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

CONGRATULATIONS

To Dr. Stephen Bradley who published in *JAMA Network Open*:

“Hypothermia for Out of Hospital Cardiac Arrest”

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!
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

Title: Expanding indications for acute stroke intervention
Speakers: Yasha Kayan, MD
Neurointerventional Radiology Section Lead
Consulting Radiologists Ltd

Mark Young, MD
Stroke Program Medical Director
Abbott Northwestern Hospital

Date: January 7, 2019
Time: 7:00 - 8:00 AM
Location: ANW Education Building, Watson Room

OBJECTIVES
At the completion of this activity, the participants should be able to:
1. Describe the patients who may benefit from acute stroke intervention.
2. Describe what interventions are available for acute stroke patients.
3. Explain how recent trial data have expanded the window for acute stroke intervention.

ACCREDITATION
Physician - Allina Health is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. Allina Health designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nurse - This activity has been designed to meet the Minnesota Board of Nursing continuing education requirements for 1.0 hours of credit. However, the nurse is responsible for determining whether this activity meets the requirements for acceptable continuing education.

DISCLOSURE POLICY & STATEMENTS
Allina Health, Learning & Development intends to provide balance, independence, objectivity and scientific rigor in all of its sponsored educational activities. All speakers and planning committee members participating in sponsored activities and their spouse/partner are required to disclose to the activity audience any real or apparent conflict(s) of interest related to the content of this conference.

The ACCME defines a commercial interest as “any entity” producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of
clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

**Moderator(s)/Speaker(s)**
Dr. Yasha Kayan and Dr. Mark Young have disclosed that they DO NOT have any real or apparent conflicts with any commercial interest as it relates to presenting their content in this activity/course.

**Planning Committee**
Dr. Alex Campbell, Jake Cohen, Jane Fox, Dr. Mario Gössl, Dr. Kevin Harris, Dr. Kasia Hryniewicz, Rebecca Lindberg, Amy McMeans, Dr. Michael Miedema, Dr. JoEllyn Moore, Pamela Morley, Dr. Scott Sharkey, and Jolene Bell Makowesky have disclosed that they DO NOT have any real or apparent conflicts with any commercial interest as it relates to the planning of this activity/course. Dr. David Hurrell has disclosed the following relationship - Boston Scientific: Chair, Clinical Events Committee.

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We would like to thank the following company for exhibiting at our activity.

| Chiesi         | Pfizer Inc. |

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When you request a transcript this serves as your personal tracking of activities attended. Most professional healthcare licensing/certification boards will not accept a Learning Management System (LMS) transcript as proof of credit; there are too many LMS’s across the country and their validity/reliability are always in question.

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**Maintaining these details are the responsibility of the individual.**

Please save a copy of this flier as your certificate of attendance.

<table>
<thead>
<tr>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td>My signature verifies that I have attended the above stated number of hours of the CME activity.</td>
</tr>
</tbody>
</table>

Allina Health - Learning & Development - 2925 Chicago Ave - MR 10701 - Minneapolis MN 55407
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)

Evolution of stroke intervention
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

90-Day mRS Distribution, Baseline CTA Occlusion Present

Endovascular N=180

<table>
<thead>
<tr>
<th>mRS 0-2</th>
<th>13.3</th>
<th>21.7</th>
<th>12.2</th>
<th>13.3</th>
<th>17.8</th>
<th>6.1</th>
<th>15.6</th>
</tr>
</thead>
</table>

IV/IA Alone N=91

| mRS 0-2 | 5.5  | 14.3 | 18.7 | 11   | 16.5 | 7.7 | 26.4 |

van Elteren test p-value 0.0114

Trend towards overall improvement in outcomes

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

Evolution of stroke intervention

SOLUMBRA (late 2012)

ADAPT (2013)
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

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

12/20/2012
50 year-old female, NIHSS 11
Post 1 3D separator pass
TICI 3
Time from puncture to reperfusion: 36 minutes
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

A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke


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

The overall crossover rate was 18/500 (3.6%).
Intervention improves outcomes

**Modified Rankin Scale Score**

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

**Intervention (N=233)**
- 0: 3, 9, 21, 18, 22, 6, 21
- 1: 13, 16, 30, 12, 22

**Control (N=267)**
- 0: 6, 13, 16, 30, 12, 22

\[ \text{acOR} = 2.16 \text{ (95% CI: 1.39 to 3.38)} \]

acOR > 1 indicates higher odds of achieving functional independence in favor of intervention

**Intervention improves outcomes**

- **mRS \leq 2 at 90 Days**
  - **Intervention:** 32.6%
  - **Control:** 19.1%

\[ \text{acOR} = 2.16 \text{ (95% CI: 1.39 to 3.38)} \]

acOR > 1 indicates higher odds of achieving functional independence in favor of intervention
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
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
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>5</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>

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>230</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

<table>
<thead>
<tr>
<th>Time to TICI &gt; = 2b</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADAPT</td>
<td>22 mins</td>
</tr>
<tr>
<td>SR</td>
<td>33 mins</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
  
  \[\text{Mechanical thrombectomy improves clinical outcomes}\]

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
• 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

• 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
        - Yes
          - LKW ≤6 hrs
            - Transfer for emergent thrombectomy
            - Favorable penumbra
          - LKW >6 hours or unknown
            - Obtain emergent CTA head / neck & CT Perfusion
              - NIR determines penumbra
              - Unfavorable penumbra
        - No
          - Not optimal candidate for thrombectomy, may consider on an individual basis
          - LKW ≤6 hrs
          - LKW >6 hours or unknown

*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
        - Yes
          - LKW ≤12 hours
            - Transfer for emergent thrombectomy
            - MRI pc-ASPECTS ≥6
          - LKW >12 hours or unknown
            - MRI pc-ASPECTS <6
              - 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
ASPECTS 10 Right ICA terminus occlusion

Abbott’s 131st ADAPT Case

75-year-old woman with left hemiparesis upon awakening
NIHSS 16
Favorable penumbra at CTP

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

ADAPTTing with ACE 68

Abbott’s 131st ADAPT Case

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

TICI 3
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
MHIF CV Grand Rounds – Jan. 7, 2019

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%)

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

196 underwent endovascular therapy (18%)

352 patients underwent endovascular therapy

7.6%

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

156 underwent endovascular therapy (4.4%)

352 patients underwent endovascular therapy

Optimizing Delivery of Neurointerventional Stroke Care

- Onset to ED Arrival
- ED Arrival to Arterial Puncture
- Arterial Puncture to Reperfusion

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>%</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</td>
<td>37</td>
<td>6%</td>
<td>203</td>
<td>122</td>
<td>64</td>
</tr>
<tr>
<td>2013</td>
<td>32</td>
<td>6%</td>
<td>157</td>
<td>101</td>
<td>56</td>
</tr>
<tr>
<td>2014</td>
<td>33</td>
<td>6%</td>
<td>157</td>
<td>73</td>
<td>52</td>
</tr>
<tr>
<td>2015</td>
<td>43</td>
<td>8%</td>
<td>188</td>
<td>35</td>
<td>37</td>
</tr>
<tr>
<td>2016</td>
<td>78</td>
<td>14%</td>
<td>263</td>
<td>40</td>
<td>36</td>
</tr>
<tr>
<td>2017</td>
<td>72</td>
<td>11%</td>
<td>223</td>
<td>47</td>
<td>31</td>
</tr>
<tr>
<td>2018</td>
<td>56</td>
<td>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

- 2013-2014: N=65
  - mRS 0-2: 37%
  - mRS 4-6: 52%

- 2015-2018: N=249
  - mRS 0-2: 48%
  - mRS 4-6: 30%
Optimizing Delivery of Neurointerventional Stroke Care

![Graph showing changes in mRS 0-2 and mRS 4-6 from 2013-2014 to 2015-2018]

Optimizing Delivery of Neurointerventional Stroke Care

![Graph showing time intervals from onset to ED arrival, ED arrival to arterial puncture, and arterial puncture to reperfusion over the years 2012 to 2018]

Standardized algorithm implemented

Positive trials

TIME IS BRAIN
Process Improvement in Door-to-Groin Puncheon Times at a Comprehensive Stroke Center Shows a Trend Towards Reduced Mortality at 90 Days

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Northwestern Medicine, Chicago, Illinois; Northwestern Memorial Hospital, Chicago, Illinois; Abbott Northwestern Hospital, Minneapolis, MN.

Abstract # 196

INTRODUCTION
Safe and effective endovascular treatment of acute ischemic stroke is dependent on early intervention. In light of the recent trials, last year we undertook our efforts to improve the process of taking patients from the emergency department to the angiography suite for endovascular revascularization.

METHODS
At the beginning of 2015, a process improvement project to improve door-to-prone puncture times for thrombectomy was started. The emergency department was redesigned to remove unnecessary barriers.

After a preliminary analysis of the process, key changes were identified (see modified flowchart).

All attempted thrombectomies performed in 2014 and 2015 were compared to those performed in 2013 to assess the following variables: door-to-PRP, door-to-IV-tPA, door-to-CT scan, mean time to stroke center, and time to perform CT scan.

RESULTS

- **Door to CT Scan (min)**
  - 2013: 35.2
  - 2014: 34.2
  - 2015: 33.6

- **Door to IV-tPA (min)**
  - 2013: 60.1
  - 2014: 58.9
  - 2015: 58.3

- **90-Day Outcome**
  - Mortality: 2013: 8.7%, 2014: 7.1%, 2015: 4.5%

CONCLUSION
Our systematic process improvement initiative significantly reduced door-to-procedure times and showed a trend towards reduced mortality at 90 days.

DISCLOSURES
None.

Optimizing Delivery of Neurointerventional Stroke Care

Door to iv-tPA bolus at Abbott’s ED

- **Door to tPA (min)**
  - 2010: 82
  - 2011: 74
  - 2012: 69
  - 2013: 56
  - 2014: 47
  - 2015: 46
  - 2016: 42
  - 2017: 39
  - 2018: 36

- **Mean and Median Values**

**Chart Description**
- **X-axis**: Year (2010 to 2018)
- **Y-axis**: Time in Minutes
- **Legend**: Mean and Median

**Graph Details**
- **Line Graph**
- **Data Points**
- **Axis Labels**
- **Legend**

**Analysis**
- **Door to tPA**
  - Improved over the years
  - Minimum time in 2018

**Conclusion**
- Efficient delivery of tPA bolus significantly improved over the years.

**Disclosure**
- None.

MHIF CV Grand Rounds – Jan. 7, 2019
Abbott’s Thrombectomy Experience

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

\textbf{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%)

---

<table>
<thead>
<tr>
<th></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></th>
<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>
<td>0.12</td>
</tr>
<tr>
<td>mRS 3:</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
<td>1</td>
</tr>
<tr>
<td>mRS 4-6:</td>
<td>38%</td>
<td>36%</td>
<td>46%</td>
<td>0.1</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>
### Abbott’s Thrombectomy Experience

**Long-Term Outcomes** in pts with moderate disability at 90-Days (mRS 3-4) with continued outpatient rehabilitation

<table>
<thead>
<tr>
<th>Long-Term Modified Rankin Scale 22 months after stroke onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>All pts (n=40):</td>
</tr>
<tr>
<td>Pts w mRS 3 at 90 days (n=18):</td>
</tr>
<tr>
<td>Pts w mRS 4 at 90 days (n=22):</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
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
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 ACE 60 after flipping the switch – TICI 2c, 17 minutes

Abbott’s 230th ADAPT Case

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


<table>
<thead>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>90%</td>
<td>88%</td>
<td>91%</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 reperfusion: (min)</td>
<td>24</td>
<td>30</td>
<td>26</td>
<td><strong>19.5</strong></td>
<td>n/a</td>
</tr>
<tr>
<td>Median number of passes:</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td><strong>1</strong></td>
<td>n/a</td>
</tr>
<tr>
<td>Stent-retriever rescue:</td>
<td>14.5%</td>
<td>26%</td>
<td>3%</td>
<td><strong>10%</strong></td>
<td>0.004</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>
</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

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