MHIF Research Highlights: DECEMBER 2018

Notable Milestones & First Enrollments

• Dr. Paul Sorajja, National PI for early feasibility study of Left Atrial shunt implanted MHI’s first device on November 20th - assisted by Lynelle Schneider, PA. Congrats Team!

• Dr. Karol Mudy and team for enrolling 35 patients in the HeartMate LVAD clinical study; the product is now FDA approved!

FEATURED MHIF STUDIES

Open for Enrollment and Referrals!

ASAP-SVG for coronary artery disease
CONTACT: Pamela Morley, 612-863-6066

MINT for myocardial ischemia & transfusion
CONTACT: Rose Peterson, 612-863-6051

XIENCE 90 for patients at high risk of bleeding who need coronary stents
CONTACT: Amy McMeans, 612-863-3895

MARK YOUR CALENDARS

Time to Run… or volunteer!

MHIF is proud to sponsor the Valentine’s 5K with Twin Cities in Motion. Mark your calendar!
Sat., Feb. 9, Lake Nokomis!

Raising Awareness of Valvular Disease!

MHIF is hosting a second annual Mechanics of a Healthy Heart event for patients.
Thurs, Feb. 21, Golden Valley Country Club!

SHOUT OUT TO…

Drs. Hryniewicz, Grey & Saxena for participating in a heart-healthy discussion at The Marsh!

CONGRATULATIONS

To Dr. Stephen Bradley who published in JAMA Network Open:
“Hypothermia for Out of Hospital Cardiac Arrest”
Extending the window for acute ischemic stroke intervention

Yasha Kayan, MD
Mark Young, MD

Neuroscience Institute
Abbott Northwestern Hospital
Minneapolis MN

Disclosures

• YK
  • Consultant for Medtronic, Penumbra
• MY
  • None
Acute ischemic stroke

- 85% of stroke in USA
- 700,000 hospital admissions per year
- Majority not caused by intracranial large vessel occlusion
- Until 2015, IV-tPA within 4.5 hours was only tx proven to improve clinical outcomes (at 90 days)
Why did the 2013 trials fail?

- **IMS 3**
  - Only 35% had ELVO
  - 20% in interventional arm had no occlusion
  - Intervention started 1 hour after IV-tPA
  - TICI 2b/3 in only 44% of patients with M1 occlusion

- **SYNTHESIS**
  - 60% of patients had only IA-tPA and microwire
  - Median IA-tPA was 40 mg
  - Did not report extent of reperfusion, time

- **MR RESCUE**

Modes of intervention in IMS 3

- Merci device: 18.6%
- IA t-PA only: 12.3%
- MicroSonic SV system: 3.4%
- Penumbra aspiration system: 9.4%
- Solitaire device: 1%
Outcomes with confirmed occlusion

Trend towards overall improvement in outcomes

Evolution of stroke intervention

Demchuk A, IMS III: Comparison of outcomes between IV and IV/IA treatment in baseline CTA confirmed ICA, M1, M2 and basilar occlusions. Presented at ISC 2013, Honolulu, HI
Latest generation stent-retriever

Abbott’s First Penumbra 3D Separator Case (IDE trial)

12/20/2012
50 year-old female, NIHSS 11
Abbott’s First Penumbra 3D Separator Case (IDE trial)

12/20/2012
50 year-old female, NIHSS 11

Time from puncture to reperfusion: 36 minutes

TICI 3
Abbott’s First Penumbra
3D Separator Case (IDE trial)

12/20/2012
50 year-old female, NIHSS 11

• Discharged home on POD #3
• mRS 0 at 3-month follow-up
2015: MR CLEAN

**Design**

- Prospective RCT comparing best medical management v. best medical management + IA therapy
- Key inclusion criteria
  - **Anterior circulation LVO** confirmed by CTA
  - IA treatment initiated **within 6 hours** from onset
  - **NIHSS ≥ 2**
- Primary outcome: mRS at **90 days** (blinded)
What was different?

- **Confirmation of LVO required** by CTA
  - Imaging confirmation not required in IMS 3
- **Specific measures taken to minimize selection bias**
  - **100% of interventional stroke centers** in Netherlands participated
Intervention improves outcomes

**Modified Rankin Scale Score**

- **mRS 0-2: 33%**
- **mRS 0-2: 19%**

**Intervention (N=233)**
- 3
- 9
- 21
- 18
- 22
- 6
- 21

**Control (N=267)**
- 6
- 13
- 16
- 30
- 12
- 22

- acOR 2.16 (95% CI: 1.39 to 3.38)
- acOR > 1 indicates higher odds of achieving functional independence in favor of intervention

**mRS ≤ 2 at 90 Days**

- **Intervention**
  - 32.6%

- **Control**
  - 19.1%

- acOR 2.16 (95% CI: 1.39 to 3.38)
Intervention is safe

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality within 7 days</td>
<td>11.6%</td>
<td>12.4%</td>
</tr>
<tr>
<td>Mortality within 30 days</td>
<td>18.9%</td>
<td>18.4%</td>
</tr>
<tr>
<td>Symptomatic ICH</td>
<td>7.8%</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

“There was no difference in the occurrence of serious adverse events between the groups during the 90 day follow-up. (p=0.31)”

MR CLEAN Investigators, A Randomized Trial of Intra-Arterial Treatment for Acute Ischemic Stroke, NEJM 2014

Intervention benefits a broad population
MHIF CV Grand Rounds – Jan. 7, 2019

4 Additional Positive RCTs after MR CLEAN

<table>
<thead>
<tr>
<th></th>
<th>TICI 2b/3 rate</th>
<th>mRS 0-2 at 90 days</th>
<th>Death rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESCAPE</td>
<td>72%</td>
<td>53% v. 29%</td>
<td>10% v. 19%</td>
</tr>
<tr>
<td>EXTEND-IA</td>
<td>86%</td>
<td>71% v. 40%</td>
<td>9% v. 20%</td>
</tr>
<tr>
<td>SWIFT PRIME</td>
<td>88%</td>
<td>60% v. 36%</td>
<td>9% v. 12%</td>
</tr>
<tr>
<td>REVASCAT</td>
<td>66%</td>
<td>44% v. 28%</td>
<td>18% v. 16%</td>
</tr>
</tbody>
</table>

Evolution of stroke intervention

SOLUMBRA (late 2012) vs. ADAPT (2013)
What’s the best way to get the clot out?

Results

<table>
<thead>
<tr>
<th></th>
<th>All patients (n=100)</th>
<th>SOLUMBRA (n=55)</th>
<th>ADAPT (n=45)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any ICH</td>
<td>36</td>
<td>26 (47%)</td>
<td>10 (22%)</td>
<td>.01</td>
</tr>
<tr>
<td>Any SAH</td>
<td>16</td>
<td>13 (24%)</td>
<td>3 (7%)</td>
<td>.03</td>
</tr>
<tr>
<td>SICH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IPH</td>
<td>8</td>
<td>7 (13%)</td>
<td>1 (2%)</td>
<td>.07</td>
</tr>
<tr>
<td>SAH</td>
<td>3</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td>.06</td>
</tr>
<tr>
<td>ICU LOS (days)</td>
<td>3.1</td>
<td>3.7</td>
<td>2.4</td>
<td>.04</td>
</tr>
<tr>
<td>90-day mortality</td>
<td>24</td>
<td>29%</td>
<td>18%</td>
<td>.24</td>
</tr>
<tr>
<td>Good clinical outcome at 90 days (mRS 0-2)</td>
<td>42</td>
<td>31%</td>
<td>56%</td>
<td>.015</td>
</tr>
</tbody>
</table>

Symptomatic SAH

- 3 (60%) received IA-tPA or IIB/IIIA inhibitor after stent-retriever
- 2 (40%) were M3 occlusion with stent-retriever
### Results

**Independent predictors of good clinical outcome at 90 days (mRS 0-2)**

<table>
<thead>
<tr>
<th></th>
<th>All patients (n=100)</th>
<th>SOLUMBRA (n=55)</th>
<th>ADAPT (n=45)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≤ 66y</td>
<td>68%</td>
<td>65%</td>
<td>71%</td>
<td>.002</td>
</tr>
<tr>
<td>Clot location</td>
<td></td>
<td></td>
<td></td>
<td>.003</td>
</tr>
<tr>
<td>ICA terminus</td>
<td>27%</td>
<td>9%</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td>M1</td>
<td>47%</td>
<td>33%</td>
<td>71%</td>
<td></td>
</tr>
<tr>
<td>M2</td>
<td>67%</td>
<td>67%</td>
<td>67%</td>
<td></td>
</tr>
<tr>
<td>M3</td>
<td>25%</td>
<td>0</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>NIHSS ≤ 21</td>
<td>49%</td>
<td>39%</td>
<td>64%</td>
<td>.034</td>
</tr>
<tr>
<td>TICI 2b/3</td>
<td>48%</td>
<td>37%</td>
<td>60%</td>
<td>.034</td>
</tr>
<tr>
<td>ASPECTS 10</td>
<td>55%</td>
<td>n/a</td>
<td>n/a</td>
<td>.041</td>
</tr>
<tr>
<td>Use of ADAPT</td>
<td>56%</td>
<td>n/a</td>
<td>n/a</td>
<td>.049</td>
</tr>
</tbody>
</table>


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**Institutional Evolution in Approach to Mechanical Thrombectomy**

<table>
<thead>
<tr>
<th>Period:</th>
<th>N:</th>
<th>Work-Horse:</th>
<th>% Thromb:</th>
<th>TICI 2b/3:</th>
<th>Puncture to reperfusion:</th>
<th>Sx SAH:</th>
<th>Sx IPH:</th>
<th>Salvage tx:</th>
<th>mRS 0-2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/1/11- 3/28/12</td>
<td>14</td>
<td>Penumbra 054 &amp; 041</td>
<td>78%</td>
<td>86%</td>
<td>89 min</td>
<td>0%</td>
<td>0%</td>
<td>29% (MERCI)</td>
<td>50%</td>
</tr>
<tr>
<td>3/31/12- 8/15/13</td>
<td>46</td>
<td>Solumbra</td>
<td>88%</td>
<td>87%</td>
<td>52 min</td>
<td>8.7%</td>
<td>4.3%</td>
<td>13% (Trevo / 5Max)</td>
<td>35%</td>
</tr>
<tr>
<td>3/11/13 9/7/18</td>
<td>200</td>
<td>ADAPT with ACE</td>
<td>78%</td>
<td>87%</td>
<td>36 min</td>
<td>1.7%</td>
<td>1.7%</td>
<td>14% (sten- retriever)</td>
<td>49%</td>
</tr>
</tbody>
</table>

16 min faster 75% 40%
ASTER and COMPASS

Effect of Endovascular Contact Aspiration vs Stent Retriever on Revascularization in Patients With Acute Ischemic Stroke and Large Vessel Occlusion

The ASTER Randomized Clinical Trial

COMPASS

A COMPARISON of DIRECT ASPIRATION vs. STENT RETRIEVER AS A FIRST APPROACH

COMPASS

Time to TICI $\geq 2b$

<table>
<thead>
<tr>
<th></th>
<th>Time (mins)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADAPT</td>
<td>22</td>
</tr>
<tr>
<td>SR</td>
<td>33</td>
</tr>
</tbody>
</table>

$p = .0194$
2017

- 2 randomized controlled trials in patients with last known well 6-24 hours are stopped prior to completing enrollment because

  - Mechanical thrombectomy improves clinical outcomes over medical management

DAWN

- Inclusion criteria:
  - LKW 6 to 24 hours & infarct <1/3 MCA
  - Selection based on age, NIHSS & infarct volume using RAPID software
  - Patients <80 years:
    - NIHSS ≥10 & infarct volume <31mL
    - NIHSS ≥20 & infarct volume <51mL
  - Patients ≥80 years:
    - NIHSS ≥10 & infarct volume ≤21mL
DAWN

- 206 patients enrolled
  - 107 intervention group
  - 99 control group
- No significant difference
  - age, sex, DM, previous stroke/TIA, NIHSS, infarct volume, occlusion site, time
- Significant difference in
  - Afib: 40% v. 24%, p=.01
  - IV-tPA: 5% v. 13%, p=.04
  - Wake-up stroke: 63% v. 47%, p=.03

DAWN

- Primary outcome
  - Functional independence at 90 days
    - 49% v. 13%
    - Absolute difference 36% (95% CI 24% to 47%)
    - NNT 3
- Safety outcomes
  - Stroke-related mortality at 90 days
    - 16% v. 18%
  - Death from any cause at 90 days
    - 19% v. 18%
  - Symptomatic ICH at 24 hours
    - 6% v. 3%
DAWN

• Primary limitations
  – Industry sponsored, single device
  – Small infarct volumes may skew towards those with anatomically less severe strokes
  – Significant differences in baseline characteristics

DEFUSE 3

• Inclusion criteria:
  – LKW 6 to 16 hours
  – NIHSS ≥6 & NCCT ASPECTS ≥6
  – Selection based on penumbral pattern with RAPID software:
    • Infarct volume <70mL
    • Penumbra/infarct ratio ≥1.8
DEFUSE 3

- Functional independence at 90 days
  - 45% v. 17%
  - OR 2.67 (95% CI 1.6 - 4.48), p<.001
  - NNT 4
- Death at 90 days
  - 14% v. 26%, OR .55 (95% CI .3 - 1.02), p.05
- Symptomatic ICH
  - 7% v. 4%, p=.75

Acute Ischemic Stroke

- 7 randomized controlled trials in pts w last known well up to **24 hours** have shown that *mechanical thrombectomy improves clinical outcomes* over iv-tPA alone

*MR CLEAN*

*SWIFT-PRIME*   *DAWN*

*ESCAPE*   *DEFUSE 3*

*EXTEND-IA*

*REVASCAT*
iv-tPA + endovascular treatment

Now standard of care for acute ischemic strokes due to large vessel occlusions up to 24 hours

Selection criteria?

a. Undertake risk of intra-procedural complications only when warranted
Selection criteria?

b. *Minimize* frequency of *futile recanalization*

c. *Minimize* risk of *symptomatic* post-procedural intracranial *hemorrhage*
ANW Mechanical Thrombectomy

**Anterior Circulation Strokes**

- Administer IV-tPA when appropriate
- NIHSS ≥5 or global aphasia
- Contact ANW Stroke Neurologist via OneCall
- NIR calculates NCCT ASPECTS*
- ASPECTS ≥5 & Age ≤90
- LKW ≤6 hrs
- Favorable penumbra
- Transfer for emergent thrombectomy
- Not optimal candidate for thrombectomy, may consider on an individual basis
- LKW >6 hours or unknown
- Unfavorable penumbra
- Obtain emergent CTA head / neck & CT Perfusion
- NIR determines penumbra

*Imaging expires after 90 minutes

**Posterior Circulation Strokes**

- Administer IV-tPA when appropriate
- NIHSS ≥5
- Contact ANW Stroke Neurologist via OneCall
- Obtain CTA to document basilar artery occlusion
- Age ≤90
- MRI pc-ASPECTS <6
- LKW ≤12 hours
- Transfer for emergent thrombectomy
- MRI pc-ASPECTS ≥6
- LKW >12 hours or unknown
- Obtain emergent brain MRI (on-site if possible)
- NIR calculates MRI pc-ASPECTS*

*Imaging expires after 90 minutes
Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16

Favorable penumbra at CTP

ASPECTS 10
Right ICA terminus occlusion

CBF (<30%) volume: 15.1 ml
Perfusion (Tmax>6.0s) volume: 136.1 ml
Mismatch volume: 121.0 ml
Mismatch ratio: 9.0
Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16

Navigating the NeuronMAX 360° using Select catheter

Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16
Right ICA occlusion
Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16

Navigating the ACE 68
270°
using
3 Max

Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16

Navigating the ACE 68 to the M1 segment
using
3 Max
Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16

ADAPTing with ACE 68

Puncture to reperfusion: 14 minutes
Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening

NIHSS 16

POD 1

POD 3

Discharged to rehab on POD 7, NIHSS 5

mRS 2 at 3 months
Optimizing Delivery of Neurointerventional Stroke Care

July 1st 2011 – October 31st 2018

4,632 pts admitted w primary dx of acute ischemic stroke
53 pts per month

1,086 pts received iv-tPA (23%)
1,086 pts

35% iv-tPA in ED
65% iv-tPA outside ED

3,546 pts did not receive iv-tPA (77%)

196 underwent endovascular therapy (18%)

7.6%

352 patients underwent endovascular therapy

Optimizing Delivery of Neurointerventional Stroke Care

<table>
<thead>
<tr>
<th>Year</th>
<th>Onset to ED Arrival</th>
<th>ED Arrival to Arterial Puncture</th>
<th>Arterial Puncture to Reperfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012, N=37, 6%</td>
<td>203</td>
<td>122</td>
<td>64</td>
</tr>
<tr>
<td>2013, N=32, 6%</td>
<td>157</td>
<td>101</td>
<td>56</td>
</tr>
<tr>
<td>2014, N=33, 6%</td>
<td>157</td>
<td>73</td>
<td>52</td>
</tr>
<tr>
<td>2015, N=43, 8%</td>
<td>188</td>
<td>35</td>
<td>37</td>
</tr>
<tr>
<td>2016, N=78, 14%</td>
<td>263</td>
<td>40</td>
<td>36</td>
</tr>
<tr>
<td>2017, N=72, 11%</td>
<td>223</td>
<td>47</td>
<td>31</td>
</tr>
<tr>
<td>2018, N=56, 10%</td>
<td>274</td>
<td>50</td>
<td>46</td>
</tr>
</tbody>
</table>

Standardized algorithm implemented

Positive trials
Optimizing Delivery of Neurointerventional Stroke Care

- Comparison between 2013-2014 (N=65) and 2015-2018 (N=249)
- Improvement from 37% to 30% with subsequent increase to 48%
- Chart highlights mRS 0-2 and mRS 4-6 outcomes over time.
Optimizing Delivery of Neurointerventional Stroke Care

- mRS 0-2 vs mRS 4-6
- 2013-2014: N=65
  - mRS 0-2: 37%
  - mRS 4-6: 52%
- 2015-2018: N=249
  - mRS 0-2: 48%
  - mRS 4-6: 35%

Optimizing Delivery of Neurointerventional Stroke Care

- Time is Brain
- Standardized algorithm implemented
- Positive trials
- Onset to ED Arrival
- ED Arrival to Arterial Puncture
- Arterial Puncture to Reperfusion
- 2012, N=37, 6%
  - 203
- 2013, N=32, 6%
  - 157
- 2014, N=33, 6%
  - 157
- 2015, N=43, 8%
  - 188
- 2016, N=78, 14%
  - 223
- 2017, N=72, 11%
  - 274
- 2018, N=56, 10%
  - 50
  - 46

MHIF CV Grand Rounds – Jan. 7, 2019
Process Improvement in Door-to-Green Puncture Times at a Comprehensive Stroke Center Shows a Trend Towards Reduced Mortality at 90 Days

Yuko Kato, MD, pistols k. Sedlaczek, Allocs, MD, Mark L. Young, MD, Jennifer L. Panza, MD, M. Schiziotakis, MD, Anna M. Myint, MD, Titel Scott, MD, MS, H. Molnaav, MD, Feuchtenbusch, MD, Ronald Torrel, MD

Norton Healthcare, Norton South Medical Center, Lexington, KY

INTRODUCTION

Safe and effective revascularization treatment of acute ischemic stroke is dependent on prompt intervention, in light of the fact that last year we identified our efforts to improve the process of taking patients from the emergency department to the angiography suite for the associated procedures.

METHODS

At the beginning of 2015, a process improvement project to improve door-to-green puncture time for mechanical thrombectomy for emergent large vessel occlusion was undertaken at our institution. After a systematic analysis of the process, key changes were prioritized (see System Process Changes).

All attempted thrombectomies performed in 2014 and 2015 were compared to those performed in 2013 to ascertain the following variables: door-to-green puncture time, symptomatic intracranial hemorrhage (SICH) rate, modified Rankin Scale (mRS) at 90 days and 1 year. For statistical analysis, the mean and median of the times were calculated, and Fisher’s exact test was performed. A p-value <0.05 was considered statistically significant.

RESULTS

Over the study period, we observed a significant improvement in door-to-green puncture time. The mean door-to-green puncture time decreased significantly from 125.6 minutes in 2013 to 118.7 minutes in 2015 (p < 0.05). In addition, the rate of SICH decreased from 28.6% in 2013 to 17.7% in 2015 (p = 0.04). The median mRS at 90 days was 2 and 3 in 2013 and 2015, respectively (p = 0.01). A composite primary outcome consisting of in-hospital mortality or 90-day mortality was significantly lower in 2015 compared to 2013 (p = 0.04).

CONCLUSION

Our systematic process improvement initiatives significantly reduced door-to-green puncture time and showed a trend towards reduced mortality at 90 days.

A multimodal quality approach and expanding hospital system involvement are key to an effective process.

DISCUSSIONS

Kato Y et al. Neurology 2016;
Schiziotakis M et al. Neurology 2018;

Optimizing Delivery of Neurointerventional Stroke Care

Door to iv-tPA bolus at Abbott’s ED

![Graph showing mean and median door to IV-tPA (min) from 2010 to 2018]
Abbott’s Thrombectomy Experience

– July 1st 2011 to November 15th, 2018
358 mechanical thrombectomies (~4 per month)
– 170 women (47.5%), 188 men (52.5%)
– Mean age: 68.8 years (5 – 99 years)
– Mean admission NIHSS: 16.7 (2 - 36)
– History of atrial fibrillation: 149 (39.4%)

Abbott’s Stroke Network:

a. 33 regional sites
b. 17 sites w Tele-Health technology
c. 15 sites w direct imaging link

Mean distance from regional sites to Abbott: 76 miles (13–182 miles)
Abbott’s Thrombectomy Experience

• 196 pts (54.7%) received IV t-PA prior to mechanical thrombectomy
• Thrombus location:
  – Middle cerebral artery: 230 (64%)
    • M1: 166 (46%)
    • M2: 49 (14%)
    • M3: 14 (4%)
    • M4: 1 (0.3%)
  – Common / internal carotid artery: 101 (28%)
    • Extending to ICA terminus: 73 (20%)
    • Cervical/petrous/cavernous carotid only: 28 (8%)
  – Posterior circulation: 26 (7%)
    • Basilar artery: 19 (5%)
    • Posterior cerebral artery: 6 (1.7%)
    • Vertebral artery only: 1 (0.3%)
  – ACA: 1 (0.3%)

Abbott’s Thrombectomy Experience

• Tandem ICA / vertebral origin occlusion: 75 (21%)
• Emergent ICA / vertebral stent deployment: 31 (9%)
Abbott’s Thrombectomy Experience

Successful recanalization (TICI 2b/3): 83%

Mean time from symptom onset to reperfusion:
324 minutes
(5 hours 24 minutes)

Abbott’s Thrombectomy Experience

• Intra-procedural complications: 25 (7%)
  – Embolus to previously-uninvolved vascular territory: 9 (2.5%, all ACA territory)
  – Vessel perforation: 7 (2%)
  – Embolus after balloon angioplasty: 3 (0.8%)
  – Acute stent thrombosis: 1 (0.3%)
  – Aneurysm perforation: 1 (0.3%)
  – Intracranial ICA dissection: 1 (0.3%)
  – Direct carotid-cavernous fistula: 1 (0.3%)
  – Catheter fracture: 1 (0.3%)
  – Solitaire detachment: 1 (0.3%)
Abbott’s Thrombectomy Experience

- **Symptomatic intracranial hemorrhage: 16 (4.5%)**
  - SAH: 9 (2.5%)
    - 3 received either IA-tPA or glycoprotein IIb/IIIa inhibitor intra-procedurally
    - 2 were M3 occlusions in which first-generation stent-retrievers were used
    - 1 was a CCF that went on to vascular rupture
  - ICH: 7 (2%)
- **Futile recanalization (large territorial infarct despite TICI 2b/3 reperfusion): 31 (8.7%)**
  - Requiring hemicraniectomy: 6 (1.7%)
  - Resulting in death: 15 (4.2%)
  - 29% were ICA / basilar occlusions
  - 39% were reperfused >5 hours from symptom onset

Abbott’s Thrombectomy Experience

- Mean Neuro-ICU LOS: 3.1 days (0 – 34 days)
- Mean hospital LOS: 6.7 days (1 – 50 days)
- **In-hospital mortality: 14.8%**
Abbott’s Thrombectomy Experience

- Discharge disposition:
  - **Home**: 87 (24%)
  - Rehabilitation facility: 152 (42.5%)
  - Skilled nursing facility: 53 (15%)
  - Expired/hospice: 66 (18.5%)

### Abbott’s Thrombectomy Experience

<table>
<thead>
<tr>
<th>mRS 0-2:</th>
<th>All Patients:</th>
<th>TICI 0-2a (17%):</th>
<th>TICI 2b/3 (83%):</th>
<th>p-value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRS 0-2:</td>
<td>47%</td>
<td>19%</td>
<td>52%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>mRS 3:</td>
<td>15%</td>
<td>10%</td>
<td>16%</td>
<td>0.3</td>
</tr>
<tr>
<td>mRS 4-6:</td>
<td>38%</td>
<td>71%</td>
<td>32%</td>
<td>0.001</td>
</tr>
</tbody>
</table>
Abbott’s Thrombectomy Experience

<table>
<thead>
<tr>
<th>All patients: 4.6 hrs</th>
<th>LKW ≤6h (79%): 3.3 hrs</th>
<th>LKW &gt;6h (21%): 9.6 hrs</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRS 0-2:</td>
<td>47%</td>
<td>48%</td>
<td>40%</td>
</tr>
<tr>
<td>mRS 3:</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>mRS 4-6:</td>
<td>38%</td>
<td>36%</td>
<td>46%</td>
</tr>
</tbody>
</table>

Abbott’s Thrombectomy Experience

<table>
<thead>
<tr>
<th></th>
<th>HERMES (N=634)</th>
<th>DAWN (N=206)</th>
<th>DEFUSE 3 (N=182)</th>
<th>Abbott (N=358)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIHSS:</td>
<td>17</td>
<td>17</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Age:</td>
<td>68</td>
<td>73</td>
<td>71</td>
<td>71</td>
</tr>
<tr>
<td>LVO (ICA, M1, M2):</td>
<td>98%</td>
<td>95%</td>
<td>100%</td>
<td>95%</td>
</tr>
<tr>
<td>Successful recanalization (TICI 2b/3):</td>
<td>71%</td>
<td>84%</td>
<td>76%</td>
<td>83%</td>
</tr>
<tr>
<td>Time sx onset to reperfusion:</td>
<td>285</td>
<td>816</td>
<td>750</td>
<td>272</td>
</tr>
<tr>
<td>Good clinical outcome (mRS 0-2):</td>
<td>46%</td>
<td>49%</td>
<td>45%</td>
<td>47%</td>
</tr>
<tr>
<td>Symptomatic ICH:</td>
<td>4%</td>
<td>6%</td>
<td>7%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Death at 90 days:</td>
<td>15%</td>
<td>19%</td>
<td>14%</td>
<td>21%</td>
</tr>
</tbody>
</table>
### Long-Term Outcomes in pts with moderate disability at 90-Days (mRS 3-4) with continued outpatient rehabilitation

<table>
<thead>
<tr>
<th></th>
<th>2:</th>
<th>3:</th>
<th>4:</th>
<th>5:</th>
<th>6:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All pts (n=40):</td>
<td>13%</td>
<td>45%</td>
<td>17%</td>
<td>5%</td>
<td>20%</td>
</tr>
<tr>
<td>Pts w mRS 3 at 90 days (n=18):</td>
<td>22%</td>
<td>61%</td>
<td>0</td>
<td>0</td>
<td>17%</td>
</tr>
<tr>
<td>Pts w mRS 4 at 90 days (n=22):</td>
<td>5%</td>
<td>32%</td>
<td>32%</td>
<td>9%</td>
<td>23%</td>
</tr>
</tbody>
</table>

30% had a reduction in disability at long-term follow-up

---

### Optimizing setup
Optimizing setup

Optimizing setup
Abbott’s 161st ADAPT Case

81 year old female with aphasia & right-sided weakness
NIHSS 18

ASPECTS 10
Left M1 segment occlusion
Abbott’s 161st ADAPT Case

81 year old female with aphasia & right-sided weakness
NIHSS 18

Advancing ACE 60 to M1 over 3 Max

Abbott’s 161st ADAPT Case

81 year old female with aphasia & right-sided weakness
NIHSS 18

TICI 3
11 minutes
Abbott’s 161st ADAPT Case

- Discharged home on POD 4, NIHSS 0
- mRS 0 at 90 days

Abbott’s 229th ADAPT Case

- 69 year-old female with aphasia & right-sided weakness
  NIHSS 8

- ASPECTS 10
- Intracranial atherosclerosis
  and left M2 segment near-occlusion
Abbott’s 229th ADAPT Case

69 year-old female with aphasia & right-sided weakness
NIHSS 8

Vacuum building prior to opening switch
Abbott’s 229th ADAPT Case

69 year-old female with aphasia & right-sided weakness
NIHSS 8
ADAPTing with ACE 60 at M2 origin after flipping the switch
Abbott’s 229th ADAPT Case

• Discharged home on POD 2, NIHSS 0

Abbott’s 230th ADAPT Case

50 year-old female with neck pain left-sided weakness
NIHSS 19

ASPECTS 5
Abbott’s 230th ADAPT Case

50 year-old female with neck pain left-sided weakness
NIHSS 19
Right ICA dissection, M1 embolus

s/p 1 ADAPT pass with Neuron Max
after flipping the switch – TICI 2b
Right ICA dissection, M1 embolus

50 year-old female with neck pain left-sided weakness
NIHSS 19

s/p 1 ADAPT pass with ACE 60 after flipping the switch – TICI 2c, 17 minutes

• Discharged to rehab on POD #5, NIHSS 5
Efficacy of ADAPT with Evolving ACE Catheter Technology

<table>
<thead>
<tr>
<th></th>
<th>All Cases (N=152)</th>
<th>ACE 60 (N=57)</th>
<th>ACE 64 (N=35)</th>
<th>ACE 68 (N=60)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TICI 2b/3 after 1 pass:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>42%</td>
<td>33%</td>
<td>37%</td>
<td><strong>53%</strong></td>
<td>0.04</td>
</tr>
<tr>
<td><strong>TICI 2b/3 with ADAPT only:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>80%</td>
<td>67%</td>
<td>89%</td>
<td><strong>88%</strong></td>
<td>0.005</td>
</tr>
<tr>
<td><strong>Overall TICI 2b/3:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>90%</strong></td>
<td><strong>88%</strong></td>
<td><strong>91%</strong></td>
<td><strong>92%</strong></td>
<td>0.7</td>
</tr>
</tbody>
</table>
## Efficacy of ADAPT with Evolving ACE Catheter Technology

<table>
<thead>
<tr>
<th></th>
<th>All Cases (N=152)</th>
<th>ACE 60 (N=57)</th>
<th>ACE 64 (N=35)</th>
<th>ACE 68 (N=60)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median puncture to</td>
<td>24</td>
<td>30</td>
<td>26</td>
<td><strong>19.5</strong></td>
<td>n/a</td>
</tr>
<tr>
<td>reperfusion: (min)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median number of</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td><strong>1</strong></td>
<td>n/a</td>
</tr>
<tr>
<td>passes:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent-retriever</td>
<td>14.5%</td>
<td>26%</td>
<td>3%</td>
<td><strong>10%</strong></td>
<td>0.004</td>
</tr>
<tr>
<td>rescue:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TICI 2b/3 after rescue:</td>
<td>68%</td>
<td>80%</td>
<td>100%</td>
<td><strong>33%</strong></td>
<td>0.09</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

## First Pass Effect

- Independent predictors of good outcome, mRS 0-2 at 90 days:
  - Successful reperfusion with 1 ADAPT pass
    - p = .0004
  - NIHSS ≤21
    - p = .0076
  - Hypertension
    - p = .026

Conclusion

- **After a tough 2013...**
- **RCT’s** finally demonstrated that thrombectomy with current technology is safe, effective & improves clinical outcomes over iv-tPA in pts with proximal intracranial large vessel occlusions – out to 24 hours from last known well in select patients

MR CLEAN  
SWIFT-PRIME  
ESCAPE  
EXTEND-IA  
REVASCAT  
DAWN  
DEFUSE 3

Conclusion

- **Future frontiers**
- Should we perform mechanical thrombectomy in pts w LVOs and:
  1. Low **ASPECTS** (<5) w significant penumbra?  
  2. Low **NIHSS** (<5)?
- Should we administer **iv-tPA** to pts w LVO who arrive at a thrombectomy-ready hospital & the neurointerventional team is immediately available?
Thank you

Abbott’s Neurovascular Team

Neurointervention
Josser Delgado, MD
Yasha Kayan, MD
Adam Wallace, MD
Jill Scholz, CNP
Anna Milner, CNP
Jennifer Fease, BS
Susan Ricketts, BS

Neurosurgery
Kyle Uittenbogaard, MD
Mahmood Nagib, MD
Michael McCue, MD
Robert Roach, MD
Hart Garner, MD
Kyle Nelson, MD
Timothy Kovanda, MD

Stroke Neurology
Mark Young, MD
Ronald Tarroll, DO
Pezhman Roohani, MD
David Dorn, MD
Adam Todd, MD
Shelley Milner, CNP
Angelina Buerck, RN

Neurocritical Care
Max Mulder, MD
Lisa Kirtland, MD
Ramiro Saavedra, MD
Clara Zamorano, MD
Omer Sultan, MD
Toni Mowbray, MD
Adrian Maarouf, MD
Roman Melamed, MD
Jon Fuerstenberg, MD
Susan Seatter, MD
William Parham III, MD
David Williams, DO
John Litell, DO
Francisco Paz, MD
Jena Wirt, DO
Erik Stoltenberg, MD
Alyssa Maizan, CNP
Hannah Gebhart, CNP
Lauren Witebsky, CNP