Interventional Stroke Treatment: The Evidence

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## Disclosures

### National/International PI/Co-PI:
- THERAPY (PI)
- FEAT (PI)
- AMERICA (PI)
- LARGE (Co-PI)
- POSITIVE (Co-PI)

### NIH:
- NIH 1U01NS086492-01 (Co-PI)
- NIH 1R01NS078828-01A1 (Co-Inv)

### Advisory Board:
- THRILL

### Steering Committee:
- MAPS

### Consultant:
- Lazarus Effect, Reverse, Pulsar, Edge Therapeutics

### Investor:
- Blockade Medical
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What is evidence?

What is the evidence for IA Stroke Treatment?

What is evidence?
What is evidence?
What is evidence?

- I strongly believe in evidence based medicine and that high quality clinical research is critical to advance our field
What is evidence?

- I strongly believe in evidence based medicine and that high quality clinical research is critical to advance our field

- However:
  - I believe that there is a well intentioned, but overzealous, misapplication of “evidence based medicine” concepts, which results in a detriment to our patients
For Example:

- WellPoint Anthem (the largest publicly traded health plan in the nation):
  - “Mechanical embolectomy is considered **investigational and not medically necessary**”

- Blue Cross of Idaho:
  - “Mechanical embolectomy is considered **investigational**”

- Blue Cross of Mississippi:
  - “Mechanical embolectomy is considered **investigational**”
What is “investigational”?  

investigation [in-ves-ti-gey-shuhn]  
1. the act or process of investigating or the condition of being investigated  
2. a searching inquiry for ascertaining facts; detailed or careful examination.
What is “investigational”?

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A great definition for what is done in a RCT
What is “investigational”?

investigation [in-ves-ti-gey-shuhn]

1. the act or process of investigating or the condition of being investigated

2. a searching inquiry for ascertaining facts; detailed or careful examination.

A great definition for what is done in a RCT
A great definition for ALL TYPES of carefully informed medical practice
What is a RCT?

Gold Standard of PROOF
Ensures that control and experimental cohorts are COMPARABLE
Uses a rigorous experimental design (inclusion/exclusion criteria; protocolized care) to address a single question about the “average” benefit of a therapy

IMPORTANT and NECESSARY
What is a RCT?

A fallacy to insist that the only worthwhile knowledge is that generated from a RCT.
What is the evidence for stroke care?

CLASS I
Benefit >>> Risk
Procedure/Treatment
**SHOULD** be performed/
administered
What is the evidence for stroke care?

**CLASS I**
Benefit >>> Risk
Procedure/Treatment **SHOULD** be performed/administered

**Level of Evidence?**
What is the evidence for stroke care?

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Benefit</th>
<th>Risk</th>
<th>Procedure/Treatment</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>&gt;&gt;&gt;&gt;</td>
<td></td>
<td>SHOULD be performed/administered</td>
<td>AHA/ASA Acute Ischemic Stroke Guidelines</td>
</tr>
</tbody>
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What is the evidence for stroke care?

CLASS I
Benefit >>> Risk
Procedure/Treatment
**SHOULD** be performed/administered

Level of Evidence?

AHA/ASA
Acute Ischemic Stroke Guidelines

LOE B or C  
LOE A
What is the evidence for stroke care?

CLASS I
Benefit >>> Risk
Procedure/Treatment
**SHOULD** be performed/administered

Level of Evidence?

AHA/ASA
Acute Ischemic Stroke Guidelines

LOE A = 16
LOE B or C = 45
What is the evidence for stroke care?

**CLASS I**
Benefit >>> Risk
Procedure/Treatment **SHOULD be performed/administered**

**Level of Evidence?**
AHA/ASA
Acute Ischemic Stroke Guidelines

LOE C

LOE A
What is the evidence for stroke care?

CLASS I

Benefit >>> Risk

Procedure/Treatment

**SHOULD** be performed/ administered

Level of Evidence?

AHA/ASA

Acute Ischemic Stroke Guidelines

LOE C = 16

LOE A = 16
What is the evidence for stroke care?

Level of Evidence C
What is the evidence for stroke care?

Level of Evidence C

In exceptional cases with systemic hypotension producing neurological sequelae, a physician may prescribe vasopressors to improve cerebral blood flow. If drug-induced hypertension is used, close neurological and cardiac monitoring is recommended (Class I; Level of Evidence C).
What is the evidence for stroke care?

Level of Evidence C

In exceptional cases with systemic hypotension producing neurological sequelae, a physician may prescribe vasopressors to improve cerebral blood flow. If drug-induced hypertension is used, close neurological and cardiac monitoring is recommended (Class I; Level of Evidence C).

Should the ICU care not be provided?
What is the evidence for IA therapy?
What is the evidence for IA therapy?
There is very reasonable data supporting a decision to pursue IA therapy
What is the evidence for IA therapy?

There is very reasonable data supporting a decision to pursue IA therapy

While definitive proof is lacking for all cases, the OVERWHELMING majority of care delivered in medicine lacks definitive proof.
What is the evidence for IA therapy?

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This DOES NOT mean we stop investigating...
What is the evidence for IA therapy?

There is very reasonable data supporting a decision to pursue IA therapy.

While definitive proof is lacking for all cases, the OVERWHELMING majority of care delivered in medicine lacks definitive proof.

This DOES NOT mean we stop investigating.

But argue that IA therapy should not be provided due to a perceived lack of “adequate” data is inconsistent with our professional responsibility AND counter-productive.
What is the evidence for IA therapy?
What is the evidence for IA therapy?

Why do we consider providing IA therapy reasonable?
What is the evidence for IA therapy?

Multiple randomized trials have demonstrated the benefit of recanalization for stroke patients

- NINDS tPA (IV)
- ECASS (IV)
- PROACT (IA)
- MELT (IA)
What is the evidence for IA therapy?

Multiple randomized trials have demonstrated the benefit of recanalization for stroke patients

- NINDS tPA (IV)
- ECASS (IV)
- PROACT (IA)
- MELT (IA)

1. All demonstrate benefit of treatment versus placebo
2. All were lytic based
3. All used early targets
4. All showed recanalization is directly correlative with outcome
What is the evidence for IA therapy?

Based upon these studies we KNOW that recanalization is better than no recanalization, for patients presenting at least within 4.5 hrs and probably <6 hrs.
What is the evidence for IA therapy?

Based upon these studies we KNOW that recanalization is better than no recanalization, for patients presenting at least within 4.5 hrs and probably <6 hrs.

The question remains however... does the method of recanalization create harm that can undermine the benefit of recanalization?
What is the evidence for IA therapy?

We also know that, based IMS III and SYNTHESIS:

IA therapy is safe
IA therapy is safe.

- IMS III Trial suspended on April 18, 2012
- 656 of 900 subjects

- Preplanned interim analysis by DSMB (n=587):
  - “Very low likelihood of demonstrating the pre-specified, clinically significant difference in benefit between the treatment arms of the study.”
  - “While enrollment was stopped because of futility, no serious safety concerns were identified.”

http://www.ninds.nih.gov/disorders/clinical_trials/NCT00359424.htm
IA therapy is safe.

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IA Therapy is safe

In SYNTHESIS, despite withholding Class-I indicated IV-tPA, and delivering IA-tPA in patients without occlusion, endovascular therapy had NO increase in death or symptomatic ICH

<table>
<thead>
<tr>
<th>SYNTHESIS Primary Safety End Points</th>
<th>Endovascular Therapy (n=181)</th>
<th>Intravenous tPA Alone (n=181)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death at 7 days - no. (%)</td>
<td>14 (8%)</td>
<td>11 (6%)</td>
<td>0.53</td>
</tr>
<tr>
<td>Symptomatic ICH at 7 days – no. (%)</td>
<td>10 (6%)</td>
<td>10 (6%)</td>
<td>0.99</td>
</tr>
</tbody>
</table>
IA Therapy is safe

SYNTHESIS conclusion: Subjecting ALL potential IV-tPA patients to IA therapy, including those with minimal deficit (NIHSS of 2 included) and without confirmation of occlusion, demonstrated EQUAL efficacy to IV-tPA with NO significant safety concerns
IA Therapy is safe

In IMS III, despite reduced dose IV-tPA, endovascular therapy had NO increase in death or symptomatic ICH

<table>
<thead>
<tr>
<th>IMS III Primary Safety End Points</th>
<th>Endovascular Therapy (n=434)</th>
<th>Intravenous tPA Alone (n=222)</th>
<th>p value</th>
</tr>
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<tr>
<td>Death at 90 days - no. (%)</td>
<td>83 (19.1%)</td>
<td>48 (21.6%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Symptomatic ICH at 30 hours – no. (%)</td>
<td>27 (6.2%)</td>
<td>13 (5.9%)</td>
<td>0.83</td>
</tr>
</tbody>
</table>
What is the evidence for IA therapy?

Given that we KNOW recanalization is of benefit

Given that we KNOW IV tPA is of benefit

Given positive findings of PROACT II and MELT

Given the we KNOW IA therapy has comparable efficacy to IV tPA, without increase risk

The evidence STRONGLY supports that for those patients who are ineligible for IV tPA and who present within 4.5 hrs IA therapy SHOULD be offered
What is the evidence for IA therapy?

What about for other patients?
What is the evidence for IA therapy?

It is not IV versus IA
What is the evidence for IA therapy?

It is not IV versus IA

In modern practice they are complimentary
Mechanical Thrombectomy of Intracranial Internal Carotid Occlusion
Pooled Results of the MERCI and Multi MERCI Part I Trials

Alexander C. Flint, MD, PhD; Gary R. Duckwiler, MD; Ronald F. Budzik, MD; David S. Liebeskind, MD; Wade S. Smith, MD, PhD; for the MERCI and Multi MERCI Writing Committee

Background and Purpose—Acute stroke from occlusion of the intracranial internal carotid artery (ICA) generally has a poor prognosis and appears to respond poorly to intravenous thrombolysis. Mechanical thrombectomy is a newly available modality for acute stroke therapy, but it is unknown whether this endovascular therapy may have a role in the specific setting of intracranial ICA occlusion. We therefore assessed the success rate of the Merci Retriever mechanical thrombectomy device in recanalization of intracranial ICA occlusions and sought to determine whether ICA recanalization with this therapy can result in better outcomes.

Methods—All patients with acute stroke from intracranial ICA occlusion were identified in the MERCI and Multi MERCI Part I trials. We determined the success rate of ICA recanalization with endovascular thrombectomy and then assessed clinical outcomes according to whether vessel recanalization was successful.

Results—Eighty patients with acute stroke from intracranial ICA occlusion were identified. Of these 80 patients, 53% had successful ICA recanalization with the Merci Retriever alone and 63% had ICA recanalization with use of the Merci Retriever plus adjunctive endovascular treatment. Baseline patient characteristics and procedural complications did not differ between the recanalized and nonrecanalized groups. Good clinical outcome, defined by a modified Rankin Scale of 0 to 2 at 90 days, occurred in 39% of patients with ICA recanalization (n=19 of 49) and in 3% of patients without ICA recanalization (n=1 of 30) (P<0.001; one patient was lost to follow up for 90-day modified Rankin Scale). Ninety-day mortality was 30% (n=15 of 50) in the recanalized group and 73% (n=22 of 30) in the nonrecanalized group (P<0.001). Symptomatic hemorrhage was not significantly different between the recanalized (6% [n=3 of 50]) and nonrecanalized (16.7% [n=5 of 30]) groups (P=0.14). Hemorrhage rates were also not found to be influenced by use of intravenous thrombolysis before mechanical thrombectomy. Multivariable logistic regression identified ICA recanalization (OR=28.4, 95% CI=2.6 to >99.9) and lack of history of hypertension (OR=0.15, 95% CI=0.04 to 0.57) as significant predictors of a good 90-day outcome. Failure to recanalize the ICA (OR=0.16, 95% CI=0.05 to 0.51) and age (per decade, OR=1.07, 95% CI=1.03 to 1.13) were significant predictors of mortality at 90 days.

Conclusions—Mechanical thrombectomy of acute intracranial ICA occlusion using the Merci Retriever device, alone or in combination with adjunctive endovascular therapy, has a high rate of successful vessel recanalization. Subjects with successful ICA recanalization by this method have improved poststroke clinical outcome and survival compared with subjects in which the ICA is not successfully recanalized. (Stroke. 2007;38:1274-1280.)
What is the evidence for IA therapy?

Single arm trial

pooled results of MERCI and Multi-MERCI

<8 hours from onset

may or may not have previously received tPA
What is the evidence for IA therapy?

80 patients treated

Mean NIHSS = 20±5

63% recanalization rate
What is the evidence for IA therapy?

80 patients treated

Mean NIHSS = 20±5

63% recanalization rate

No difference between tPA and non-tPA cohorts
What is the evidence for IA therapy?

SYNTHESESIS Expansion

- Endovascular pts did not receive IV tPA while waiting for treatment
- Median time to treatment start was 3.75 hrs for endovascular and 2.75 hrs for IV tPA (p<0.001)
What is the evidence for IA therapy?

IMS III

• 6 years of enrollment
• Only the last ~10 months did patients get full dose IV tPA in IA arm
• Vast majority of patients received low-dose “bridging” therapy
What is the evidence for IA therapy?

IV tPA is a proven Class I therapy

Appropriate patients should not be denied its benefit
What is the evidence for IA therapy?

Time is important

*Time is Brain*
What is the evidence for IA therapy?

IMS III

• Trend toward better outcomes for the endovascular group treated with tPA in < 2 hours
• Trend toward better outcomes with time from start IV tPA to groin puncture < 90 min
• Every 30 minute delay = 10% decrease in probability of mRS < 2
What is the evidence for IA therapy?

IMS III

- Time to endovascular treatment was 32 minutes longer than in IMS-I
  - IMS III -> 126 min between IV treatment and IA treatment
- Median time from groin puncture to start of therapy 44 minutes
What is the evidence for IA therapy?

IMS III

- Time to endovascular treatment was 32 minutes longer than in IMS-I
  - IMS III -> 126 min between IV treatment and IA treatment
- Median time from groin puncture to start of therapy: 44 minutes

This is unacceptable in modern practice
What is the evidence for IA therapy?

Two Monday’s ago:

47 yo female

Known Mechanical Valve, INR = 2.5

NIHSS 14 – dense left hemiplegia, neglect
What is the evidence for IA therapy?
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Time from groin puncture to TICI 3 Recan:
What is the evidence for IA therapy?

Time from groin puncture to TICI 3 Recan:

6 minutes
What is the evidence for IA therapy?

NIHSS 2
What is the evidence for IA therapy?

This past Monday:

38 yo male

Coagulopathy with DVT/PE hx

On full dose Lovenox Prophylaxis

Presents with neck pain at 9 am to OSH – sent home with muscle relaxant
What is the evidence for IA therapy?

Returns to OSH at 2 with slurred speech

Develops some altered sensorium at 4 pm

MRI at 6 pm shows cerebellar DWI positive and VB occlusion on MRA
What is the evidence for IA therapy?

9:30 pm Call to Lifeflight to transfer to Vanderbilt

10 pm arrives at VUH

10:45 in the angio suite
What is the evidence for IA therapy?
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Time from groin puncture to TICI 3 Recan:
What is the evidence for IA therapy?

Time from groin puncture to TICI 3 Recan:

17 minutes
What is the evidence for IA therapy?

Rapid recanalization is becoming the norm.
What is the evidence for IA therapy?

Rapid recanalization is becoming the norm

My last 10 consecutive cases:

Groin to TICI 2B or better
15, 17, 6, 21, 9, 13, 9, 16, 12, 7 min
What is the evidence for IA therapy?

We must make rapid efficient management and recanalization a priority
What is the evidence for IA therapy?

If IA therapy is going to work…

*the vessel needs to be opened*
What is the evidence for IA therapy?

IMS-III endovascular reperfusion rates:

<table>
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<tr>
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<th>$\geq$ TICI 2a</th>
<th>$\geq$ TICI 2b</th>
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<tbody>
<tr>
<td>ICA</td>
<td>65%</td>
<td>38%</td>
</tr>
<tr>
<td>M1</td>
<td>81%</td>
<td>44%</td>
</tr>
<tr>
<td>M2</td>
<td>77%</td>
<td>44%</td>
</tr>
<tr>
<td>Overall</td>
<td>70%</td>
<td>40%</td>
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What is the evidence for IA therapy?

IMS-III endovascular reperfusion rates:

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<td>77%</td>
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</tr>
<tr>
<td>Overall</td>
<td>70%</td>
<td>40%</td>
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**TREVO2** – 92%  

**SWIFT** – 94%  

Both are high quality Independent Core Lab adjudicated  
Both published in Lancet
What is the evidence for IA therapy?

MR Rescue

27% TICI 2b recan
What is the evidence for IA therapy?

SYNTHEISIS Expansion

Recanalization rate NOT REPORTED
### What is the evidence for IA therapy?

IMS III

- Total endovascular treatments = 334/434
- IA tPA – 138
- EKOS + tPA – 22
- Merci – 38
- Merci + tPA – 57
- Penumbra – 16
- Penumbra + tPA – 38
- Solitaire – 2
- Solitaire + tPA – 3
- Other (???) – 7

‘modern’ devices = 13% of endovascular cohort
What is the evidence for IA therapy?

SYNTHESESIS Expansion

- Total endovascular treatments = 165/181
- IA tPA – 109
- Solitaire – 18
- Penumbra – 9
- Trevo – 5
- Merci – 5

Total = 146  (19 cases unaccounted for)
What is the evidence for IA therapy?

Confirmation of large vessel occlusion is required
What is the evidence for IA therapy?

…the patient must have the disease

IMS III
18.9% of patients had no occlusion on angiography

SYNTHESIS Expansion

“In patients with a neurologic deficit but no corresponding occlusion, the endovascular procedure involved injecting t-PA into the vascular area that was presumably affected.”
What is the evidence for IA therapy?

What if we confirm that the patient DOES have the disease?

IMS III - prespecified analysis for patients with confirmation of LVO (180 patients)
What is the evidence for IA therapy?

90-Day mRS Distribution, Baseline CTA Occlusion Present

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular N=180</td>
<td>13.3</td>
<td>21.7</td>
<td>12.2</td>
<td>13.3</td>
<td>17.8</td>
<td>6.1</td>
<td>15.6</td>
</tr>
<tr>
<td>IV tPA Alone N=91</td>
<td>5.5</td>
<td>14.3</td>
<td>18.7</td>
<td>11</td>
<td>16.5</td>
<td>7.7</td>
<td>26.4</td>
</tr>
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van Elteren test p-value 0.0114

A. Demchuk, IMS III: Comparison of Outcomes between IV and IV/IA Treatment in Baseline CTA Confirmed ICA, M1, M2 and Basilar Occlusions, slide 20, Presented at ISC 2013, Honolulu, Hawaii
What is the evidence for IA therapy?

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van Elteren test, p-value 0.0114

Endovascular confers a benefit across the spectrum of mRS

With CTA-confirmed occlusion at baseline, representative of current practice, IMS III has a positive outcome for endovascular therapy.
What is the evidence for IA therapy?

Occlusion must be confirmed prior to IA...

And if occlusion is confirmed, patients do better with IA therapy
What is the evidence for IA therapy?
What is the evidence for IA therapy?

LVO is a devastating disease
What is the evidence for IA therapy?

Poor Natural History
What is the evidence for IA therapy?

Poor Natural History $\rightarrow$ PROACT II
What is the evidence for IA therapy?

PROACT II

90 day Good outcome (mRS 0-2)
What is the evidence for IA therapy?

**PROACT II**

90 day Good outcome (mRS 0-2)

UK 40% vs. Control 25% (p = 0.04)
What is the evidence for IA therapy?

**PROACT II**
Prospective high quality data
IA appropriate population
Confirmed large vessel occlusion
Placebo
What is the evidence for IA therapy?

PROACT II
Prospective high quality data
IA appropriate population
Confirmed large vessel occlusion
Placebo

75% Poor Outcome (mRS 3-6)
What is the evidence for IA therapy?

**PROACT II**
Prospective high quality data
IA appropriate population
Confirmed large vessel occlusion
Placebo

27% Mortality
What is the evidence for IA therapy?

Poor Natural History → FIRST
What is the evidence for IA therapy?

**FIRST**
Prospective, multicenter study of a stroke cohort eligible for, but untreated by mechanical thrombectomy within 8 hours of symptom onset large vessel occlusion NIHSS ≥10.
What is the evidence for IA therapy?

**FIRST**

90 day Good outcome (mRS 0-2)
What is the evidence for IA therapy?

**FIRST**

90 day Good outcome (mRS 0-2)

20%
What is the evidence for IA therapy?

**FIRST**
Prospective high quality data
IA appropriate population
Confirmed large vessel occlusion

80% Poor Outcome (mRS 3-6)
What is the evidence for IA therapy?

FIRST
Prospective high quality data
IA appropriate population
Confirmed large vessel occlusion

41% Mortality
What is the evidence for IA therapy?

Poor Natural History → MR Rescue
What is the evidence for IA therapy?

MR Rescue

Subgroup: Medical Arm with Penumbra
What is the evidence for IA therapy?

MR Rescue

Subgroup: Medical Arm with Penumbra

90 day Good outcome (mRS 0-2) IV arm

23%
What is the evidence for IA therapy?

Poor Natural History → IMS III
What is the evidence for IA therapy?

IMS III

Subgroup: CTA+ for ICA T and ICA T + M1
What is the evidence for IA therapy?

IMS III

Subgroup: CTA+ for ICA T and ICA T + M1

90 day Good outcome (mRS 0-2) IV arm
What is the evidence for IA therapy?

IMS III

Subgroup: CTA+ for ICA T and ICA T + M1

90 day Good outcome (mRS 0-2) IV arm

4%
What is the evidence for IA therapy?

IMS III
Subgroup: CTA+ for ICA T and ICA T + M1

90 day Good outcome (mRS 0-2) IV arm

4%

Treated pts in cohort: 26% Good Outcome
On Balance
On Balance

1) Evidence strongly supports IA for early non-IV pts
2) Evidence for other patients is comparable or better
   LOE to ~75% of acute stroke Class I recs
3) New technologies/techniques are PROVEN to be better than old technologies/techniques
4) If LVO is confirmed, patients with IA appear to experience better outcomes
5) Clearly established terrible natural history
On Balance

IA therapy should be offered to non-IV tPA eligible pts <4.5 hrs
-and-
Very reasonable and appropriate to offer IA therapy to IV tPA eligible or >4.5 hr patients with confirmed LVO
THANK YOU