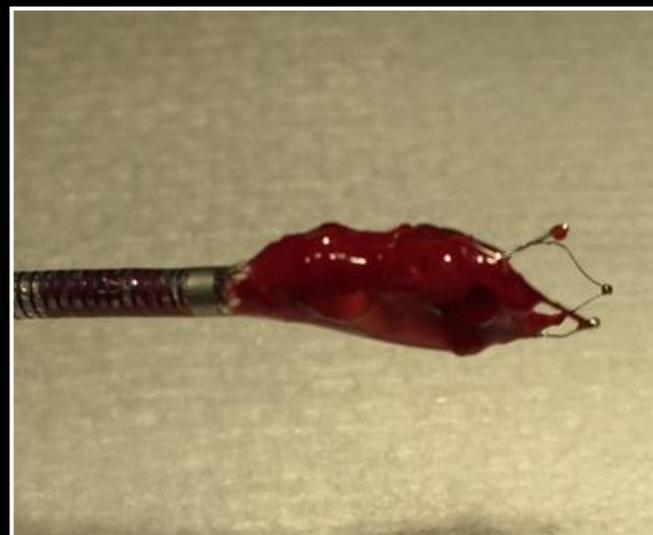
Cone Beam CT  
Perfusion



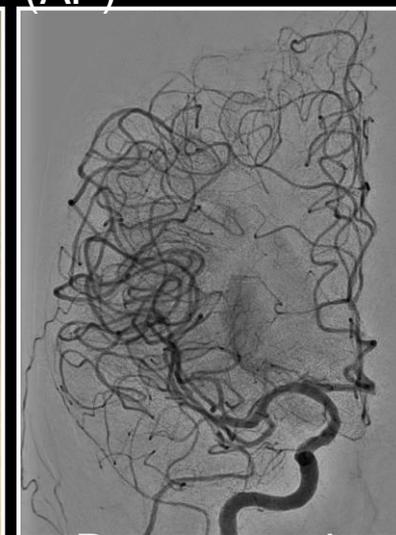
Mechanical  
Thrombectomy  
(AP)



Mechanical  
Thrombectomy  
(LT)



Post-ARTS Clot Removal



Post-procedural  
Angiogram  
(TICI 3 recanalization)

# Distal M2/M2 occlusions

Concentric  
Medical®

Trevo® XP ProVue Retriever REF 93067  
Procedure Pack

Trevo® XP

Contents (1) 4 mm 30 mm

TREVO® XP PROVUE RETRIEVER

Retriever / Extraktor / Genvindingsenhed / Rücknahminstrument / Vältåmbamisvahend / Recuperador / Εργαλείο ανάκτησης / Extracteur / Recuperador / Uslidilje / Verwijderaar / Konkretrekker / Urządzenie do wyjmowania / Recupérator / Извлекающее устройство / odstranjevalnik / Poistoválnik / Upphåtare / Yakalayıcı

Trevo® Pro 18

Contents (1) 150 cm 0.021in ID

MICROCATHETER

Microcatheter, Microcathète, Mikrokatheter, Microcathetere, Mikrokatheter, マイクロカテーテル, Mikrokater, Микрокатетр / τρας, Microcater, Mikrokater, Mikrokäter, Mikrokäter, Mikrocewnik, Mikrokater, 微导管, 마이크로카테터, Mikrokater

Trevo® XP ProVue Retriever REF 93067  
Procedure Pack LOT 38642

Trevo® XP ProVue Retriever REF 93067 LOT 38642  
Trevo® XP ProVue Retriever REF 93067 LOT 38642  
Procedure Pack

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Trevo® XP ProVue Retriever  
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LOT 38642



LA92081-01\_A\_8337  
F09007-001

LABEL STOCK# N000010051-01

CardinalHealth

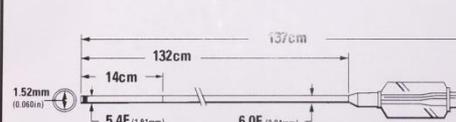
stryker®  
Neurovascular

AXS Catalyst™ 6

Distal Access Catheter

0.060in  
x132cm

Contents (1)



- Includes Tauby-Borst Valve
- Includes Introducer Sheath
- Includes Rotating Membratic Valve

UPN Product No. M0031C0601320

REF Catalog No. IC060132

Use By 2018-03-31

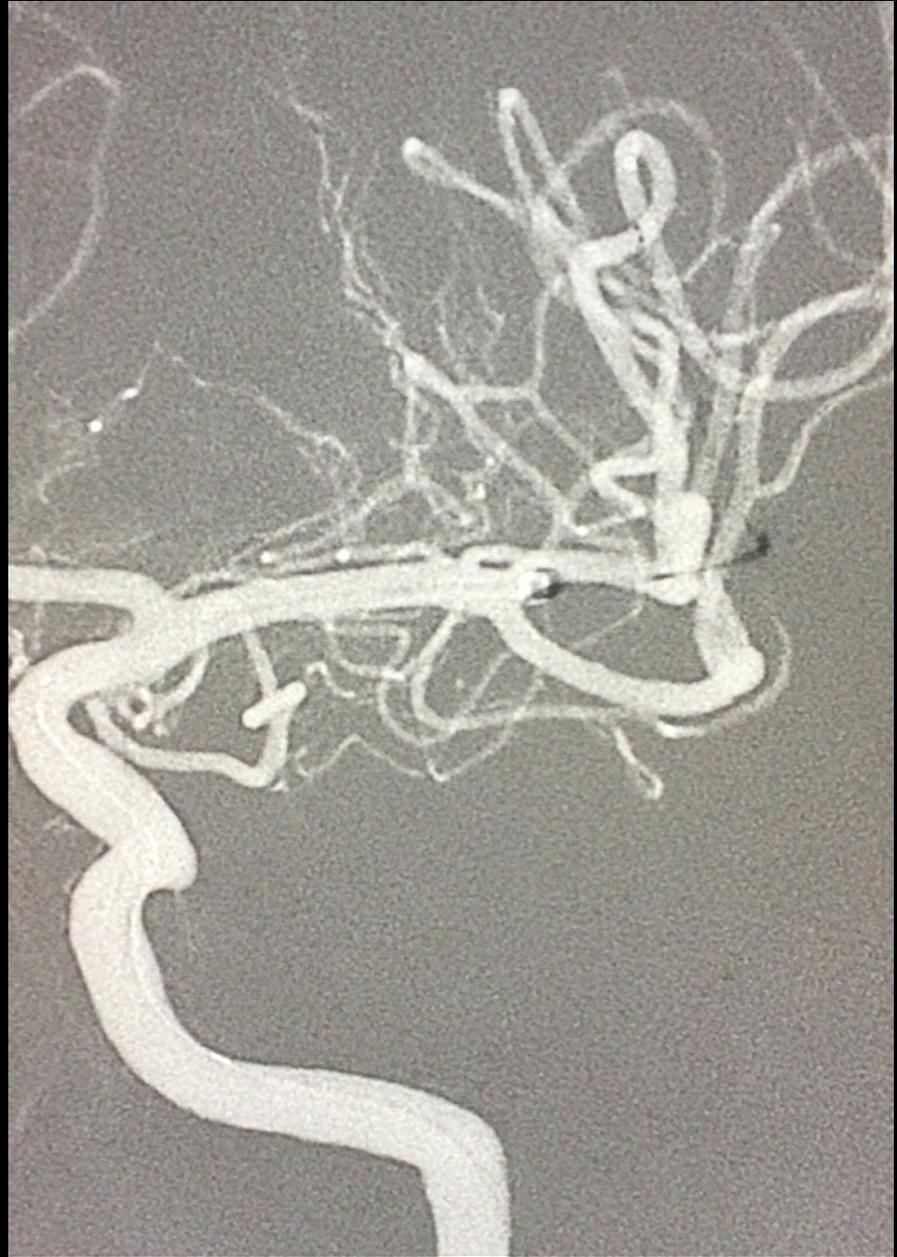
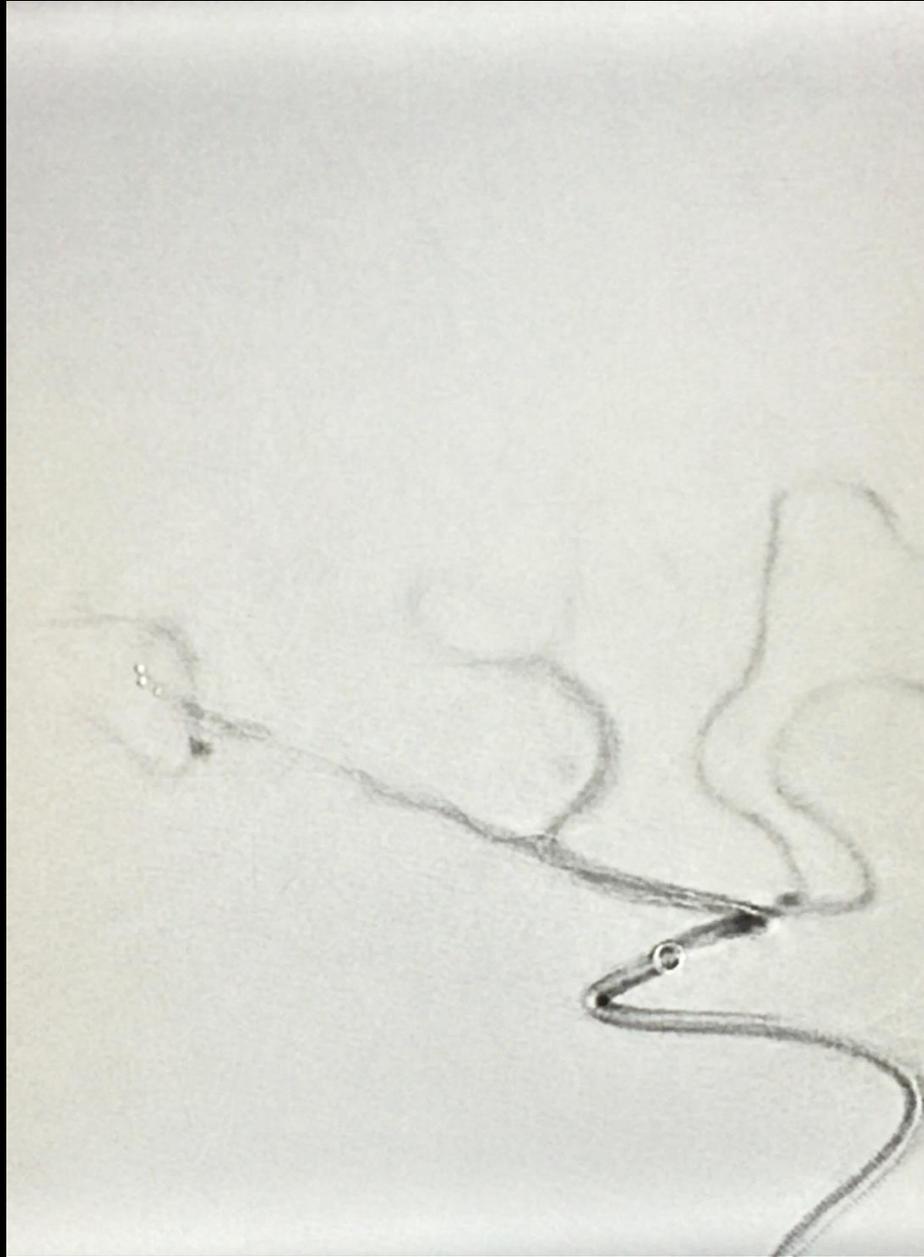


(01076133270120317)18033110118934869

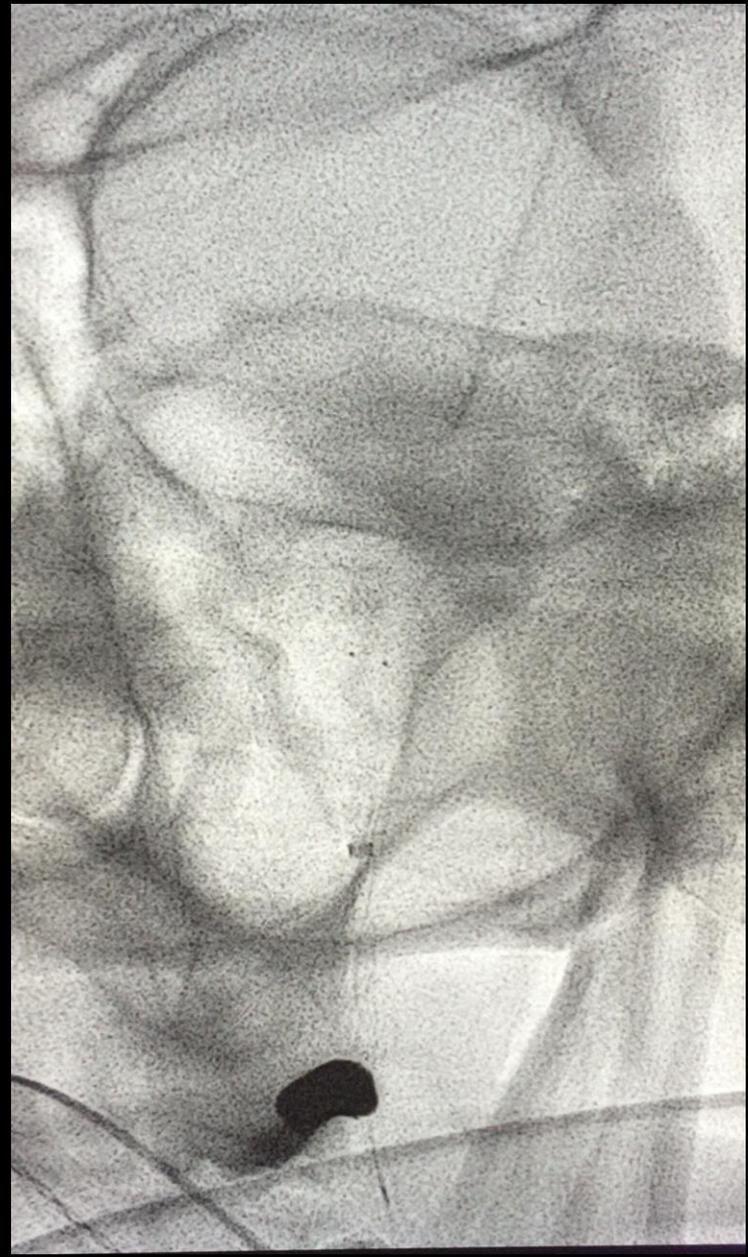
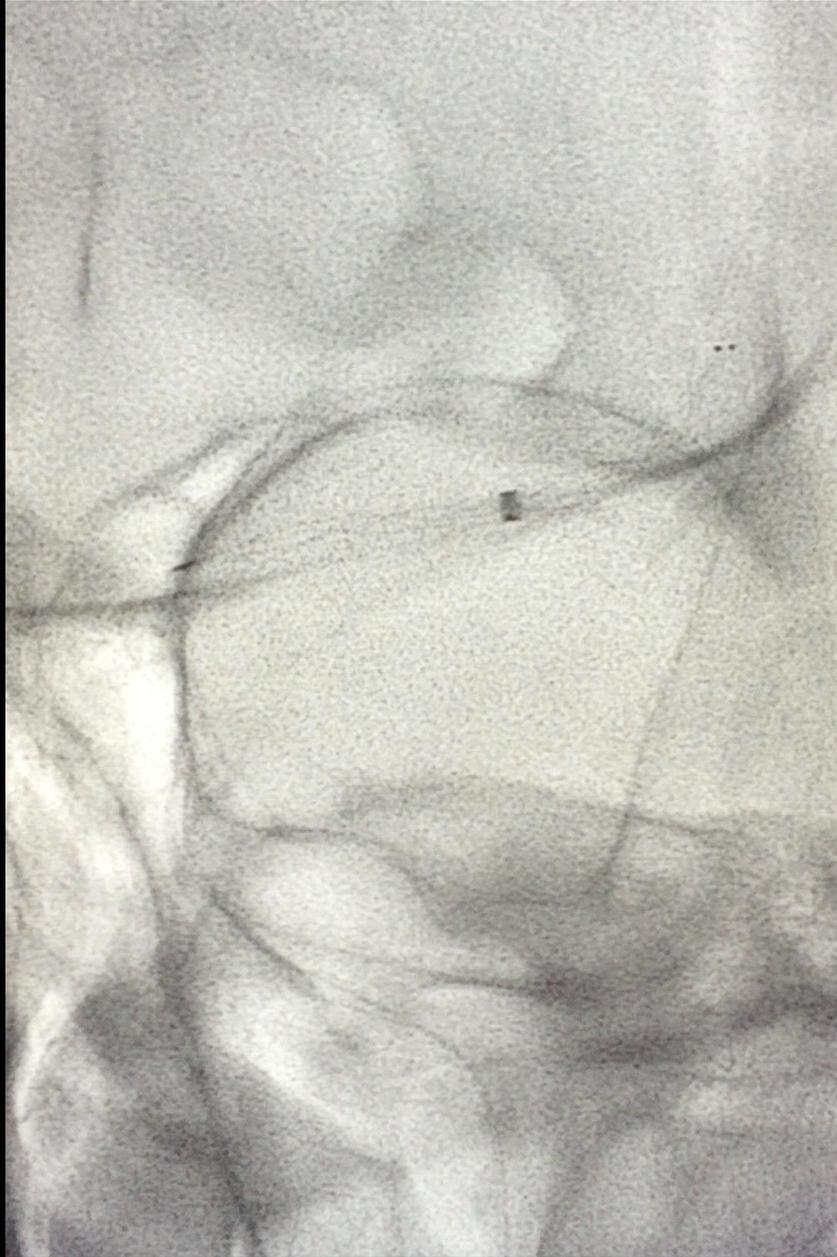
# Distal M2/M2 occlusions



# Distal M2/M2 occlusions



# Distal M2/M2 occlusions





# STAIR IX

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

## Acute Stroke Trials: Advancing Design, Regulation and Implementation

October 5-6, 2015  
Bethesda Marriott Hotel  
Bethesda, Maryland

### 1. Consensus Statement on Imaging Selection and Outcomes in Acute Stroke Reperfusion Clinical Trials

Steven J. Warach, Marie Luby, Gregory W. Albers, et al. for the STAIR IX Consortium

### 2. STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE - The Next Generation of Endovascular Trials

Tudor G. Jovin<sup>1</sup>, MD, Gregory W. Albers<sup>2</sup>, MD, David S. Liebeskind<sup>3</sup>, MD for the STAIR IX Consortium

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The Foundation of the American Society of Neuroradiology

thestair.org

Organized &  
Managed by  
The  
Stroke  
Group

# Three key directions for advancing the field were identified

- 1) development of systems of care for ET in LVO stroke
- 2) development of therapeutic approaches adjunctive to ET and
- 3) expanding the patient population that may derive benefit from ET. beyond conventional time windows, in patients with large baseline ischemic core lesions and in other important subgroups

Methodological issues such as optimal trial design and outcome measures have also been addressed. Development of systems of care strategies should be geared both towards ensuring broad access to endovascular therapy for eligible patients and towards shortening time to reperfusion to the minimum possible.

Adjunctive therapy development includes neuroprotective approaches, adjuvant microcirculatory/collateral enhancing strategies and peri-procedural management.

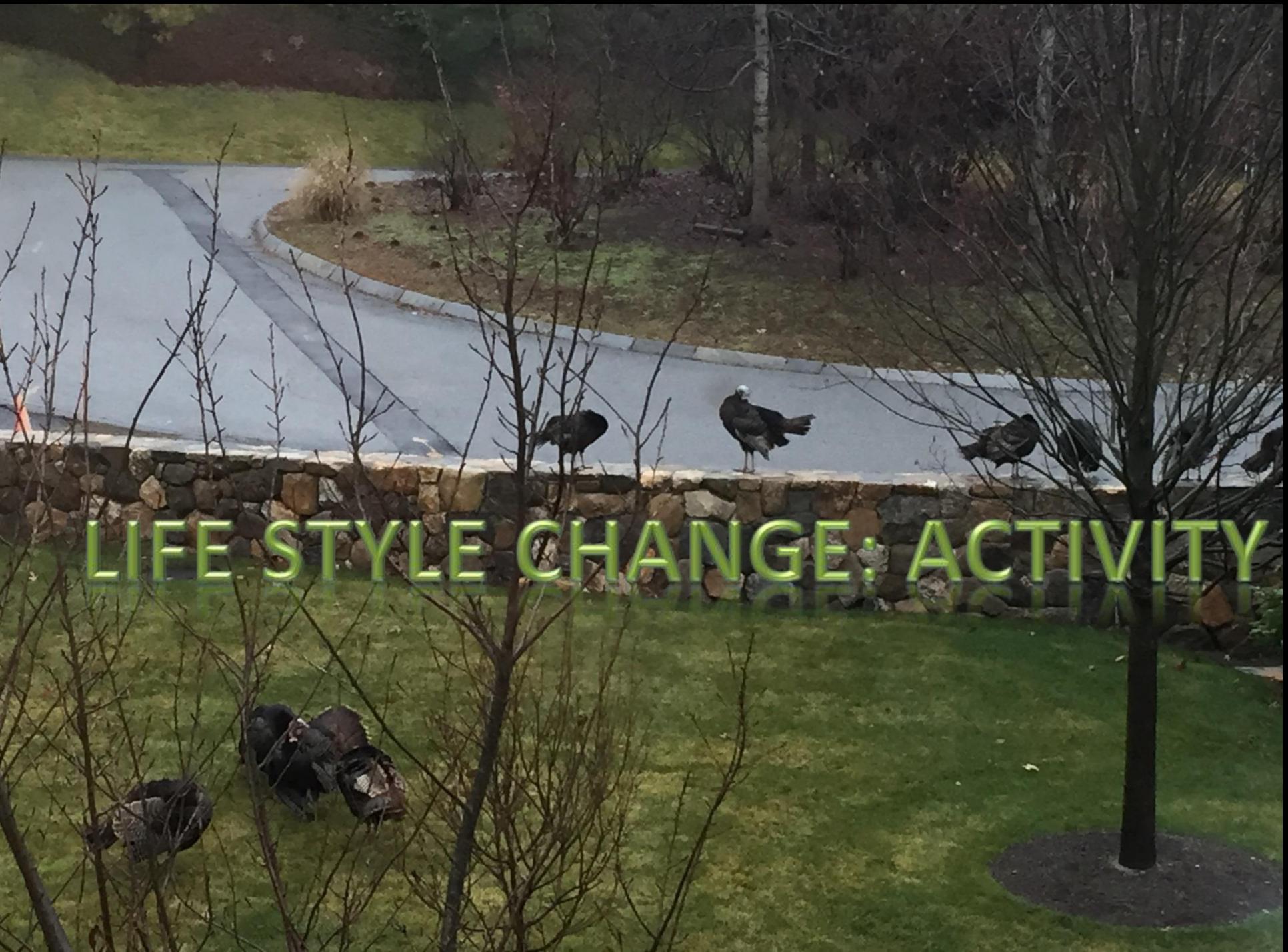
Unmet clinical needs  
from patient  
admission to rehab

Its starts with a good diet

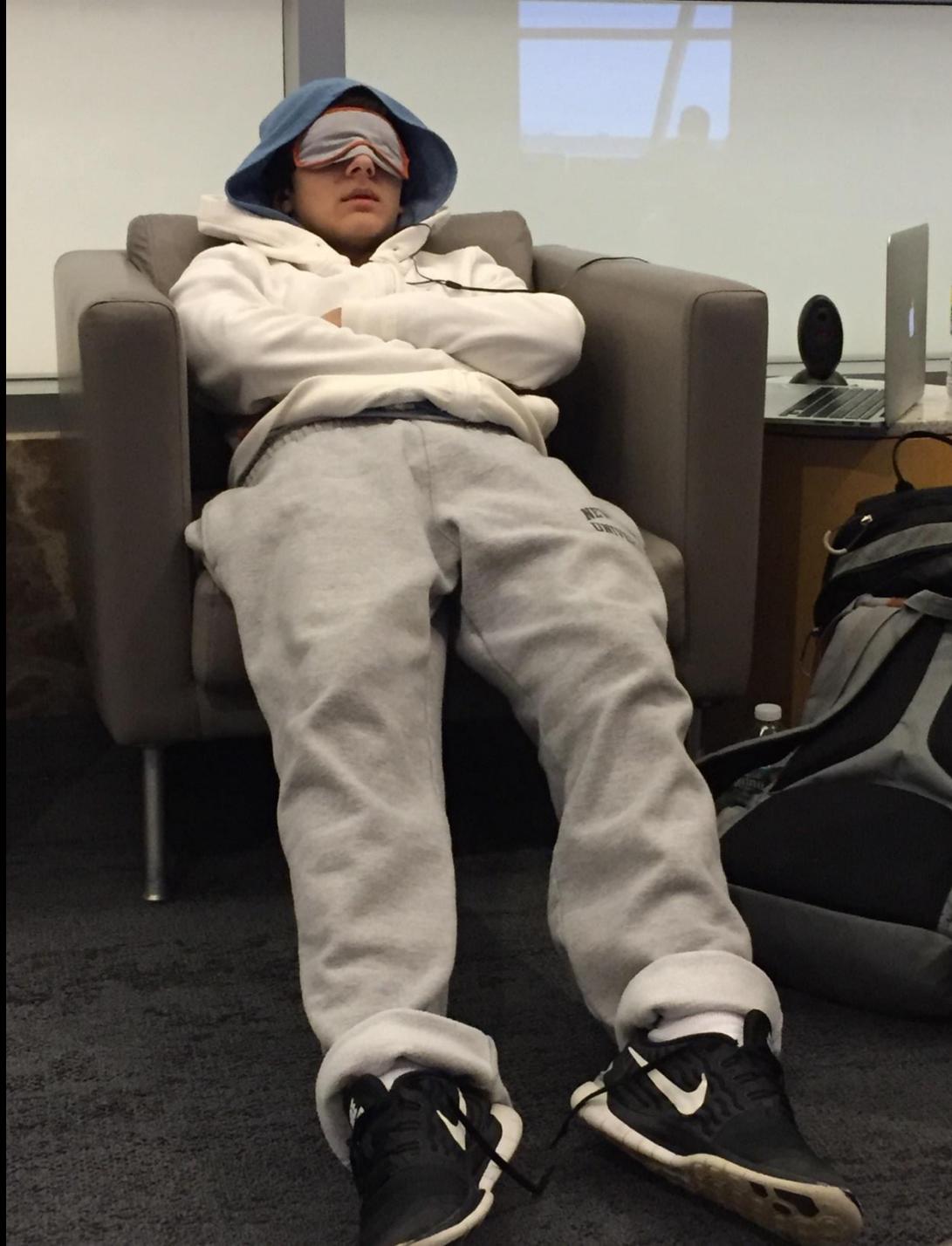


and a glass of MALBEC





LIFE STYLE CHANGE: ACTIVITY





# Needed Tools

- “Stroke bed” from Ambulance – ER – cath-lab-stroke unit
- Headrest
- Anesthesia unit
- Shunts EVD
- Decompression
- Clot removal (Apollo, Nokia)
- Larger bore suction catheters

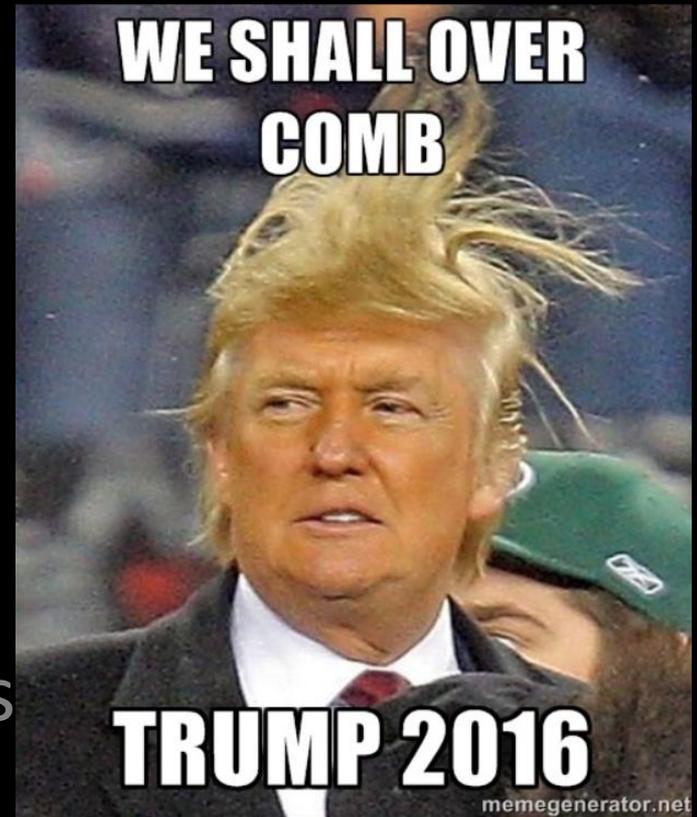
# Needed Tools

- “Stroke bed” from Ambulance – ER – cath-lab-  
stroke unit
- Headrest
- Anesthesia unit
- Shunts EVD
- Decompression
- Clot removal (Apollo, Nok)
- Larger bore suction catheter



# Needed Tools

- “Stroke bed” from Ambulance – ER – cath-lab-stroke unit
- Headrest
- Anesthesia unit
- Shunts EVD
- Decompression
- Clot removal (Apollo, Nokia)
- Larger bore suction catheters



19

**UT**

**Mobile Stroke Unit**

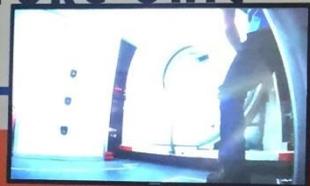
**AMBULANCE**



**MS1**

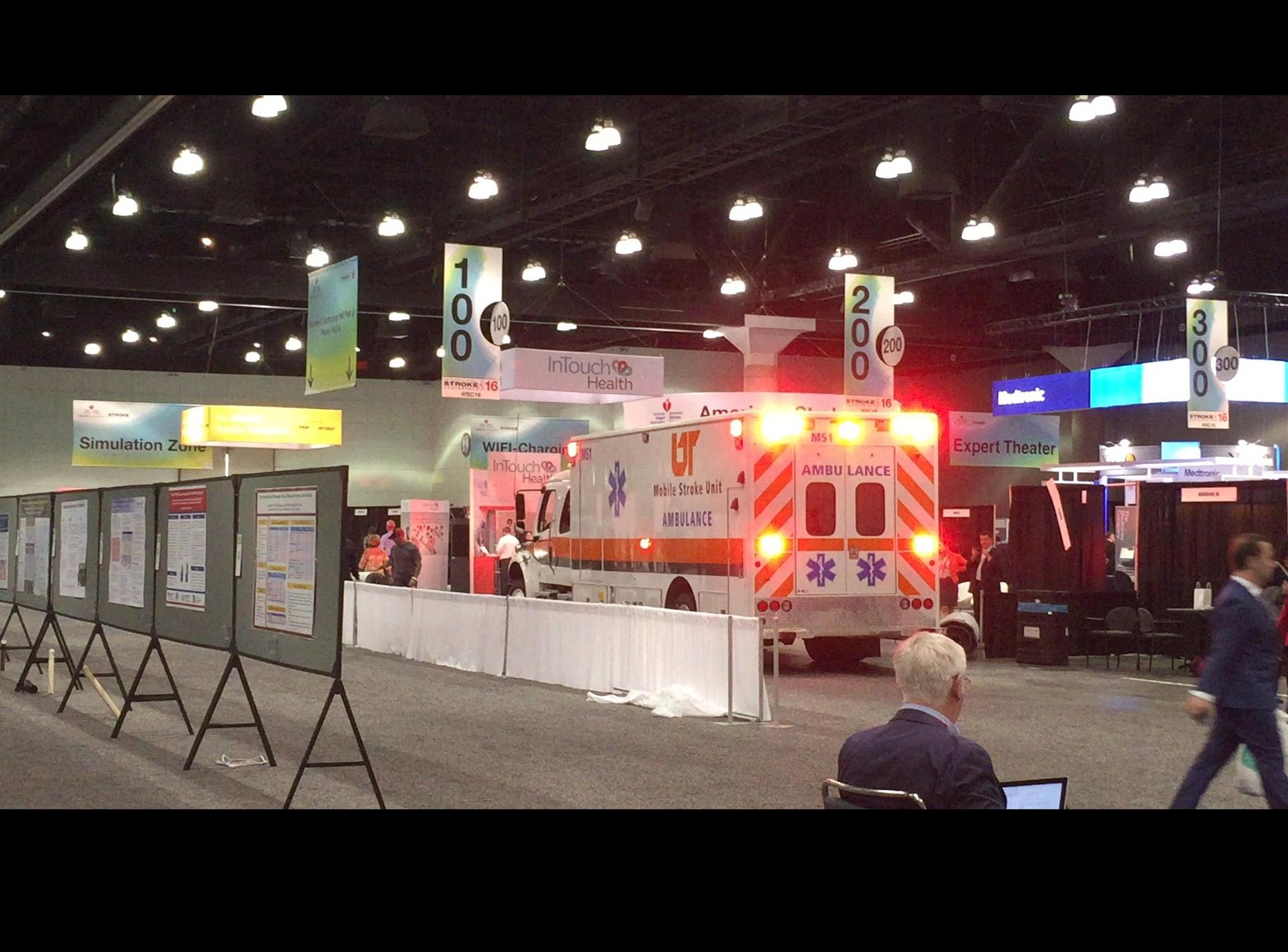
**3**

**UT**  
THE UNIVERSITY OF  
TENNESSEE  
HEALTH SCIENCE CENTER  
COLLEGE OF MEDICINE



107





STROKE  
Simulation Zone

100  
100  
STROKE 16  
#ISC16

InTouch Health

200  
200  
STROKE 16

MSU  
Mobile Stroke Unit  
AMBULANCE  
AMBULANCE

Expert Theater

300  
300  
STROKE 16

Medtronic



Ceretome



Siemens



**STROKE MOBILE UNIT IN BUENOS AIRES**

# Cooling for Penumbra Freeze

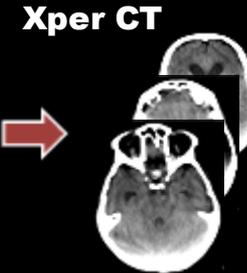


# Envisioned Stroke Workflow

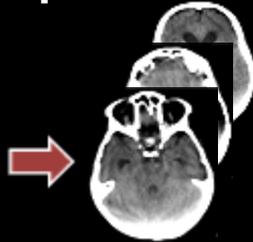
**Hemorrhagic Stroke**



**XperGuide For Ventricular Drainages**

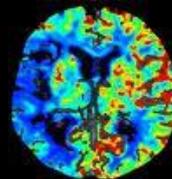


**Xper CT**

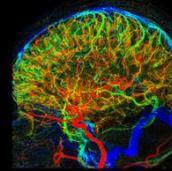


**2D Fluoro + Rotational Angiography**

**Ischemic Stroke**



**CBV**

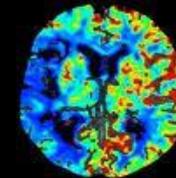


**2D Perfusion**



**VasoCT**

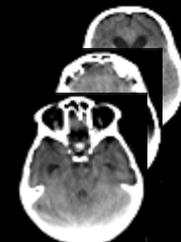
**3D Roadmap on VasoCT**



**CBV**



**2D Perfusion**



**XperCT**



# Conclusions

- Historic times in Endovascular treatment of acute stroke
- Development of Stroke Center of Excellence and Education
- Quantification of Imaging for better patient selection – Define the infarct volume
- Better devices and techniques, better outcomes
- We need to be fasteER from symptom onset to recanalization (<60min), goal 30 min
- Hypothermia? Neuroprotection?
- Goal: Penumbra Freeze and patient transfer to Comprehensive Stroke Centers

Thank you for all the critical support and advancing STROKE



**LET'S FIGHT STROKE**