

## No relevant disclosures

## Objectives

- Review 2015 endovascular stroke trials and impact on clinical practice
- Review updated AHA/ASA guidelines for endovascular treatment of acute ischemic stroke



2015 Endovascular Stroke

### Trials

- MR CLEAN Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands
- **ESCAPE** Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke
- **EXTEND-IA** Extending the Time for Thrombolysis in Emergency Neurological Deficits Intra-Arterial
- SWIFT PRIME Solitaire With the Intention For Thrombectomy as Primary Endovascular Treatment
- REVASCAT Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours
- THRACE Trial and Cost Effectiveness Evaluation of Intra-arterial Thrombectomy in Acute Ischemic Stroke THERAPY Assess the Penumbra System in the Treatment of
- Acute Stroke



Caudate Putamen Internal capsule Insular cortex Insular cortex M1: frontal operculum M2: anterior temporal lobe M3: posterior temporal lobe M4: anterior frontal lobe M5: middle/posterior frontal lobe M6: parietal lobe

Supraganglionic Level

## TICI Score

Class	Description
TICI 0	No antegrade flow beyond point of occlusion
TICI 1	The contrast material passes beyond the area of obstruction but fails to opacify the entire corobral hed distal to the obstruction for the duration of the angiographic run
TICI 2a	The contrast mixinel passes beyond the detruction and epochies the arteral bad data to the detruction, however, the note of entry of contrast, inso the viscal data the detruction or is not and clearance hom the data the of the aperceptibly beaution than its entry of the arteral bad parameters are not partnered by the provide acceleration arterial contrast bad provided in the distribution of the arterial bad provided in the distribution of the d
TICI 26	Same as TICI 2a, except flow is seen into two-thirds or more of the expected vascular tree but is slower than normal; for example, in a patient, with an MI segment occlusion, all M2 branches proximally are open with areas of small segmental distal occlusion or slow flow
TICI 3	Complete perfusion; antegrade flow into the bed distal to the obstruction occurs as promptly as into the obstruction and clearance of contrast material from the involved bed is as rapid as that from an uninvolved other bed of the same vessel or the opposite cerebral artery

### The NEW ENGLAND JOURNAL of MEDICINE

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### A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke

OA, Berkhemer, P.S.S. Fransen, D. Beurner, LA. van den Berg, H.F. Lingsma, A.J. Yoo, W.J. Schonewille, J.A. Yos, P.J. Nederkoorn, M.J.H. Werner, M.A.A. van Waldeneven, J. Staals, J. Hofmeijer, J.A. van Oostayen, G.J. Lycklama à Nijshoht, J. Boiten, P.A. Brouwer, B.J. Emmer, S.F. de Bruijn, L.C. van Dijk, LJ. Kappelle, R.H. Lo, 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 Hasselt, L.A.M. Aerden, R.J. Dallinga, M.C. Visser, J.C.J. Bot, P.C. Vroomen, O. Eshglin, T.H.C.M.L. Schreuder, R.J.J. Heijboer, K. Keizer, A.V. Tiebbeek, H.M. den Hertog, D.G. Gerrits, R.M. van den Berg, Vos, G.B. Karas, E.W. Steyerberg, H.Z. Tach, H.A. Marquering, M.E.S. Sprengers, S.F.M. Jenniskens, L.F.M. Beenen, R. van den Berg, P.J. Koudstaal, W.H. van Zwam, Y.B.W.E.M. Roos, A. van der Lug, R.J. van Oostenbrugge, C.B.L.M. Majoie, and D.W.J. Dippel, for the MR CLEAN Investigators<sup>a</sup>

## MR CLEAN (2015)

- Netherlands
- N = 500
- Age ≥ 18
- Pre-stroke mRS no cutoff
- ASPECTS > 5
- Endovascular treatment w/in 6 hours

   Allowed GA

## **MR CLEAN (2015)**

· Primary outcome: mRS at 90 days

- Secondary outcomes:
  - NIHSS at 24 hours and 1 week
  - Barthel index at 90 days
  - EuroQoL at 90 days

## **MR CLEAN (2015)**

- · 233 endovascular arm vs 267 medical arm - IV TPA in most (87% in endovascular arm and 91% in medical arm)

  - Median ASPECTS 9
  - Median NIHSS 17
  - Acute carotid stenting in 13% of cases
  - Stent retriever in 97% of cases
  - TICI 2b/3 in 58.7%
  - 33% mRS 0-2 (c/w 19% in medical arm)
  - No significant difference in hemorrhage (7.7% vs 6.4%) or death

## **MR CLEAN (2015)**

- · RCT clearly showed benefit of endovascular treatment for LVO in AIS
- · Domino effect on other concurrent/subsequent endovascular trials!

#### The NEW ENGLAND JOURNAL of MEDICINE

#### 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. Dowlatshahi, 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\*

## **ESCAPE (2015)**

- Canada and US
- N = 500 (halted at 316)
- Age ≥ 18
- Pre-stroke mRS  $\leq 1$
- ASPECTS > 5
- Multiphase CTA (Menon et al. Radiology, 2015)
- Endovascular treatment w/in 12 hours
- CT to groin 60 min; CT to recanalization 90 min
- Discouraged GA or CAS

## ESCAPE (2015)

- 165 endovascular arm vs 150 medical arm
  - IV TPA in most (73% in endovascular arm and 79% in medical arm)
  - Median ASPECTS 9
  - Median NIHSS 16
  - Stent retriever in 86% of cases
    TICI 2b/3 in 72.4%
  - 53% mRS 0-2 (c/w 29% in medical arm)
  - No significant difference in hemorrhage (3.6% vs 2.7%) or death

## ESCAPE (2015)

 Halted following MR CLEAN results and showed similar clear benefit for endovascular treatment for LVO

#### The NEW ENGLAND JOURNAL of MEDICINE

#### 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\*

## EXTEND-IA (2015)

- Australia
- N = 100 (halted at 70)
- Age ≥ 18
- Pre-stroke mRS ≤ 1
- No minimum ASPECTS or NIHSS
- RAPID software for CTP or MRI/P
   assessment
- · Endovascular treatment w/in 6 hours
  - Allowed GA
  - Discouraged CAS

## EXTEND-IA (2015)

- · 35 endovascular arm vs 35 medical arm
  - IV TPA in all
  - Median ASPECTS 9
  - Median NIHSS 17
  - Stent retriever in 100% of cases (Solitaire)
    TICI 2b/3 in 86.2%
  - 71% mRS 0-2 (c/w 29% in medical arm)
  - No significant difference in hemorrhage (0% vs 5.7%) or death

## EXTEND-IA (2015)

 Halted following MR CLEAN results and showed similar clear benefit for endovascular treatment for LVO

#### The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

### Stent-Retriever Thrombectomy after Intravenous t-PA vs. t-PA Alone in Stroke

Jeffrey L. Saver, M.D., Mayank Goyal, M.D., Alain Bonafe, M.D., Hans-Christoph Diener, M.D., Ph.D., Elad I. Levy, M.D., Vitor M. Pereira, M.D., Gregory W. Albers, M.D., Christophe Cognard, M.D., David J. Cohen, M.D., Werner Hacke, M.D., Ph.D., Olav Jansen, M.D., Ph.D., Tudor G. Jovin, M.D., Heinrich P. Mattle, M.D., Raul G. Nogueira, M.D., Adnan H. Siddiqui, M.D., Ph.D., Dileep R. Yavagal, M.D., Blaise W. Baxter, M.D., Thormas G. Devlin, M.D., Ph.D., Demetrius K. Lopes, M.D., Vivek K. Reddy, M.D., Richard du Mesnil de Rochernont, M.D., Oliver C. Singer, M.D., and Reza Jahan, M.D., for the SWIFT PRIME Investigators\*

## SWIFT PRIME (2015)

- US and Europe
- N = 477 (halted at 196)
- Age 18-80
- Pre-stroke mRS  $\leq 1$
- ASPECTS  $\geq 6$
- NIHSS 8-29
- Endovascular treatment w/in 6 hours

## SWIFT PRIME (2015)

- 98 endovascular arm vs 98 medical arm
  - IV TPA in all
  - Pre-stroke mRS 0
  - Median ASPECTS 9
  - Median NIHSS 17
  - Stent retriever in 100% of cases (Solitaire)
     TICI 2b/3 in 88%
  - 60.2% mRS 0-2 (c/w 35.5% in medical arm)
  - No significant difference in hemorrhage (0% vs 3.1%) or death

## SWIFT PRIME (2015)

 Halted following MR CLEAN results and showed similar clear benefit for endovascular treatment for LVO

## ESO 2015

- European Stroke Organisation 2015 meeting (late April)
- Results of REVASCAT announced
- Preliminary results of THRACE and THERAPY announced

### The NEW ENGLAND JOURNAL of MEDICINE

### ORIGINAL ARTICLE

### Thrombectomy within 8 Hours after Symptom Onset in Ischemic Stroke

T.G. Jovin, A. Chamorro, E. Cobo, M.A. de Miquel, C.A. Molina, A. Rovira, L. San Román, J. Serena, S. Abilleira, M. Ribó, M. Millán, X. Urra, P. Cardona, E. López-Cancio, A. Tomasello, C. Castaño, J. Blasco, L. Aja, L. Dorado, H. Quesada, M. Rubiera, M. Hernández-Pérez, M. Goyal, A.M. Demchuk, R. von Kummer, M. Gallofré, and A. Dávalos, for the REVASCAT Trial Investigators\*

## REVASCAT (2015)

- Spain
- N = 690 (halted at 206)
- Age 18-80 (extended to 85 in mid 2014 if ASPECTS 9-10)
- Pre-stroke mRS ≤ 1
- ASPECTS  $\geq$  7
- NIHSS  $\geq 6$
- Endovascular treatment w/in 8 hours

## **REVASCAT (2015)**

- 103 endovascular arm vs 103 medical arm
  - IV TPA in most (68% in endovascular arm and 78% in medical arm)
  - Pre-stroke mRS 0 in 83-86%
  - Median ASPECTS 7-8
  - Median NIHSS 17
  - Stent retriever in 100% of cases (Solitaire) • TICI 2b/3 in 65.7%
  - 43.7% mRS 0-2 (c/w 28.2% in medical arm)
  - No significant difference in hemorrhage (1.9% in both) or death

## **REVASCAT (2015)**

• Halted following MR CLEAN, ESCAPE, EXTEND-IA and SWIFT-PRIME results and showed similar clear benefit for endovascular treatment for LVO

## **THRACE (2015)**

- France
- N = 414
- Age 18-80
- Symptoms < 4 hours</li>
- NIHSS 10-25
- All received IV TPA
  - Assigned to endovascular arm if no/minor (< 5 points) NIHSS improvement</li>
  - Endovascular treatment to be completed by 6 hours

## **THRACE (2015)**

- 190 endovascular arm vs 195 IV TPA arm
- Mean NIHSS 17
- 85% had M1 occlusion
- 54.2% mRS 0-2 (c/w 42.1% in IV TPA arm)
- No reported significant difference in hemorrhage or death

## THERAPY (2015)

- N = 692 (halted at 108)
- Use of Penumbra aspiration thrombectomy devices rather than stent retrievers
- Looked at clot length (≥ 8 mm)
- NIHSS ≥ 8
- Inclusion w/in 4.5 hours of onset
- Final results pending but preliminary results indicate benefit in endovascular treatment vs IV alone

Trial	MRCLEAN	ESCAPE	EXTEND-IA.	SWIFT PRIME	REVASCAT	THERAPY	THRACE
Key inclusion criteria	NHSS22, agez 18	NHSS>5, ASPECTS>5, moderate/good collaterals (CTA)	Bigible for M-BN <4.5 hours from stroke onset, ischamic core <70 cm <sup>3</sup> , mismatch <sup>1</sup>	Bigible for N-IPA <4.5 hours from stroke onset, age 18-80, NI-ISS 8-29, AS- PECTS 2-6	<sup>1</sup> Age 18-80, NHSS≥6, ASPECTS≥7	Eigible for №6A <4.5 hours from stroke onset, age 18-65, NHSS> 8, Olot length ≥ 8 mm	Eligible for N-IPA <4.5 hours from stroke onset, ago 18-80, NIHSS 10-25
Interventional arm	Intra-anterial therapy	Intro-orterial therapy	Endovascular thrombactomy with Solitains FR stantriover	Endowascular thrombectomy with Solitaire FR stantriever	Endovescular thrombectomy with Solitaire FR stantriever	Endosascular thrambactomy with Panumbra aspiration system	Endovescular mechanica thrombactomy
Control arm	Best medical monogement (4/1V-tPA)	Best medical management (4/- N-6'A)	IN-tPA only	N-6% only	Best medical management (4/- 16-67A)	IV-tPA only	NHPA only
Time window for intervention	<6 hours from onset	<12 hours from onset	<6 hours from anset	<6 hours from onset	<8 hours from onset	<4.5 hours from onset	<5 hours from onset
Number of patients	500 (l: 233, C: 267)	315 (t 165, C: 150)	70 (t. 35, C. 35)	196 (t. 98, C: 98)	206 (t 103, C: 103)	108 (I: 54, C: 54)	385 (l: 190, C: 195)
Moary/median age (year)	L 65/8, C: 65/7	1:71, C:70	1:68.6, C: 70.2	1:66.3, C: 65.0	t 65.7, C: 67.2	NR	1:62, C:62
Median NIHSS	L 17, C: 18	I: 16, C: 17	E 17, C: 13	E 17, C: 17	1: 17, C: 17	NR	E 17, G: 17
Median ASPECTS	L9,C.9	1:9,C:9	NR	1.9, C. 9	1:7,0:8	NR	NR
Received IV-IPA	1:87.1%, C:90.8%	1:72.7%, C:78.7%	1: 100%, C: 100%	E 100%, C: 100%	1.68.0%, C: 77.7%	1: 100%, C: 100%	1: 100%, C: 100%
Median time from stroke-onset to-grain puncture (minute)	290	241"	210	224	209	226	295
Intervention with stertriever device	81.5%	86.1%	100%	100%	100%	0%*	NR
Improvement in mFS 0-2 at 90 days	13.5%* (t. 32.6, C. 19.1%)	23.7%* (1:53.0%, C: 29.3%)	31,4%* (1:71,4%, C:40,0%)	24,7%* (1:60,2%, C:35,5%)	15.5%* (I:43.7%, C 28.2%)	7.0% (1:38.0%, C:30.4%)	12.1%* (1:54.2%, C:42.1%)
Decrease in mortality at 90 days	1.1% (I:21.0%, C:22.1%)	8.6* (1: 10.4%, C: 19.0%)	11.4% (18.6%, C. 20.0%)	3.2% (I:9.2%, C: 12.4%)	-2.9% (: 18.4%, C. 15.5%)	11.9% (12.0%, C.23.9%)	0.6% (t 12.5%, C: 13.1%)
TICI grade 2b/3 recanalization	58.70%	72.40%	86.20%	88.00%	65,70%	NR	NR
Symptomatic ICH	177%, 0.64%	1:38%, 0:27%	1.0%, 0.5.7%	E0%, C: 3.1%	1:19%, 0:19%	E 10.9%, C: 11.3%	NR
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#### AHA/ASA Guideline

#### 2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment

A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists.

Endorsed by the American Association of Neurological Surgeons (AANS); Congress of Neurological Surgeons (CNS); AANS CNS Cerebrowacular Section; American Society of Neuroradiology; and Society of Vascular and Interventional Neurology

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American Heart Association Stroke Council



## 2015 AHA Guidelines

### · Recommendations:

- Give IV TPA when able (up to 4.5 hrs per ECASS III)
- Do no wait to look for improvement after IV TPA
- Pre-stroke mRS 0-1
- Baseline CT head ASPECTS  $\geq 6$
- NIHSS ≥ 6
- Proceed with CTA or MRA to look for LVO
- Benefits of CTP/MRP not clear

## 2015 AHA Guidelines

- · Recommendations:
  - Groin puncture w/in 6 hrs
  - Favor conscious sedation rather than GA when possible
  - Use stent retriever or other thrombectomy device
  - Use balloon-guide catheter or large-bore distal access catheter
  - Aim for TICI 2b/3 reperfusion
  - Salvage IA TPA can be used if needed

## Take Home Points

## • Endovascular thrombectomy for AIS has become a standard of care

- Important considerations:
  - Pre-stroke mRS ≤ 1
  - Baseline CT head ASPECTS  $\geq$  6
  - NIHSS ≥ 6
  - CTA or MRA with LVO and (ideally) good collaterals
  - Take for revascularization ASAP (< 6 hrs to groin puncture)</li>

Thank You!

### Devices and Techniques: Review of stent retrievers, suction, and combination therapy

Joseph J Gemmete, MD, FACR, FSIR Professor of Radiology and Neurosurgery University of Michigan Hospitals

### Outline

### Access issues

- · Balloon guides / Sheaths
- Stent retrievers
  - Solitare
  - Trevo
- Suction thrombectomy
  - ADAPT technique
- Solumbra

#### Summary

### **Access Issues**

- CTA done in emergency room
   -aortic arch (type 1, 2, 3)
   -carotid/ vertebral tortousity
  - -Ca2+/atherosclerotic plaque
- Access common femoral, direct carotid, radial access
  - -puncture access site under U/S
    - Micropuncture kit 19G single wall with 0.035 glide / Amplatz
  - -8/9F sheath (24 cm / 13 cm) CFA/carotid access
  - -radial limited 6F female/ ?7F male
  - -right radial (RVA, LCCA), left radial (LVA, RCCA)

### **Carotid/Vertebral Access**

• Which Carotid Access Technique?

-Front loading telescopic technique (Neuron Max, FlowGate, Cook shuttle sheath)

-Back loading serial stiffening technique (wire in external carotid then advanced sheath or guide) (Cello 8F / 6F)

-Remote or Direct access



### **Balloon Guides / Sheaths**



Sheath -Cook shuttle sheath (.087in), Neuron Max (.088in)

### **Preparation of Balloon Guide**

- Inspect balloon guide
- Attach RHV or Tuohy Borst with Side port to the BGC
- Flush lumen of BGC with heparinised saline
- · Insert dilator/catheter through the lumen and flush with HS
- · FlowGate Attach the flow valve, Cello no value
- Attach a 20 ml syringe with 50:50 contrast : saline using a negative prep
- Inflate the balloon with a 50:50 contrast : saline for flow arrest during stent retrieval
- During aspiration attached a three way with two 60 ml syringes so can apply negative aspiration

### Indication Overview

The indication for the Solitaire<sup>™</sup> FR revascularization device is as follows:

The Solitaire<sup>™</sup> FR Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV I+PA) or who fail IV I+PA therapy are candidates for treatment.



### Solitaire<sup>™</sup> FR Revascularization Device Overview

Solitaire" FR Revascularization Device Ordering Information										
Reference Number	Recommended Vessel Diameter (mm)	(A) Total Length (mm)	(B) Retrieval Zone (mm)	(C) Device Diameter (mm)	(D) Push Wire Length (cm)	(E) Distal Markers	(F) Proximal Markers	Minimum Micro Catheter ID (in)		
SFR-4-15	2.0-4.0	26	15	4	180	3	1	0.021		
SFR-4-20	2.0-4.0	31	20	4	180	3	1	0.021		
SFR-6-20	3.0-5.5	31	20	6	180	4	1	0.027		
SFR-6-30	3.0-5.5	42	30	6	180	4	1	0.027		



#### Procedural Overview Procedure Components



altaire<sup>ne</sup> FR revascularization device procedural steps taken from IFU. For complete instructions for use please se

Procedural Overview Position the microcatheter

Advance the microcatheter distal to the thrombus position so that when the Solitaire<sup>™</sup> FR revascularization device is fully deployed, it will extend beyond both ends of the thrombus.



iolibile<sup>TM</sup> FR revescularization device procedural steps taken from IPU. For complete instructions for use please see FU.

Procedural Overview Flush the introducer sheath



Insert the introducer sheath partially into the RHV, tighten the RHV and verify that fluid exits the proximal end of the sheath.

itaire<sup>14</sup> FR revacularization device procedural steps taken from FU. For complete instructions for use please see FU.

#### Procedural Overview Introduce the Solitaire™ FR Device into the microcatheter



Loosen the RHV. Advance the introducer sheath into the microcatheter hub until firmly seated. Tighten the RHV and advance the Solitaire<sup>®</sup> FR revascularization device into the microcatheter. Once the flexible portion of the push wire has entered the micro catheter shaft, remove the sheath.

iditale.<sup>14</sup> FR revaculatization device procedural steps taken from IFU. For complete instructions for use please see IFU.

#### Procedural Overview Deliver the Solitaire™ FR Device

Continue to advance the Solitaire<sup>™</sup> FR until its distal radiopaque markers reach the end of the properly positioned microcatheter.



WARNING: IF EXCESSIVE RESISTANCE IS ENCOUNTERED DURING THE DELIVERY OF THE SOLTAIRE™ FR REVASCULARIZATION DEVICE, DISCONTINUE THE DELIVERY AND IDENTIFY THE CAUSE OF THE RESISTANCE. ADVANCEMENT OF THE SOLTAIRE" FR REVASCULARIZATION DEVICE ADMARST RESISTANCE WAR RESULT DEVICE DAMAGE MIDIOR PATIENT HURRY.

in <sup>w</sup> FR reveau/aduation device procedural steps taken from FU. For complete instructions for use please see FU.

#### Procedural Overview Positioning and Deployment

To deploy the Solitaire<sup>®</sup> FR revascularization device, fix the push wire to maintain position of the device and carefully withdraw the microcatheter in the proximal direction.

To ensure full deployment, the microcatheter must be proximal to the proximal radiopaque marker on the Solitaire<sup>®</sup> FR revascularization device. The usable length of the deployed Solitaire<sup>®</sup> device should extend beyond each side of the thrombus.



taler<sup>te</sup> FR evancularization device procedural steps taken from FU. For complete instructions for use please see FU.

#### Procedural Overview Prior to retrieval

Reposition the micro catheter to cover the proximal zone (proximal 3-4mm) of the Solitaire™ FR revascularization device. Lock the RHV onto the Solitaire™ FR device pushwire. Wait for 5 minutes to let stent incorporate into thrombus



Solitaire<sup>ne</sup> FR revascularization device procedural steps taken from IPU. For complete instructions for use please see IPU.

Procedural Overview Recovery

- Prior to retrieval, inflate the balloon in the balloon guide catheter, if a balloon guide catheter has been selected.
- Do not perform more than three (3) recovery attempts in the same vessel.
   Do not use each Solitaire<sup>™</sup> FR revascularization device for more than two (2) thrombus recoveries.

Soltain\*\* FR measculatzation device procedural steps taken from FU. For complete instructions for use please see FU.

#### Procedural Overview Recovery



Retrieve the Solitaire™ FR revacularization device and the micro catheter as a unit into the guiding catheter under constant aspiration. Continue to aspirate on the guiding catheter until there is good flow reversal.

Remove the Solitaire<sup>™</sup> FR revascularization device out of the distal end of the micro catheter in order not to damage the device. If additional flow restoration attempts are desired with the same device clean the device with saline solution. Do not use solvents or autoclave.

P R musicularization device procedural steps taken from FU. For complete instructions for use please see FU.

### Trevo® XP Pro Retriever

### Sizes

- 6 mm x 25 mm Excelsior XT-27 microcatheter
- 4 mm x 20 mm Trevo Pro 18
- 3 mm x 20 mm Trevo Pro 14, Trevo Pro 18

### Trevo® XP Pro Retriever



#### PROCEDURAL DESCRIPTION

PATIENT OVERVIEW 22-year-old male collapsed in the bathroom at 7am. Patient arrived to the ED hemiplegic with aphasia

> Left M1 CASE CONCLUSION Number of passes: 1
>  Post Trevo Revesc: TICL3
>  Comments: Patient woke with
>  only mild slurred speech

CLOT LOCATION

Access IS<sup>1</sup> Evolution: Database Tools
 Access IS<sup>1</sup> Evolutions
 Database Tools
 Distribution: Click burden removed with the Trevo XP ProVue Retriever 4x20mm -the physician noted no "weist" in the device which was consistent with the soft click that was retrieved



#### PATIENT OVERVIEW

#### PROCEDURAL DESCRIPTION

 Initial NIHSS: 9
 Patient History: 56-year-old male with a history of aortic valve replacement presented with recoptive aphasia. Non-invasive CT demonstrated a left, posterior M2 branch occlusion

CLOT Loft temporal M2 LOCATION trifurcation

CASE CONCLUSION

Number of Passes: 1
 Post Trevo Revasc: TICL3
 Case Time: 18 minutes from
 groin puncture to recanalization



### **ADAPT / Solumbra**

ADAPT

-place large bore suction catheter at the face of the thrombus, then turn on pump

Solumbra

-place 8 Fr guide catheter into the cervical ICA, then 5 MAX /ACE catheter into M1 segment, advance a microcatheter distal to the thrombus, deploy the stent retriever within the thrombus and then remove the microcatheter, under local aspiration remove the 5 MAX/ACE catheter with the stent retriever as a unit into the guide catheter











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Training Standards, Credentials, and Education for Intra-arterial Catheter-directed Treatment of Acute Ischemic Stroke

> David Sacks, MD The Reading Health System Dec 2015

## Disclosures

- No conflicts of interest
- Intracranial drugs are off label

## IA Stroke Issues

- Benefits of IA stroke care
- Risk/benefit very dependent on pt selection, physician skills, infrastructure
- Hospital desire to keep stroke pts
- Need for IA manpower (24x7)
   Hirsch et al JNIS 2009
- Interest in IA from several specialties
- Problems with current training

## **Training paradigms**

- · ABR certified
  - Exclusive, what is the training provided?
- Fellowship
  - Exclusive, what is the training?
- Case experience
  - Must check outcomes
  - Do outcomes meet benchmarks?
  - What benchmarks
- · What should you know, do you know, and can you do?

## Positions on IA stroke training

- SNIS
  - Investigational, difficult, need ESN fellowship, transport pt to regional center
    - Meyers et al. J NeuroInterv Surg 2009 Heck JNIS 2011
- SIR
  - Not investigational, difficult, can train committed and skilled interventionist, treat patient locally • Connors et al. JVIR 2009
    - Sacks and Connors commentary JVIR 2009
       Sacks JNIS 2011

## **Evidence**

- Not Class 1: RCT, case series, registries
- Local anecdotes
- INSTOR results
- Case series by IR, IC
  - Belisle et al. JVIR 2009;20:327-333
    - Fjetland et al. Cardiovasc Interv Radiol 2012;35:1029-1035
    - Burkart et al. JVIR 2013;24:1267-1272
    - Sanak et al. JVIR 2013;24:1273-1279
    - Htyte et al. Cath Cardiovasc Interv 2015;85:1043-1050
    - Goktekin et al. Eurointervention 2014;10:876

## SIR IA Stroke Training JVIR Dec 2009

- Cognitive and Clinical
- Imaging
- Technical
- Stroke specific experience
- Facility
- Exam

## Cognitive

- 1. Understanding of and certification in assessing the NIHSS
- 2. 6 months ACGME formal neuroscience training including neuroanatomy, neuropathology, neurovascular imaging, hemodynamics
- 3. Stroke specific training in clinical presentation of stroke and associated vascular territories
- 4. Training in stroke specific exams for stroke mimics and conversion reactions
- 5. Ability to evaluate imaging criteria for appropriate patients for acute stroke treatment

## Cognitive

- 6. Ability to differentiate acute ischemic lesions as compared to chronic lesions and/or tumors, etc.
- 7. Ability to differentiate TIA from acute infarct
- 8. Ability to recognize etiology of TIA and acute stroke, including stenosis and embolus
- 9. Knowledge of cerebrovascular hemodynamics as it relates to perfusion imaging, and clinical presentation
- 10. Knowledge of pharmacological agents used for acute stroke therapy
- Understanding peri-procedural and post-procedural hemodynamics and implications for appropriate patient care

## **Brain Imaging**

- 1. Interpretation of 200 CT and 50 CTA
- 2. Interpretation of 200 MRI and 50 MRA
- 3. Interpretation of 25 CT/MR perfusion
- 4. Interpretation of 200 cerebral arteriograms

## What about a Team Approach

- Clinical is done by neurologist
- Imaging is done by dx radiologist
- · Patient selection is done by neurologist
- Procedure is done by interventionist
  - No need for neuro skills (IR, IC)
  - No need for imaging skills (IC)
- Is this model good enough???

If so, discard the SIR training and INR fellowship

## Technical

- 1. Hands on equipment experience
- 2. Arteriography performance
  - a. 100 cerebral (bilateral carotid and at least singlevessel vertebrobasilar injections)
     OR

50 cerebral and 150 non cerebral

#### AND

b. 30 selective microcatheter procedures including 5 ICA/ECA

## IA Stroke Specific

• 5 proctored – in person

OR

electronically/telephonically What does this mean?

## Facility

- 1. Primary stroke center or equivalent
- 2. Quality assurance program specifically assessing stroke patients, acute stroke treatments, and clinical outcomes
- 3. Facility support for submission of all cases to a national stroke registry for interventional stroke therapy
  - Commitment of facility
  - Education
  - National QA

## Are these Standards Restrictive?

### YES

- This is not like hepatic embo for an exanguinating trauma patient
- Stroke pts may improve spontaneously or may be harmed by attempted revasc
- You need to know how to select and treat patients
- Dirty Harry
- NO

The standards define your competence

## Problems with this Training Model

- 1. Is it all really necessary? Obsolete? What about the team approach?
- 2. There are few cerebral angios to do.
- 3. Who will proctor, how?
- 4. Local hospitals want it, want me to do it, and if not me, who?
- 5. Where can I learn?
- 6. Who offers a test?

### QA

- Locally
  - 90 day clinical outcomes
  - Times from sx onset to ER, CT/MRI, IR, treatment
  - Multisociety QA benchmarks
- Nationally
  - INSTOR registry
  - Need to revise training?

# Multisociety QA Sacks et al. JVIR 2013;24:151-163

- Door to puncture < 2 hrs (75%)
- Puncture to start of revasc < 45 mins (50%)
- Recanalization (60%)
- SICH < 12%
- 90 day good outcomes > 30%
- · Cases submitted to registry (100%)
- Submitted for publication
- May be adopted for accreditation

## IA Stroke Courses

- SIR Vancouver 1 day add on to meeting
- SIR ? Stand alone meeting
   Course prep prior to meeting
- CIRSE annual meeting
- ICCA Prague 2016 (www.iccaonline.org)

## What do I really Think?

- 1. IR can do an excellent job treating strokes
- 2. Training needs are between the SIR standards and the "Team" approach
- 3. The facility is every bit as critical as the interventional physician
- 4. Not every hospital should offer IA Offering this care badly but locally is worse than a transfer
- 5. Hospitals will do what they want, and they may want you
- 6. QA QA QA QA QA QA

## An Algorithm for Treating the Acute Stroke Patient: Door to Lab Protocol

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### Disclosures

• Stryker – Medical Advisory Board



## **Improving Patient Selection**

MR CLEAN REVASCAT EXTEND-IA SWIFCPRIME ESCAPE THRACE THERAPY

### Indications for IA Stroke Therapy (Class I; Level of Evidence A). (New recommendation):

- a. Prestroke mRS score 0 to 1
- Acute ischemic stroke receiving intravenous r-tPA within 4.5 hours of onset according to guidelines from professional medical societies
- c. Causative occlusion of the internal carotid artery or proximal MCA (M1)
- d. Age ≥18 years
- e. NIHSS score of ≥6
- f. ASPECTS of ≥6
- Treatment can be initiated (groin puncture) within 6 hours of symptom onset

2015 AHA/ASA Stroke Guideline

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### **Optimizing Door to Lab Time**

- Pre-Hospital Assessment
  - NIHSS
  - LAMS (L.A. Motor Scale)
  - RACE (Rapid Arterial oCclusion Evaluation)
- Stroke Protocol
  - Alert ED/Stroke/Interventional Teams
  - EMS vs POV
- Rapid Assessment with Imaging
   Point of care Renal Function Testing
- Prompt Treatment for patients with LVO



### Facilitate patient care and movement

- Have designated transport monitoring equipment ready
- Have a designated health care provider accompany patient from the time they enter hospital
  - They get TPA in ED
  - They go for intervention



Thank you! Martin Radvany

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