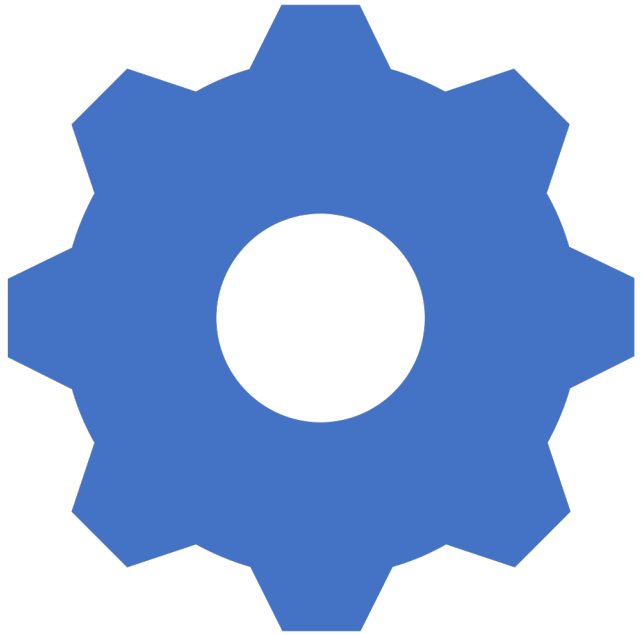


# MECHANICAL THROMBECTOMY

Michael Bruce Horowitz, MD, FAANS, CAST

# SOBERING FACTS

- THE AVERAGE BRAIN HAS 86 BILLION NEURONS

- WHAT IS THE BRAIN DAMAGE DURING A LARGE VESSEL OCCLUSION (LVO)?

- 120 MILLION NEURONS DIE EACH HOUR
- 1.9 MILLION NEURONS DIE EACH MINUTE

•

# BEFORE WE GET INTO DETAILS, WHAT'S THE SKINNY? (WHY IS STROKE MANAGEMENT A TOPIC OF INTEREST?)

- **REASON #1:** 795,000 ischemic strokes/year in the US with 15% 30d mortality and $34 billion cost to US economy/year due to care, death and disability
- **REASON #2:** Effective window for intervention has extended from 0-4 hrs (IV-TPA) to 0-24 hours meaning more patients can be offered potentially beneficial treatments
- **REASON #3:** While IV-TPA use alone on average loses a hospital approximately $890/patient treated (some institutions do develop positive revenue because of high reimbursements), Mechanical Thrombectomy for LVO (135,000 cases/year)can earn a hospital $9,000 - $15,000+/patient if done correctly
- **REASON #4:** In order to participate in stroke care, hospitals will need to be Comprehensive Stroke Certified (SSC) or EMS will bypass them for another CSC.
- **REASON #5:** In order to be CSC, a hospital will require vascular neurosurgeons and CAST certified neuroendovascular providers

# PERSONNEL/INFRASTRUCTURAL REQUIREMENTS

- **PERSONNEL**
  - CEO/CFO with long term vision to budget for and then build a CSC (3-5 year plan) and provide ongoing embedded FINANCIAL ANALYST support
  - CMO with long term vision to medically support CSC infrastructural needs
  - NEUROSCIENCE DIRECTOR with neurosurgical and endovascular skill set and experience to build a CSC, organize its daily activitIes and plan for future directions and needs
  - NEUROLOGIST with interest in vascular neurology
  - TELENEUROLOGY to staff ER 24/7 for acute stroke
  - RADIOLOGIST interpretation of imaging 24/7/265 or installation of automated interpretation software such as RAPID
  - ER PERSONNEL, INTENSIVISTS, HOSPITALISTS, NURSES, APs, REHAB SERVICES, SOCIAL SERVICES, MARKETING PERSONNEL, interested in working together to build a seamless program
- **INFRA-STRUCTURE**
  - NEUROVASCULAR OUTPATIENT LOCATION WITH CLINIC AND OFFICES
  - AP X2, MA, FRONT DESK PERSONNEL, SCHEDULING PERSONNEL
  - BIPLANE ANGIOGRAPHY SUITE
  - ANGIOGRAPHY TECHS X2
  - CTA CAPABILITY (24/7/365)
  - CT capability (24/7/365)
  - CTP CAPABILITY (24/7/365)
  - RAPID software (?)
  - MRI

# STROKE FACTS AND SOCIETAL IMPACTS

# CEREBRAL ISCHEMIC STROKE

- 87% of strokes are ischemic
- 10-18% of confirmed ischemic strokes are due to large vessel occlusions (LVO) and potentially eligible for EV/MAT
- 795,000 ischemic strokes/year in US (610,000 of these are first time strokes)
- 34% of stroke patients are less than 65 yo
- Risk factors include hypertension, hypercholesterolemia, diabetes
- Black:White ratio 2:1
- 1 stroke in US every 40 seconds
- 1,000,000 ischemic strokes/year in European Union
- 30-day mortality rate is estimated at 15%
- $5^{th}$ leading cause of death in US
- 140,000 Americans die/year secondary to stroke (1 in 20 deaths)
- 1 death every 4 minutes in US secondary to stroke
- Stroke is primary cause of long-term disability
- Estimated cost to US Economy/year = $34 Billion

# WHAT IS THE BASIC PHYSIOLOGY BEHIND STROKE AND LVO?

- LVO results in various degrees of CBF reduction
  - CBF < 23 ml/100 g tissue/min results in neurologic dysfunction and CBF >18 ml/100 g/min can survive indefinitely, but is vulnerable to intermittent reductions in local CBF **(PENUMBRA)**
  - CBF 10-18 ml/100 g tissue/min can survive for +/-3 hours, but is vulnerable to intermittent reductions in local CBF **(PENUMBRA)**
  - CBF < 10 ml/100 g tissue/min for +/- >30+ minutes results in irreversible neuronal injury. This tissue will not benefit from reperfusion and in fact might hemorrhage if re-perfused **(ISCHEMIC CORE)**

# MECHANICAL ARTERIAL THROMBECTOMY (MAT)
# AKA
# ENDOVASCULAR THROMBECTOMY (EVT)

# WHAT IS MECHANICAL ARTERIAL THROMBECTOMY (MAT)?

- MAT is the manual removal of thromboemboli from extracranial and intracranial arterial vasculature using catheter-based devices
  - 45,000 MAT performed in US in 2019
  - 24,000 MAT performed in EU in 2019
- Categories
  - MERCI
    - The OG
  - Suction thrombectomy
    - Manual aspiration
    - Vacuum pump aspiration
      - Penumbra (Penumbra, Alameda CA)
  - Stent retrieval (aka: Stentriever)
    - Trevo (Stryker Neurovascular, Fremont, CA)
    - Solitaire (Medtronic, Irvine, CA)

# WHY MECHANICAL TROMBECTOMY

IV-TPA Outcomes. Stroke 2013. 44:3109-3113; Stroke 2019. 50(3)

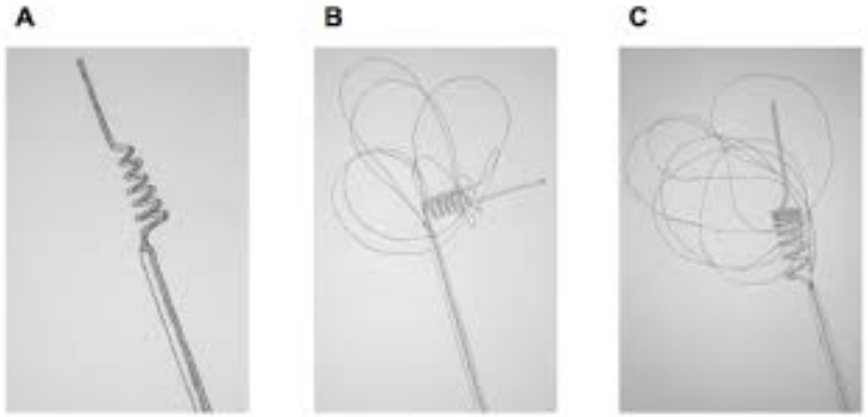
40% 90 day mRS 0-1 when administered within 90m minutes of stroke onset

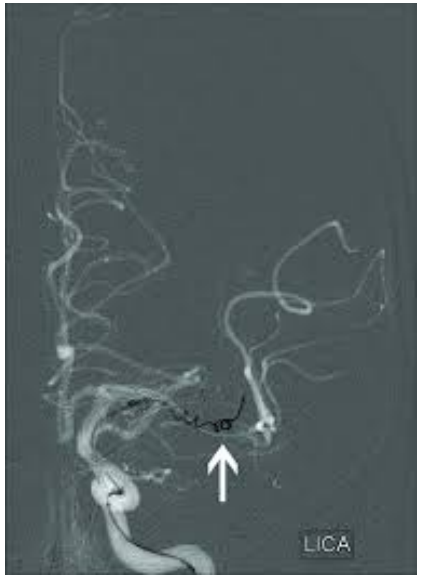
45% 90 day mRS 0-1 when administered within 91-180 minutes of stroke onset

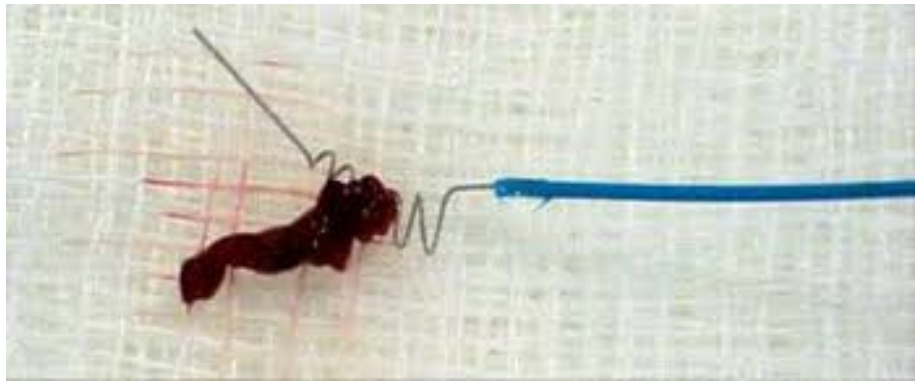
35% 180 day mRS 0-2 after IV-TPA for LVO and NIHSS > 10

**THIS IS NOT ACCEPTABLE**

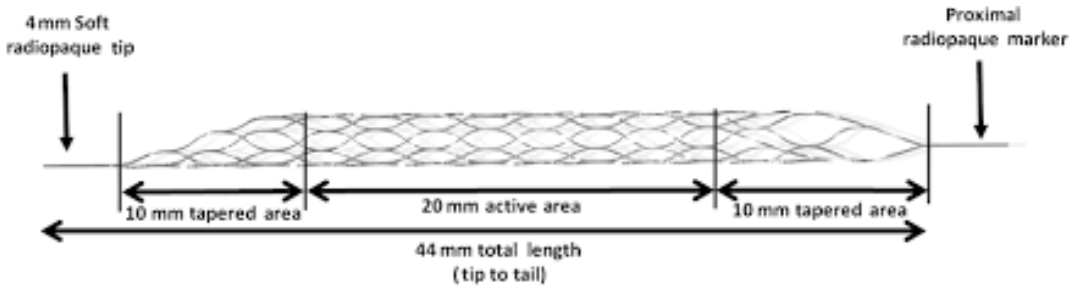
# MERCI THROMBECTOMY DEVICE (THE OG- 2008)

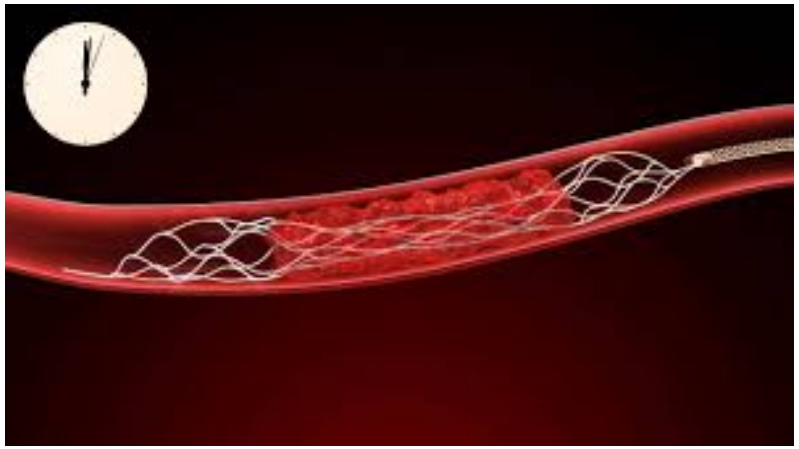


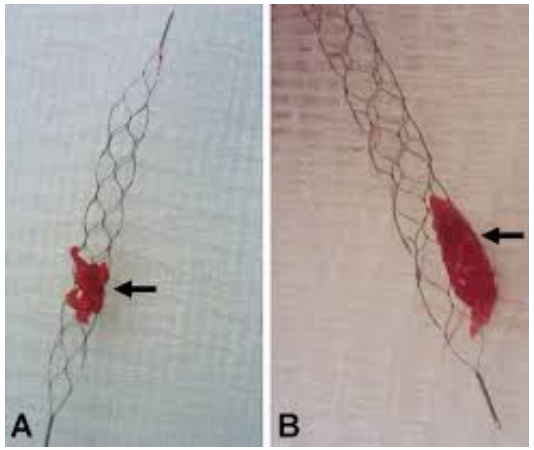



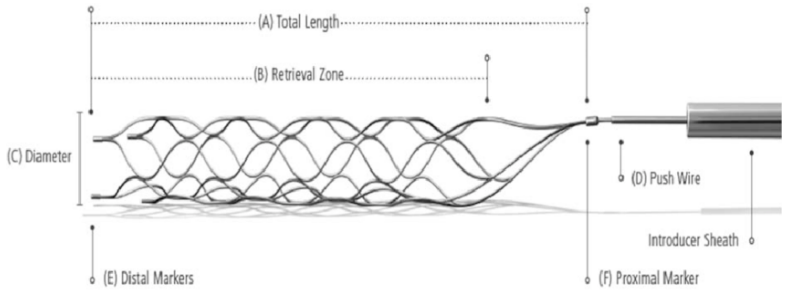
# STENT RETRIEVAL DEVICES (TREVO)



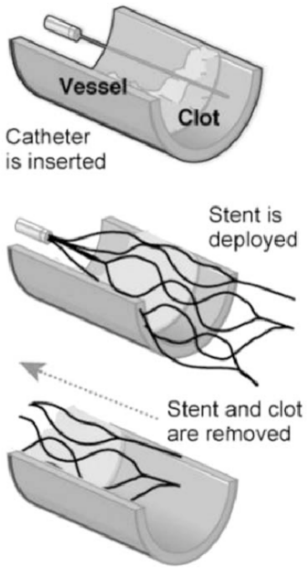





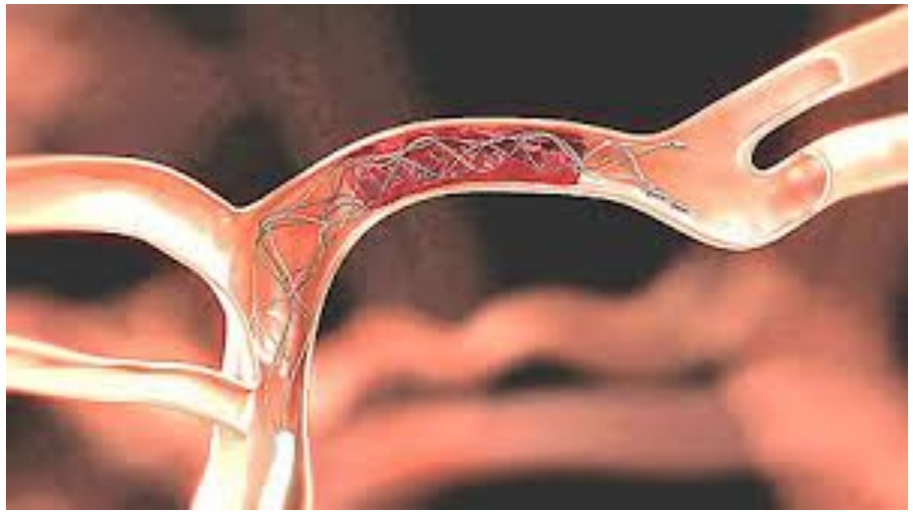
# STENT RETRIEVAL DEVICES (SOLITAIRE)

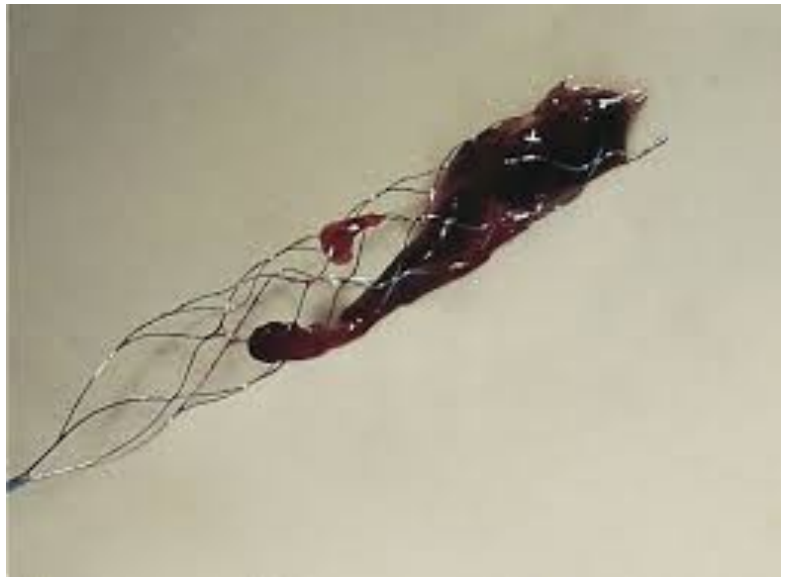



(a)

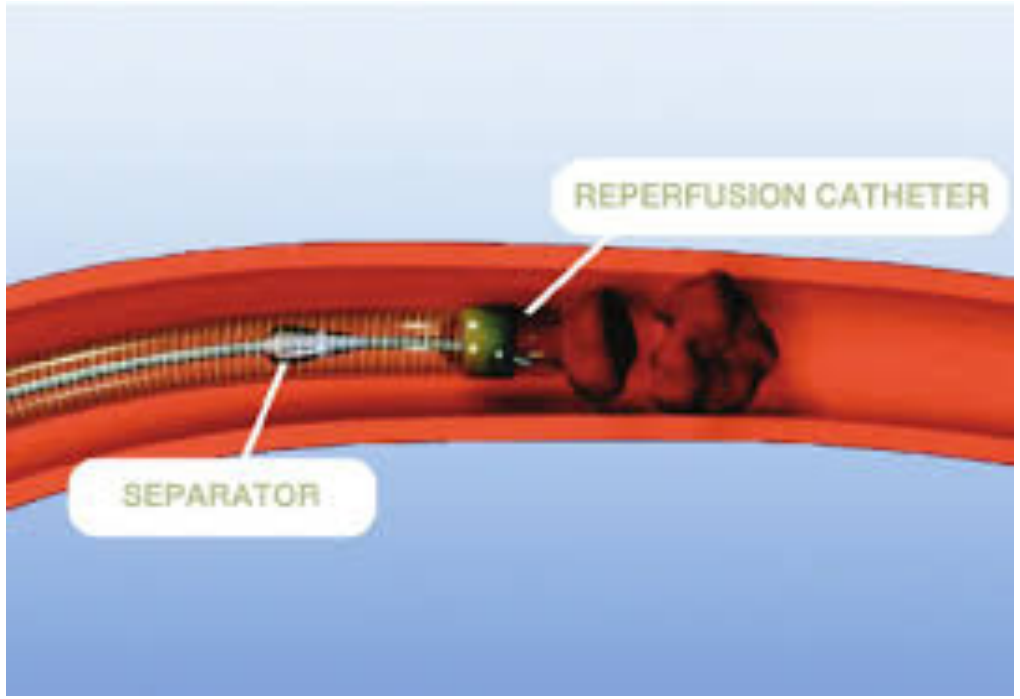



(b)



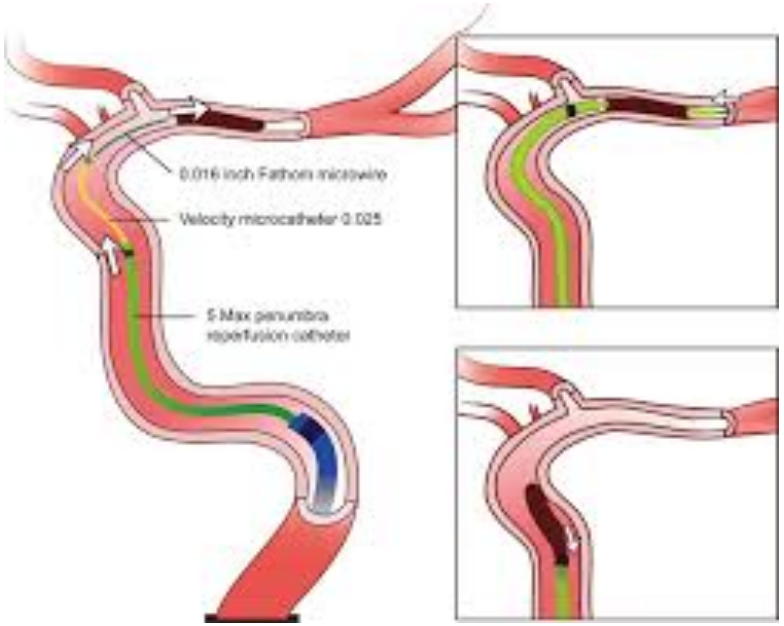


# ASPIRATION (PENUMBRA)

# ASPIRATION (MANUAL)

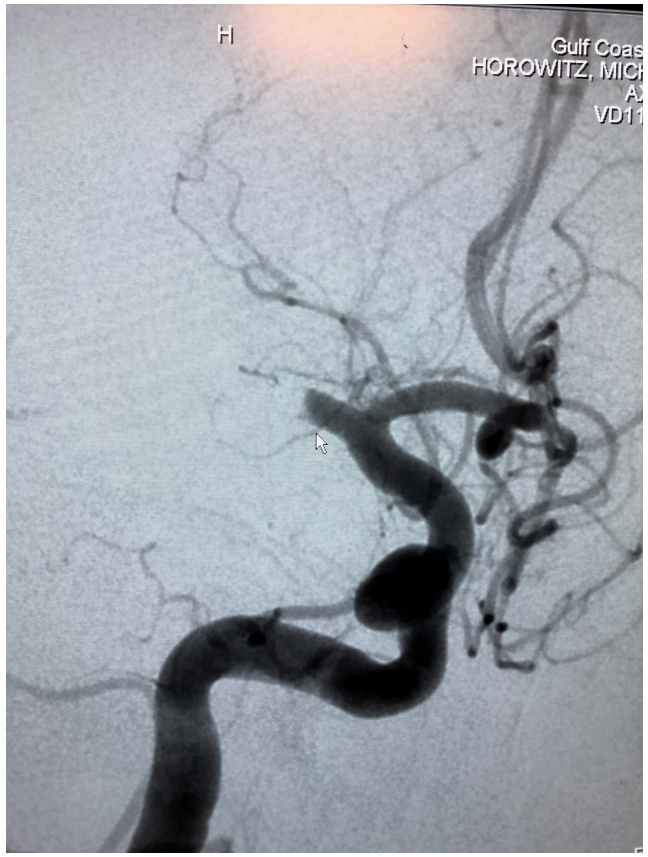


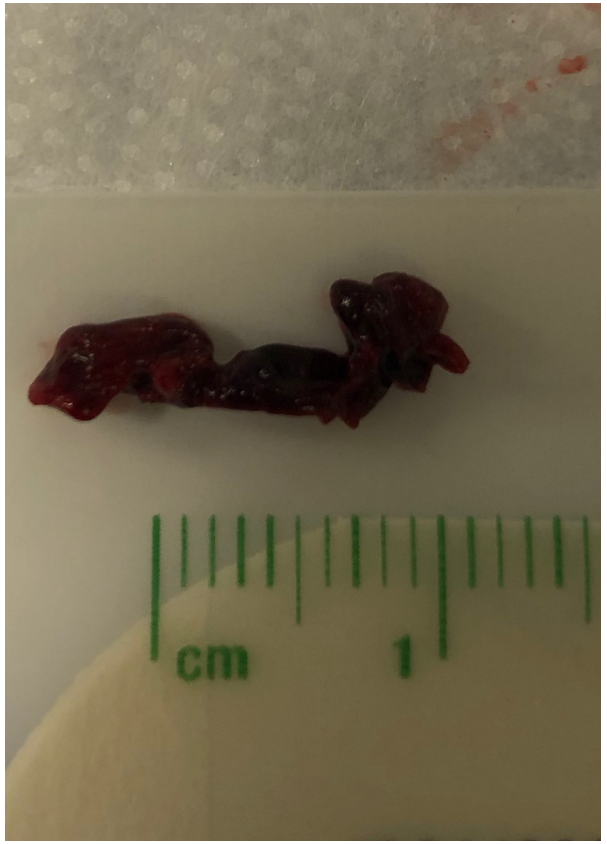
# PERSONAL CASE EXAMPLES WITH IMAGES

- 4-month period (11/2019 – 2/2020)
- 37 LVO thrombectomies
  - 90% suction (28 cases)
  - 10% suction + stentriever (5 cases)
  - 3 intracranial stents (MCA x1; BA x2)
- Mean Groin Puncture to TICI 2b/3 Revascularization Time = 27 min
  - Mean Groin to TICI 2b/3 Revasclarization Time if octogenarians excluded (N=3) = 22 min
- Procedure related complications 1 (2%)

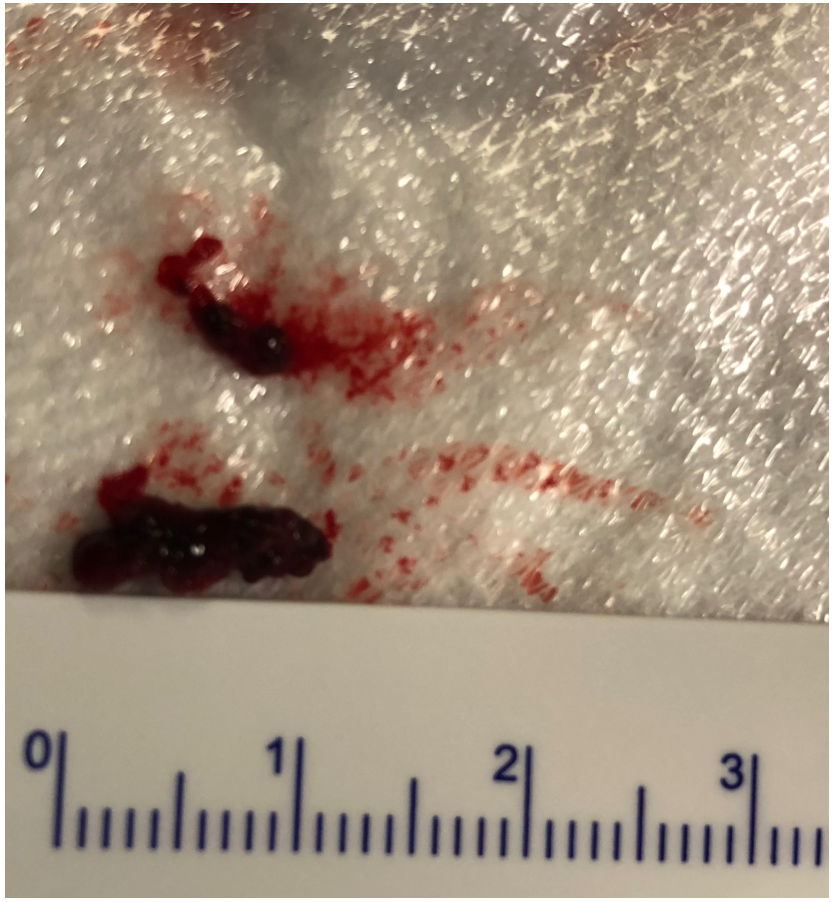
# RIGHT MCA M1 MANUAL SUCTION THROMBECTOMY



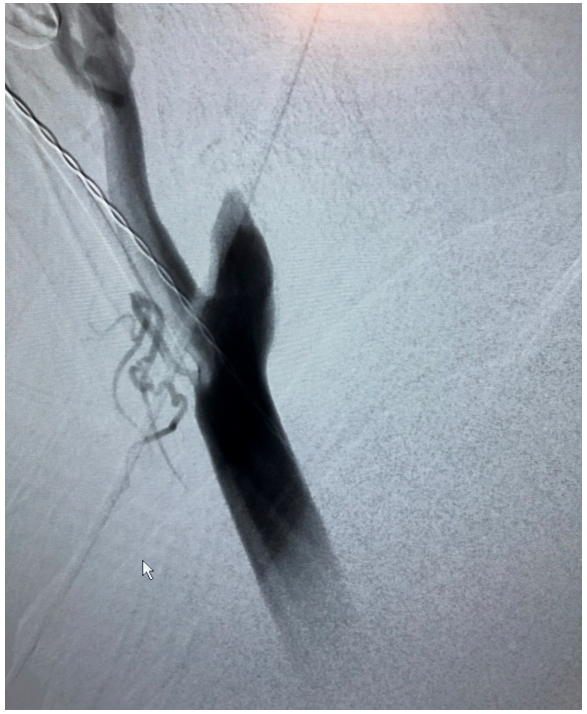


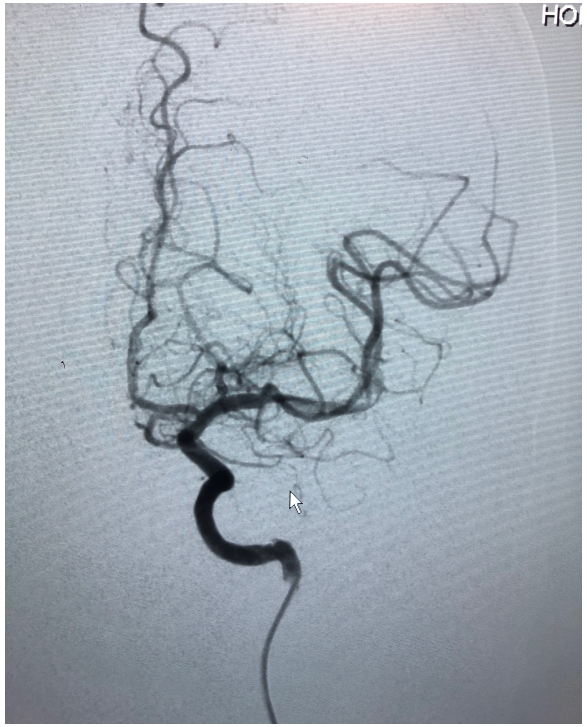


# BASILAR ARTERY APEX MANUAL SUCTION THROMBECTOMY



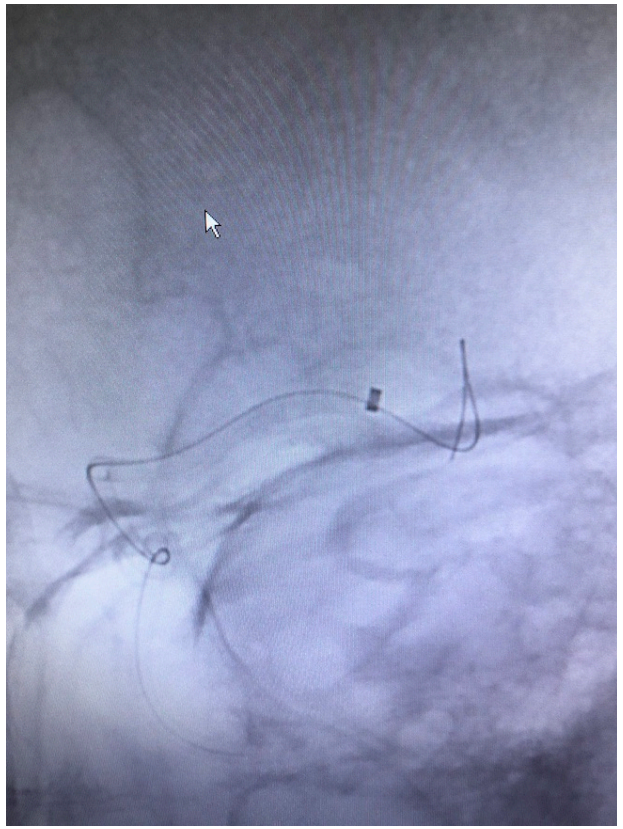
# ACUTE LEFT INTERNAL CAROTID ARTERY OCCLUSION STENTING



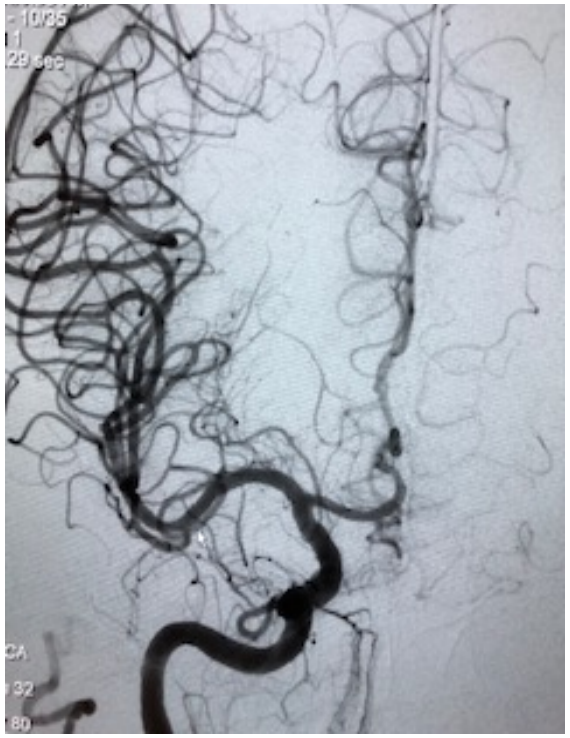


# RIGHT M1 MCA STENOSIS WITH FILLING DEFECT WINGSPAN STENT/ANGIOPLASTY

# LEFT M1 MCA COMBINED MANUAL SUCTION ASPIRATION AND STENT RETRIEVER THROMBECTOMY



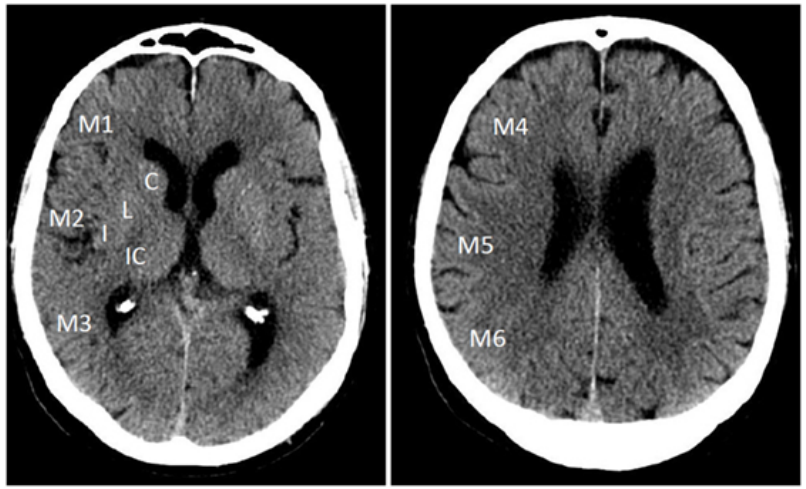
# RIGHT MCA M2 MANUAL SUCTION THROMBECTOMY



# TERMINOLOGY

# KEY TERMS AND DEFINITIONS

- ASPECTS
  - Scale used to rate extent of ischemic stroke on CT images of the brain
  - No evidence of ischemic changes =10
  - Diffuse hemispheric ischemic stroke = 0



# CT PERFUSION TERMS

- Core (A) (aka: infarcted/dead brain; cannot be saved)
  - Tissue volume that demonstrates CBF that is 30% less than corresponding normal brain
- Critically Hypo-perfused Tissue (B )
  - Tissue volume that demonstrates a time to maximum perfusion longer than 6 seconds
- Penumbra (aka: Mismatch; aka: brain tissue that can potentially be saved from infarction and return to normal function)
  - Tissue that is at risk to infarct
  - B – A = Penumbra

# LARGE VESSEL OCCLUSION (LVO)

- WHAT IS THE INCIDENCE OF LVO IN 2,245 TRUE STROKE PATIENTS?
  - (J Stroke Cerebrovasc Dis. 2020 Feb; 29(2):104504)

- LVO N=418 (18.6%) confirmed with CTA or MRA
  - M1 N= 139 (33.3%)
  - M2 N=114 (27.3%)
  - ICA N=69 (16.5%)
  - ICA + MCA (Tandem lesions) N=44 (10.5%)

# VESSEL PATENCY

- eTICI
  - 0 — No perfusion
  - 1 — Decreased thrombus.  No distal opacification
  - 2A — >0 -49% opacification
  - 2B50 — 50-66% opacification
  - 2B67 — 67-89% opacification
  - 2C — 90-99% opacification
  - 3 — 100% opacification

- TICI
  - 0 — No perfusion
  - 1 — Penetration with minimal opacification
  - 2A — Partial filling (less than 2/3 of vascular territory opacifies)
  - 2B — Complete filling of vascular territory but slower than normal
  - 3 — Complete perfusion

# Modified Rankin Scale (mRS)

- Measurement of a patient's degree of disability
  - 0 No symptoms
  - 1 No significant disability. Able to carry out usual activities despite some symptoms
  - 2 Slight disability. Can look after own affairs without assistance but unable to carry out all previous activities
  - 3 Moderate disability. Requires help but able to walk unassisted.
  - 4 Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted
  - 5 Severe disability. Requires constant nursing care and attention, bedridden, incontinent
  - 6 Dead

# ACUTE STROKE MANAGEMENT STEPS

# CURRENT ACUTE STROKE MANAGEMENT ALGORITHM AND TIME METRIC GOALS (ANTERIOR CIRCULATION)

- **IN THE SETTING OF AN ANTERIOR CIRCULATION LVO, AN AVERAGE OF 2 MILLION NEURONS DIE PER MINUTE WITH AN ESTIMATED RANGE BETWEEN <35,000 - >27 MILLIOM.** STROKE. 2019. 50:34-37
- **"EVERY 30 MINUTE DELAY FROM SYMPTOM ONSET TO REPERFUSION EQUATES TO AN APPROXIMATE 10% DECREASE IN THE LIKELIHOOD OF A GOOD OUTCOME. GOAL FOR TREATMENT SHOULD BE 60 MINUTES OR LESS DOOR TO GROIN PUNCTURE"** TUDOR JOVIN, MD. LINCC MEETING. PARIS, FRANCE 2015

| | | |
|---|---|---|
| • ER arrival | **DOOR TIME** | **0 M** |
| • Assessment with neurologic screening test (VAN)<br>  • Relevant PMH + LKN (LKN 0-3; 3-4.5; >6 and <24 H | **DOOR TO STROKE TEAM NOTIFICTION TIME** | **<15 M** |
| • CT Head<br>  • ASPECTS<br>  • Hemorrhage | **DOOR TO CT TIME** | **<25 M** |
| • Determine iv-TPA candidacy<br>  • NIHSS; PMH; LKN; Labs; Meds<br>  • Administer ivTPA if indicated | **DOOR TO NEEDLE TIME** | **60 M IN 75%; 45 M IN 50%** |
| • CT Angiogram Head/Neck (?)<br>  • +/- LVO | | |
| • CT Perfusion (when LKN ≥ 6 and ≤24 HRS)<br>  • Core volume (< or > 70 ml)<br>  • Penumbra volume (< or >15 ml)<br>  • Penumbra:Core > or < 1.8 | | |
| • Endovascular Treatment | **DOOR TO LAB TIME**<br>**DOOR TO GROIN PUNCTURE TIME**<br>**GROIN TO DEVICE CROSSING AND REVASC TIME** | **MH AVG. GROIN TO REPERFUSION 26M** |

- **HOLY GRAIL = DOOR TO REVASCULARIZATION TIME <60 MINUTES**

H

# STUDIES SUPPORTING EVT/MAT

# RANDOMIZED TRIALS EVALUATING EVT (ENDOVASCULAR THROMBECTOMY)

- **MR CLEAN** (EVT +/- IA-TPA vs IV-TPA)
  - N=500
  - NIHSS >2 within 6H LKN
    - 90 day mRS ≤2 — 32.6% vs 19.1%
    - Symptomatic ICH — 7.6% vs 6.4%
    - Mortality — 21% vs 22%
- **SWIFT PRIME** (EVT +/- IA-TPA vs IV-TPA)
  - N=196
  - NIHSS >8 <30
    - 90 day mRS ≤2 — 60% vs 36%
    - Symptomatic ICH — 1% vs 3.4%
    - Mortality — 9% vs 12%

# RANDOMIZED TRIALS EVALUATING EVT (ENDOVASCULAR THROMBECTOMY)

- **EXTENDED IA** (EVT +/- STENT vs IV-TPA)
  - N=70
    - 90 day mRS ≤2 — 72% vs 39%
    - Symptomatic ICH — 1% vs 3.4%
    - Mortality — 9% vs 12%
- **ESCAPE** (EVT vs IV-TPA)
  - N=315
    - 90 day mRS ≤2 — 54% vs 29%
    - Symptomatic ICH — 3.6% vs 2.7%
    - Mortality — 10.4% vs 19%

# RANDOMIZED TRIALS EVALUATING EVT (ENDOVASCULAR THROMBECTOMY)

- **THRACE** (IA TPA +/- EVT vs IV-TPA
  - N=414
  - NIHSS >10 <25
    - 90 day mRS ≤ 2 — 53% vs 42%
    - Symptomatic ICH — 2% vs 2%
    - Mortality — 12% vs 13%
- **REVASCAT** (EVT vs IV-TPA)
  - N=206
  - NIHSS >6 LKN 8H
    - 90 day mRS ≤ 2 — 43.7% vs 28%
    - Symptomatic ICH — 1.9% vs 1.9%
    - Mortality — 18.4% vs 15.5%

# EVT/MAT RANDOMIZED STUDY RESULTS

- 59% - 88% TICI 2b/3 recanalization
- Functional outcome rate improved in EVT group (33% -71%)
- Using CT alone (no CTP) EVT beneficial vs IV-TPA
- Per 100 patients treated, 38 will be less disabled than IVT alone and 20 more will reach functional independence
- Number to treat for 1 patient to have reduced disability of a least 1 mRS point is 2.6
- EVT benefits in mRS seen at 90 days are preserved at 1-2 years
- No safety difference between EVT and IVT
- EVT risk of bleeding is likely related to IVT prior to EVT
- EVT remained superior in patients >80 yo, >300 min from LKN, and not eligible for IVT

# EVT/MAT NON-RANDOMIZED REGISTRIES

- J American Heart Association. 2018. December. 18;7(24)
- **Trevo Prospective Registry** (N=2008 @76 centers/12 nations)
  - Median NIHSS = 16
  - Location
    - ICA 17.8%
    - MCA 73.5%
    - Distal MCA 1.6%
    - Posterior Circulation 1.6%
  - Endpoints
    - TICI 2b/3a 92.8%
    - 90d mRS $\leq$2 55%
    - Symptomatic ICH 1.7%

# EVT/MAT NON-RANDOMIZED REGISTRIES

- J Neurointerven Surg. 2018. June. 10(6):516-524.
- **Trevo Prospective Registry** (N=634 @ 23 centers from 2013-2015)
  - Mean NIHSS 17 +/- 6
  - Mean age 66 +/- 14
  - Mean Groin Puncture to Revascularization 79 +/- 50 min
- Endpoints
  - TICI 2b/3a 80.3%
  - 90 day mRS $\leq$ 2 48%
  - 90 day mortality 20%

# EVT/MAT NON-RANDOMIZED REGISTRIES

- J Neurointerven Surg. 2018. July. 10:45-49.
- **Solitaire Registry** (N=354 @ 24 centers)
  - Mean procedure time 101 +/- 58 min
  - TICI >2a 87.5%
  - 90 day mRS ≤ 2 42%

# IS STENT RETRIEVER THROMBECTOMY BETTER OR WORSE THAN MANUAL SUCTION THROMBECTOMY?

# Stent Retriever Thrombectomy vs Suction Thrombectomy

- JAMA. 2017. August. 318(5):443-452.
- **Contact Aspiration vs Stent Retriever (ASTER Trial)**
  - Anterior circulation: Aspiration 192 Stent Retriever 189)
    - TICI 2b/3 85.4% 83.1%

---

- Medicine. 2018. October. 97(41)
- **Direct Aspiration vs Stent Retriever (Meta-analysis 9 studies)**
  - Endpoints
    - Identical recanalization rates
    - 3m mRS better in aspiration group
    - Aspiration had shorter treatment times
    - ICH and embolization lower with suction

# OUTCOMES

# PREDICTORS OF OUTCOME IN PATIENTS TREATED USING EVT/MAT?

- ASPECTS [Circulation: Cardiovascular Interv. 2018. 11(1)]
  - EVT improves outcomes in ASPECTS 8-10 (odds ratio 2.1)
  - EVT improves outcomes in ASPECTS 5-7 (odds ration 2.04)
  - EVT not currently found to be beneficial in ASPECTS 0-4
- Collateral Patterns
  - Robust collaterals predict improved outcomes (how do you evaluate collaterals well? CTA?)
- GETA vs Sedation [Cerebrovascular Dis. 2019. 48(1-2):91-94]
  - No clear benefits when either is used
  - 90 day mRS $\leq$ 2 identical  in both groups
- CTP/DWI [DAWN; DIFFUSE]
  - Penumbra:Core >1.8
  - Core <70cc
  - Penumbra >15cc

# PREDICTORS OF OUTCOME IN PATIENTS TREATED USING EVT/MAT

- Functional Outcome Following Thrombectomy [Stroke. 2019. Sep. 50(9):2500-2506]
- DEMOGRAPHICS
  - N=2794 LVOs evaluated prospectively @ 25 German centers over 3 years
    - Anterior Circulation LVO 88%
    - Posterior Circulation LVO 12%
  - Mean age 75
  - Median NIHSS 15
  - 56% received iv-TPA
  - Successful reperfusion in 83%
- RESULTS
  - 37% had 90 day mRS $\leq$ 2
  - 29% mortality at 90 days
  - No difference between anterior and posterior LVO outcomes
- Good outcome predictors
  - Younger age
  - No interhospital transfer
  - Lower stroke severity
  - Smaller infarct size
  - Iv-TPA use
  - Reperfusion success

# CT PERFUSION INFLUENCE ON OUTCOMES

- Lancet Neurol. 2019. 18(1): 46-55
  - Do Penumbra and Core volumes influence 90 day mRS after mechanical thrombectomy?

- FINDINGS
  - Increased Core volume reduces mRS, but does not modify benefits of EVT over medical therapy
  - Penumbra volume was not associated with functional independence
  - In patients with >50% endovascular reperfusion on CTP, functional outcomes were improved

# CT IMAGING AS RELATED TO OUTCOMES

- Lancet Neurol. 2018. Oct. 17(10):895-904.
- N=1764 with LVO
  - 871 EVT vs 893 no EVT
  - Both groups matched for
    - LVO location
    - IV-TPA administration (88% vs 91%)
    - ASPECTS
    - NIHSS (mean 17)
    - Collateral opacification scores
    - MCA perfusion deficit

# CT IMAGING AS RELATED TO OUTCOMES (continued)

- **OUTCOMES**

| | |
|---|---|
| • 90 day mortality | EVT (15%) vs No EVT (17%) |
| • 90 day morbidity EVT vs no EVT | |
| • 90 day mRS 0-2 in ASPECTS 0-2 | EVT (0%) vs No EVT (12%) |
| • 90 day mRS 0-2 in ASPECTS 3-5 | EVT (31%) vs No EVT (16%) |
| • 90 day mRS 0-2 in ASPECTS 6-10 | EVT (51% vs No EVT (33%) |
| • 90 day mRS 0-2 in <33% MCA stroke | EVT (51%) vs No EVT (33%) |
| • 90 day mRS 0-2 in >33% MCA stroke | EVT (27%) vs No EVT (18%) |
| • 90 day mRS 0-2 in ICA occlusion | EVT (33%) vs No EVT (15%) |
| • 90 day mRS 0-2 in M1 proximal occlusion | EVT (47%) vs No EVT (29%) |
| • 90 day mRS 0-2 in M1 distal occlusion | EVT (59%) vs No EVT (48%) |
| • 90 day mRS 0-2 in M2 occlusion | EVT (58%) vs No EVT (40%) |
| • Symptomatic ICH | EVT (3.8%) vs No EVT (3.5%) |
| • Symptomatic ICH when ASPECTS 0-4 | EVT (19%) vs No EVT (5%) |
| • Symptomatic ICH when MCA stroke distribution >33% | EVT (14% ) vs No EVT (4%) |

# CT IMAGING AS RELATED TO OUTCOMES (continued)

- **CONCLUSION**
  - EVT group had better 90 day outcomes than no EVT group even when MCA distribution infarct was >33% or ASPECTS was as low as 3 .
  - Improved outcomes were demonstrated even though EVT had a higher risk for ICH
  - Improved outcomes were demonstrated when occlusion was more distal.

# EVT FOR ANTERIOR CIRCULATION LVO IN PATIENTS OVER 90 YEARS OLD

- J Interventional Surgery. 2019. Nov. 11(1):1091-1094.
- **OUTCOMES DATA** (N=79)
  - Time Groin Puncture to Revascularization — 39 min
  - TICI $\geq$ 2B Revascularization — 70%
  - Symptomatic ICH — 5%
  - In Hospital Mortality — 29%
  - 90 day Mortality — 47%
  - 90 day mRS $\leq$ 2 — 16%

# EVT FOR MILD ANTERIOR CIRCULATION LVO STROKES

- Intervent Neurol. 2018. Oct. 7(16):431-438
- N=160
  - LVO distal ICA, M1, M2
  - NIHSS ≤ 10
- **OUTCOMES**
  - Discharge mRS 0-2 — IVT (56%) vs EVT +/- IVT (59%)
  - Discharge mRS 0-1 — IVT (32%) vs EVT +/- IVT (38%)
  - Symptomtic ICH — No differences
  - Infarct size — No differences
- **CONCLUSION**
  - NO benefit to EVT compared to IVT in anterior circulation LVO when NIHSS ≤ 10
  - **IMPLICATIONS FOR CARE?**
  - **IMPLICATIONS FOR RESOURCE UTILIZATION/COST IMPACT?**
  - **NEED FOR PROSPECTIVE RANDOMIZED STUDY NEEDED?**

# EVT IN SETTING OF TANDEM OCCLUSIONS

# EVT IN THE SETTING OF TANDEM OCCLUSIONS

- TANDEM OCCLUSION DEFINITION
  - Extracranial ICA occlusion in the setting of Intracranial LVO (ICA, MCA)

- QUESTIONS
  - Does prior heparin or TPA use increase the risk of treating tandem occlusions using angioplasty, stenting, and EVT/MAT?
  - Does management of LVO in the setting of extracranial ICA occlusion have benefits?

- WHAT IS THE EVIDENCE?

# EVT IN THE SETTING OF TANDEM OCCLUSIONS AND IV-TPA USE

- Stroke. 2019. Aug. 50(8):2250-2252.
- Emergent Carotid Stenting and Thombectomy after Thrombolysis in Tandem Strokes- TITAN Registry
- QUESTION
  - Is treatment of this condition using stenting and EVT dangerous in the setting of prior IV-TPA use?
    - N=205
    - The use of IV-TPA prior to carotid stenting and EVT is not associated with an increased ICH rate compared to no IV-TPA use (5% vs 8%)
    - 90 day all cause mortality rate was lower in IVT group vs no-IVT group (8% vs 20%)
- CONCLUSION
  - IVT prior to EVT treatment of tandem occlusions has no negative effects

# EVT IN THE SETTING OF TANDEM OCCLUSIONS AND IV HEPARIN USE

- Cardiovascular Intervent Radiol. 2019. 42(8):1160-1167.
- QUESTION
  - Is treatment of this condition using stenting and EVT dangerous in the setting of prior heparin use?
  - N=369
  - 18.6% of patients received 1500-2500 IU heparin

- OUTCOMES
  - 90 day mRS $\leq$ 2 — Heparin (51.3%) vs No-Heparin (58%)
  - TICI 2B/3 — No differences

# EVT IN THE SETTING OF TANDEM OCCLUSIONS AND PLATELET USE

- Stroke. 2019. February. 50(2):516-519
- QUESTION
  - Is treatment of this condition using stenting and EVT dangerous in the setting of prior antiplatelet use?
  - N=289
- OUTCOMES
  - 25% Hemorrhagic infarction rate at 24h
  - 14% Parenchymal hematoma rate at 24h
  - Not associated with increased mRS at 90d
  - Independent predictors of hemorrhagic infarction include
    - Intracranial carotid occlusion
    - Diabetes mellitus
    - Complete EICA occlusion

# EVT IN THE SETTING OF TANDEM OCCLUSIONS

- J Neurointervent Surg. 2019. October 11(10):970-4
- N=305
  - 135 complete EICA occlusions
  - 170 near complete EICA occlusions
- QUESTION
  - Does severity of EICA disease affect tandem treatment results?
- OUTCOMES
  - TICI 2B/3 — 70% in complete group/81% in non-complete group
  - 90 day mRS $\leq$ 2 — Identical results
  - ICH — Identical results
  - Complications — Identical results

# EVT IN THE SETTING OF TANDEM OCCLUSIONS

- JACE Cardiovasc Interv. 2018. July 9.  11(13):1290-1299.
- N=482
- QUESTION
  - Do treatment strategies alter outcomes?
    - Thrombectomy/ICA Stent/Antithrombotic Therapy (Group A)
    - Thrombectomy/ICA Stent (Group B)
    - Thrombectomy/ICA Plasty (Group C)
    - Thrombectomy (Group D)

# EVT IN THE SETTING OF TANDEM OCCLUSIONS

| | **GROUP A**<br>Thrombectomy<br>ICA Stent<br>Antithrombotic | **GROUP B**<br>Thrombectomy<br>ICA Stent | **GROUP C**<br>ICA Angioplasty<br>Thrombectomy | **GROUP D**<br>Thrombectomy |
|---|---|---|---|---|
| TICI 2B/C | 83% | 73% | 69% | 60% |
| mRS $\leq$ 2 @ 90 d | 58% | 44% | 40% | 42% |
| 90 d MORTALITY | 9% | 18% | 12% | 17% |
| SYMPT. HEMOR | 5% | 9% | 0% | 5% |

# CAN ACUTE STROKE BE EVALUATED AND TREATED MORE EFFICIENTLY?

# CONSIDERATIONS

- Acute ischemic stroke management has evolved rapidly over the past 25 years
- In order for this evolution to take place,  rigorous outcomes testing has been conducted using basic and advanced imaging and detailed scaled neurologic examinations
- Rigorous testing has defined best practices based on long term outcomes.
- Prospective randomized studies have supported benefits of IV-TPA and EVT/MAT in selected patient populations.
- Now that current best practices are understood, it is prudent to reduce unnecessary testing burden to reduce costs and shorten treatment times (which improves outcomes). This can be achieved by eliminating tests and studies that continue to be used to collect data, but which, in reality, do not impact acute decision making.
- Using current proven technologies, outcomes improvement will be achieved by shortening ER Door to Needle (IV-TPA infusion), ER Door to Groin Puncture, and ER Door to Reperfusion/Mechanical Revascularization times.
- As new technologies and techniques develop, evaluation and validation of efficacy can temporarily revert to utilizing the more detailed and extensive testing that has been employed in the past to validate current treatment paradigms and algorithms.

# SIMPLIFY

- **QUESTIONS:**
- #1: Can we identify which elements of the currently standardized patient evaluation are critically important and which elements are not critically important when it comes to patient selection and outcomes?

- #2: Can we reduce ER Door to Revascularization times to <60 min by making patient triage and assessment more efficient?

# SIMPLIFY

- **QUESTION:** What steps can be taken to appropriately triage patients from the field to those medical centers that can most definitely address their specific stroke etiology?

- **RATIONALE BEHIND QUESTION:** By initially transporting LVO and non-LVO stroke patients to the appropriate level Stroke Center, EMS can shorten the time to treat eligible non-LVO patients with IV-TPA and to treat eligible LVO patients with IV-TPA and/or EVT by directing them to the closest appropriate facility

- **POTENTIAL SOLUTION: Appropriate transport to Comprehensive vs Non-Comprehensive Stroke Center using VAN testing or alternative examinations or technologies to detect LVO.**

# SIMPLIFY

- **Question:** Obtaining a patient's exact NIHSS (a time-consuming process) was necessary when initially evaluating new treatments for efficacy. However, now that efficacy of current treatments are known, does determining the exact NIHSS score in setting of LVO matter or is it clinically significant to simply know if NIHSS is: ≤4 // 5-10 // >10

- **Rationale Behind Question:**
  - NIHSS ≤ 4 — These patients are generally not treated with IV-TPA
  - NIHSS 5-10 — Studies suggest these patients when eligible for IV-TPA may not do any better with EVT compared to those treated with IV-TPA alone
  - NIHSS >10 — Patients eligible and not eligible for IV-TPA benefit from EVT
- **If only NIHSS range is needed to triage for appropriately care as it pertains to known long term outcomes (mRS, infarct size, symptomatic ICH), then a more rapid NIHSS can be performed. This will shorten evaluation time and time to treatment (Door to Needle and Door to Groin). Shortening of Time Metrics will improve outcomes.**

# SIMPLIFY

- **QUESTION:** Which imaging modalities are critically important to ensure rapid therapy? Which imaging modalities are of interest, but are not absolutely necessary, to achieve equivalent results in two clinically equivalent patient populations that vary only on the imaging studies provided prior to initiating the appropriate endovascular therapy.

- **RATIONALE:** By eliminating non-critical imaging, patients can transition into therapy (IV-TPA, EVT) more rapidly. This acceleration towards definitive care should translate into shorter Door to Needle, Door to Groin, and Door to Revascularization times. The final result, will be improved patient recovery with a higher mRs 0-2 outcome percentage while reducing resource utilization and expenditures.

- **ESSENTIAL VS. NON-ESSENTIAL IMAGING:**
- Plain Head CT to identify ICH, intracranial mass, or hypodense brain tissue (Core) is the only necessary imaging study for patients who present within 4 hours of stroke symptom onset
- CTP to identify and quantitate Core and Penumbra in only necessary when patients present $\geq$ 6 of LKN
- CTA Head(except after hours or on weekends to avoid unnecessary mobilization of resources) is unnecessary
- MRI/MRA Head and Neck in most cases provides information but does not affect outcomes and is therefore not necessary on a routine basis. It can be done as an outpatient after the patient has stabilized so that the final extent of brain injury is documented.

# SIMPLIFY

- Head CT is required to determine if a patient has intracranial hemorrhage, visible stroke, or and intracranial mass because these findings can exclude a patient from IV-TPA eligibility.
- CT acts as the “choke point” for treatment initiation.
- Because recent studies suggest that ASPECT >2 benefits from EVT and that an intracranial mass rarely presents with sudden focal neurologic deficits, the only imaging information needed prior to EVT is imaging that can detect ICH.
- Uni and biplane angiography can now be used to identify the presence of ICH (CT capability).
- Obtaining CT in the angio suite could further shorten time to treat and improve outcomes.  This process also reduces CT scan traffic so non stroke patients can be imaged in a timely fashion.

# EXPEDITED EVIDENCE BASED ALGORITHM FOR EVALUATING AND TREATING ACUTE STROKE PATIENTS AND FOR FURTHER EVALUATING AND TREATING LVO PATIENTS WHO ARE≤ 6H LKN

- EMS arrives on scene for suspected acute ischemic event
  - VAN exam conducted and Acoustic LVO Detection Device utilized to determine LVO status
    - LVO(+) to Comprehensive Center ER and LVO(-) to closest IV-TPA treatment capable Center
- LVO(+) arrives at ER.
  - PMH/PSH/Meds/LKN/Coags determined
  - Rapid NIHSS performed to determine if NIHSS ≤4, 5-10, or >10
    - If NIHSS ≤ 4, then no lytic/EVT therapy warranted. Admit to hospital.
    - If NIHSS 5-10, then proceed to "Imager" to assess ASPECT, presence of ICH, and presence of mass. Consider IV-TPA if patient is medically eligible
    - If NIHSS >10, then patient taken directly to NI lab
- Angio Detector (Imager) used to screen for ICH, Mass and ASPECT
  - If patient is negative for ICH, ASPECT >2, and IV-TPA eligible then administer IV-TPA and initiate EVT
  - If patient is negative for ICH, ASPECT >2, and IV-TPA ineligible then initiate EVT

# FINANCIAL CONSIDERATIONS

## KEY FACTS

**HEMORRHAGIC STROKES / 13% OF STROKES / INCREASING BY 3-6%/YEAR**

**ACUTE ISCHEMIC STROKE / 87% OF STROKES / INCREASING 25-30%/YEAR**

**10% OF ACUTE ISCHEMIC STROKES CURRENTLY UNDERGO EVT/MAT**

**40,500 EVT/MAT IN US IN 2019**

**34,000 EVT/MAT in EUROPE IN 2019**

**15% OF ACUTE ISCHEMIC STROKES CURRENTLY RECEIVE IV-TPA ALONE**

# SAMPLE HOSPITAL

- County Community Hospital System, Southwest Florida
  - Level 2 Trauma Center
  - 1162 total beds (4 adult hospitals)
  - 1 million person catchment area
- Ischemic Stroke diagnoses/year at two primary hospitals
  - Lee Memorial Hospital ischemic strokes = 1,138 discharge diagnoses/y (approx. 70,000 ER visits/year)
  - Gulf Coast Medical Center ischemic strokes = 1,772 discharge diagnoses/y (approximately 70,000 ER visits/year)

# LET’S BE REAL

**NO ENTITY OTHER THAN A GOVERNMENT THAT PRINTS MONEY, EXISTS IN PERPETUITY, CAN REPEATEDLY ISSUE DEBT IN THE FORM OF BONDS, AND CAN CONTINUALLY PUSH DEBT INTO THE FUTURE CAN DELIVER AN ONGOING SERVICE WHILE SIMULTANEOUSLY RUNNING AT A DEFICIT.**

# CAN INCREASED EFFICIENCY IN CARE DELIVERY COINCIDE WITH REDUCTIONS IN COST OF CARE DELIVERY WITHOUT COMPROMISING CLINICAL OUTCOMES?

# FINANCIAL ANALYSIS

**QUESTION #1:** How is acute stroke reimbursed?

**QUESTION #2:** What can be done to control costs and maximize revenue?

**QUESTION #3:** Can revenue be maximized without negatively impacting clinical outcomes?

**QUESTION #4:** Can the process of maximizing revenue simultaneously increase the likelihood of improved outcomes (such as by treating more rapidly)?

# FINANCIAL CONSIDERATIONS (HOSPITAL SPECIFIC)

- **REIMBURSEMENT REVENUE POST ER TO DISCHARGE** — **$40,116 (TOTAL)**
  - **DRG 23 (Mechanical Thrombectomy with Major Comorbidity** — **$38,000 (Average)**
    (Start IV-TPA in the ER so cost is not counted against DRG 23)
  - **CPT** — **$876** for Thrombectomy
    **$1,240** for angio (if CTA not done)

- **COSTS**
- NI Lab Materials w/Stent Retriever + Phar/Rad/Lab Work +Avg LOS (6d) — **$29,479 (TOTAL)**
- NI Lab Materials w/ Suction + Pharm/Rad/Lab WRk + Avg LOS (6d) — **$23,000 (TOTAL)**

- **POTENTIAL NET REVENUE/CASE** — **$10,637 – 17,116**

# REVENUE

- Since reimbursement for acute stroke is fixed and controlled by the Federal Government via DRG and CPT, and because private insurance uses these payment guidelines to set their reimbursement, the only way to reliably maximize revenue is to control costs while at the same time not compromising clinical outcomes. This can be achieved by eliminating wasted and unnecessary testing and minimizing clinical complications
- It is important that we focus on identifying what tests and procedures used in the past to assess treatment efficacy are no longer necessary since they no longer provide information that influences decision making and care and, as such, do not affect outcomes.

# PRO FORMA FOR A STROKE SERVICE BEGINS WITH UNDERSTANDING PATIENT POPULATION AND EXPECTED AVERAGE PROCEDURE RATIOS AND NUMBERS

- 25% of all patients diagnosed with confirmed strokes (discharge diagnosis of stroke) receive either IV-TPA and/or mechanical thrombectomy
  - National avg  for LVO EVT in patients with true diagnosis of stroke = 10%
  - National avg for IV-TPA alone in patients with true diagnosis of stroke = 15%
- Therefore, for every 100 patients admitted and found to have suffered a stroke
  - 10 should be undergoing thrombectomy
  - 15 should be undergoing IV-TPA alone

# PRO FORMA FOR MAT CAPABLE ISCHEMIC STROKE SERVICE (DRG)

- STEP 1: How many patients **(N)** are discharged with the diagnosis of ischemic stroke?
- STEP 2: What is LVO incidence or number? **18%** or **(0.18)(N)**
- STEP 3: Based on 2019 National Average how many patients will undergo mechanical thrombectomy? **10%** or **(0.10)(N)**
- STEP 4: Based on 2019 National Average how many patients will undergo IV-TPA? **15%** or **(0.15)(N)**
- STEP 5: Determine Medicare payment for MAT for DRG 23 and 24
- STEP 6: Document to maximize justifications for DRG 23
- STEP 7: Determine Medicare population % and multiply by [(0.18)(N)] to get number of patients **(A)** that will be reimbursed at the AMP. To Calculate Average Medicare Payment **(AMP)** will be based the % DRG 23 and % DRG 24 diagnoses.
- STEP 8: Determine private insurance patient population % and multiply by [(0.18)(N)] to get number of patients **(B)** that will be reimbursed at the insurance rate which is assumed on average to be 125% Medicare. **(1.25)(AMP)**
- STEP 9: Determine NO PAY population percentage and multiply by (0.18)(N) to get **(D)** and assume payment of **(0)(AMP)**
- STEP 10: Calculate expected DRG revenue for MECDHANICAL THROMBECTOMY SERVICE as follows:
- (A)(AMP) + (B)[(1.25)(AMPP] + (D)(0) = TOTAL ANNUAL **(R)** REIMBURSEMENT. **RANGE OF AVERAGE REIMBURSEMENT PER PATIENT RANGES BETWEEN $30,000 - $40,000**
- STEP 11: Determine expected costs assuming 1-2 hospital days in ICU and 2-3 days in stepdown (4-6 days total) + costs for NI lab materials of $4,000 - $12,000 + cost for additional imaging, labs work, pharmacy. **TOTAL COST SHOULD BE $24,000 – 30,000**

# SAMPLE PRO FORMA FOR STROKE SERVICE AT ONE OF MY HOSPITALS
# AVERAGE PROFIT FOR EVT = $8,500

- The average profit assumes a Stent Retriever is utilized for each case at a cost of $8,600
  - In my practice, a Stent Retriever is only needed for 10% of cases
- Using National averages, 10 thrombectomies should be performed for every 100 strokes
  - 9 cases should generate (9 x $16,511) $148,499. (STENTRIEVER NOT USED)
  - 1 case should generate (1 x $8,600) $ 8,600 (STENTRIEVER USED)
- **TOTAL REVENUE FOR EVERY 10 THROMBECTOMY CASE + $157,199**

- Average Reimbursement for Thrombectomy **$38,511**
  - Assumes
    - Avg Medicare Payment $37,818
    - Private pay adjustment 1.25%
    - Medicare patients 62%
    - No pay patients 7%

- Average Hospital Cost For Thrombectomy Hospitalizaton **$30,000**
  - Assumes
    - Procedure Cost
    - Avg LOS 6 days
    - Avg cost per day $1,575
    - Pharm/Radiology/Labs $11,457

# SAMPLE PROFORMA FOR STROKE SERVICE AT ONE OF MY HOSPITALS
# AVERAGE PROFIT FOR IV-TPA ALONE = -$850

- Average  Reimbursement for IV-TPA **$15,730**
- Average Cost For IVTPA Only Patient **$16,584**
  - Assumes
    - Avg LOS 4 days
    - Avg LOS cost/day $1,575
    - Pharm/rads/labs $10,284

# VARIATIONS IN REIMBURSEMENT AND COSTS BETWEEN HOSPITALS

| STROKE FINANCIALS BY HOSPITAL | | | | |
|---|---|---|---|---|
| **THROMBECTOMY** | | | | |
| | | REIMBURSEMENT PER PATIENT | COSTS STENTRIEVER VS SUCTION PER PATIENT | PROFIT/LOSS PER PATIENT |
| **HOSPITAL A (NJ)** | | 42,347 | 24,479 - 29.479 | **12,868 - 17,868** |
| **HOSPITAL B (NJ)** | | 41,855 | 50,441 | **-8585** |
| **HOSPITAL C (NJ)** | | 34,926 | 24,476 - 29,476 | **6,091 - 11,091** |
| **HOSPITAL A (FL)** | | 32,947 | 29,479 | **3,458** |
| **HOSPITAL B (FL)** | | 32,230 | 29,479 | **2,759** |
| **HOSPITAL C (FL)** | | 29,620 | 29,479 | **141** |
| **HOSPITAL A (OHIO)** | | 30,077 | 29.476 | **601** |
| **TPA** | | | | |
| **HOSPITAL A (NJ)** | | 19,628 | 16,584 | **3,044** |
| **HOSPITAL B (NJ)** | | 16,535 | 23,882 | **-7,346** |
| **HOSPITAL C (N J)** | | 13,763 | 20,297 | **-6,281** |
| **HOSPITAL A (FL)** | | 13,474 | 10,728 | **2,746** |
| **HOSPITAL B (FL)** | | 14,181 | 8,846 | **5,335** |
| **HOSPITAL C (FLL** | | 13,074 | 12,317 | **757** |
| **HOSPITAL A (OHIO)** | | 13,892 | 14,954 | **-1,062** |

# THROMBECTOMY COSTS FOR MATERIALS

XXXX = NOT NEEDED

XXXX = CAN BE CAPITATED TO REDUCE COST

| | COST ($) |
|---|---|
| • Basic Angio Pack | 84 |
| • 100 cc 50% contrast | 13 |
| • 5F micropuncture needle introducer set | 29 |
| • 6F Sheath | 85 |
| • 5F Diagnostic catheter | 21 |
| • 0.038" Exchange Length Glide wire | 47 |
| • Amplatz 0.035" Exchange Length wire | 42 |
| • 7F Shuttle Base Catheter | 137 |
| • Trevo compatible microcatheter | 1,075 |
| • 0.010" microwire | 572 |
| • Aspiration catheter | 2,495 |
| • Aspiration Syringes x2 | 8.73 |
| • Trevo/Solitaire Stent Retrieval Device (33% OF MY CASES) | 7,322 |
| • Flowgate 8F guide balloon catheter (0% OF MY CASES) | 1,236 (substitutes for 7F shuttle base catheter. Net cost +1.100) |
| • Mynx Closure Device | 215 |
| • TOTAL WITH MANUAL SUCTION (66% OF MY CASES) | 4,827 |
| • TOTAL WITH STENT RETRIEVER (33% OF MY CASES) | 12,149 |
| • TOTAL WITH FLOWGATE CATHETER AND MANUAL SUCTION (0% OF MY CASE) | 5,927 |
| • TOTAL WITH FLOWGATE CATHETER AND STENT RETRIEVER (0% OF MY CASES) | 13,249 |

# DRG 23 REIMBURSEMENT BEGINS COVERING COSTS ONCE PATIENT ENTERS NI LAB

- **COST CONTAINMENT BEGINS IN THE NI LAB**

- USE OF A **STENT RETRIEVAL** DEVICE AT ONE OF MY CENTERS **INCREASES** THE MATERIAL **COST** FOR INTRACRANIAL THROMBECTOMY FROM $4,827 TO $12,150 (**252%** INCREASE IN MATERIALS COST)
- Published literature* indicates manual suction thrombectomy:
  - Has equivalent TICI 2b/3 revascularization 85.4% Aspiration vs 83.1% Stent Retriever)
  - Yields better 90d mRS
  - Reduces the risk of procedure related embolizaiton and ICH,
  - Reduces Groin to Revascularization times.

*Contact Aspiration vs Stent Retriever (ASTER Trial). 2017. August. 318(5):443-452.

*Direct Aspiration vs Stent Retriever (Meta-analysis 9 studies). 2018. Medicine. October. 97(41)

# COST CONTROLS

- **Correct triage from field to the appropriate treatment center reduces costs associated with subsequent interhospital patient transfers**
  - **Shortens time to treat LVO(-) and LVO(+) patients which improves outcomes and reduces hospital LOS**
- **CTA not needed (counts against catheter angio costs and adds no additional information)**
- **CTP only if ≥ 6h LKN**
- **Begin administration of IV-TPA in ER so $8,000 cost will not count against DRG-23**
- **Capitate NI lab costs by using single vendors (Capitate with and without Stent Retriever)**
- **Do not open devices, wires, catheters until diagnostic completed and plan devised. Then only open packaging as needed.**
- **Utilize Suction Thrombectomy as first line EVT (can reduce procedure cost by $6000 -$8000 in 66% of cases).**
- **Utilize Stent Retriever only if Suction Thrombectomy fails**
- **Utilize half strength contrast for catheter angio diagnostic imaging**
- **Utilize hand injections of contrast as opposed to injector runs**
- **Eliminate unnecessary imaging and testing (All orders should be standardized with hard stops on routine test ordering after PSD #1)**
- **Does MRI improve outcomes or change management? When should MR be performed? 1-month post discharge?**
- **Do CTs need to be repeated post day 1 in stable patient?**
- **What labs are needed and when? (All routine testing should have hard stop after PSD #1)**
- **Admit non-intubated patients to step down unit**
- **Streamline discharge planning and aim for 4-day LOS post-treatment.**

# PRO FORMA FOR STROKE SERVICE

- 100 patients with discharge diagnosis of stroke
- 10 managed using thrombectomy + $157,199
- 15 managed using iv-TPA - $12,750
- NET REVENUE $144,449

- **ONCE THE COSTS ARE CONTROLLED FOR PATIENTS RECEIVING IV-TPA AND MAT, ONE MUST NEXT LOOK AT COSTS FOR THE 75 PATIENTS (75% OF CURRENT STROKE PATIENTS) WHO ARE DIAGNOSED WITH DISCHARGE DIAGNOSIS OF STROKE BUT ARE NOT TREATED WITH EITHER IV-TPA OR THROMBECTOMY**.