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The Evolution of Endovascular Selection Criteria

An MGH Perspective

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NEUROSURGERY

Disclosures

Consultant

Penumbra

Medtronic

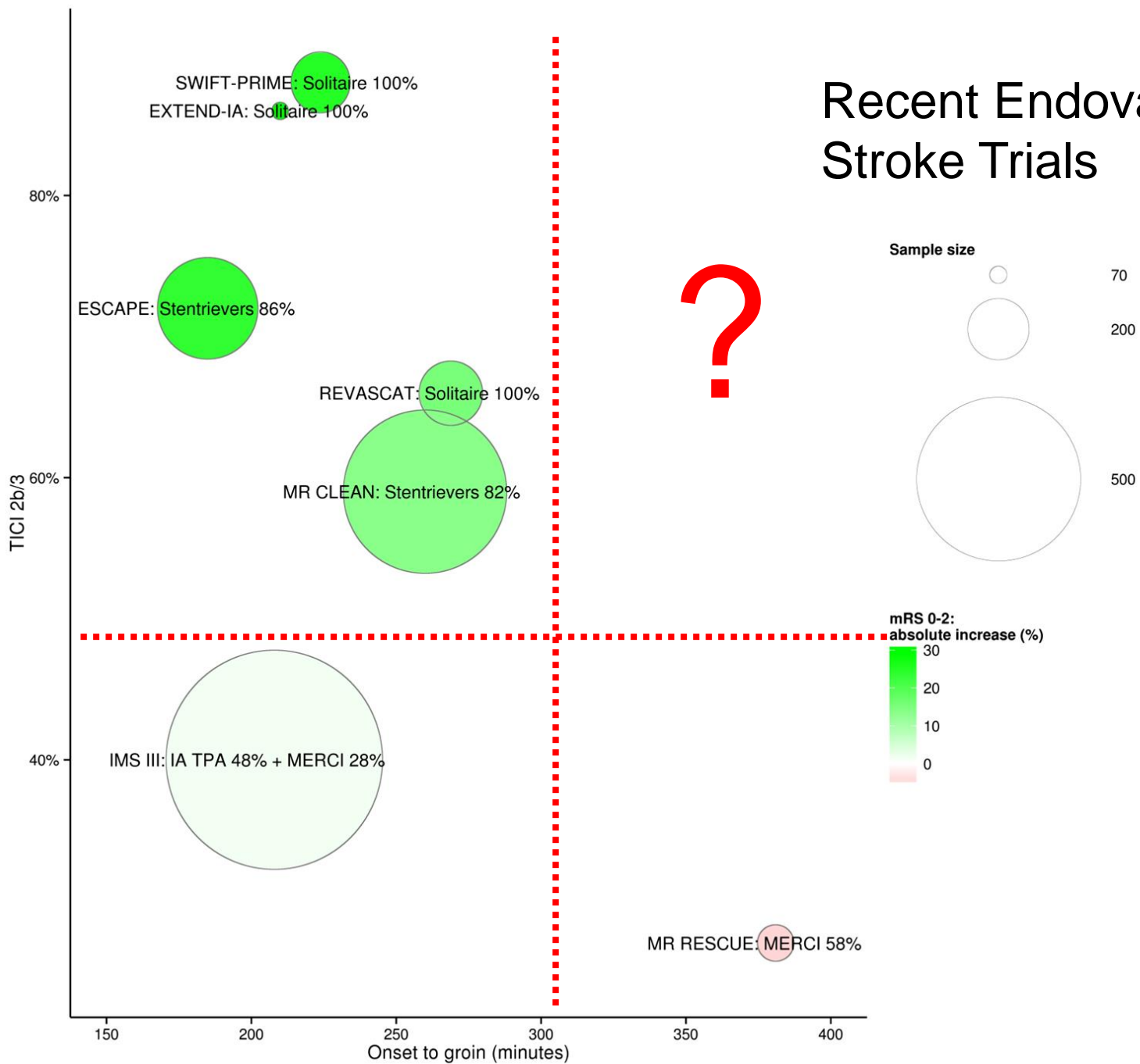
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Recent Endovascular Stroke Trials



Who Do We Know Benefits?

Clinical criteria

Age >18 (no clear upper age limit)

Functionally independent (mRS <2)

Significant neurologic deficit (NIHSS ≥ 6)

Onset to groin puncture ≤ 6 hrs

Radiological criteria

No large established stroke (ASPECTS ≥ 6)

Anterior vessel occlusion (ICA and/or M1 MCA segments)



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But There Are Many in Need

750000 ischemic strokes

/year in the USA

120000 Large vessel occlusions

5000 stroke rescues



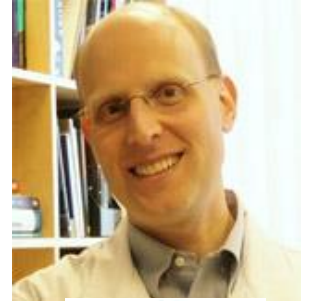
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Selection History at MGH



The Challenge of Variability



Stroke Neurology



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Selection circa 2012

Likely to Benefit

IAT Selection Criteria

All of the below must be met

Clinical

NIHSS ≥ 8
Time ≤ 6 hours anterior circulation/ ≤ 12 hours posterior circulation

Age < 80

Premorbid condition

- Normal baseline functional status (mRS ≤ 1)
- Life expectancy > 12 months
- Reperfusion reasonably expected to prevent infarction of tissue at risk

Radiological

Anterior circulation

Infarct core < 70 cc (DWI) or ASPECTS > 7 (NCCT)
Proximal arterial occlusion (ICA, M1 or proximal M2)

Posterior circulation

Minimal brainstem or thalamic infarct core
proximal arterial occlusion (basilar artery or dominant vertebral artery)

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Unlikely to Benefit

IAT Selection Criteria

One of the below needs to be met

Clinical

NIHSS < 4

Age > 90

Time > 8 hours Anterior circulation/ > 24 hours Posterior circulation

Premorbid condition

- Moderate-severe dementia (leading to loss of independence)
- Significantly impaired baseline functional status (mRS ≥ 4 ; inability to walk *and* attend to activities of daily living)
- Life expectancy of < 6 months

Radiological

Anterior

Infarct core > 100 cc (DWI) or ASPECTS ≤ 4 (NCCT)
Distal arterial occlusion (Mid M2, A2 or distal)

Posterior

Pontine, midbrain or thalamic infarcts $> 50\%$ of the territory
Proximal vertebral arterial occlusion
Distal arterial occlusion (isolated PCA)



MGH Algorithm:
Both clinical and radiological criteria



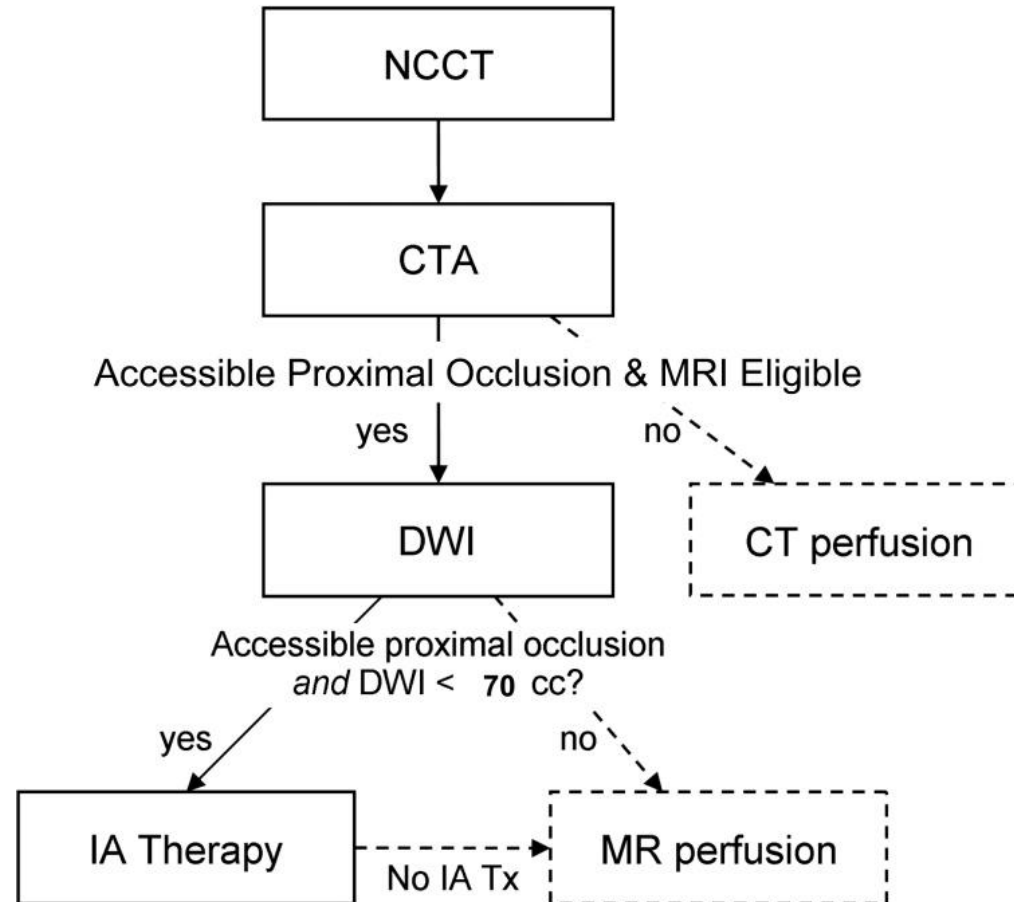
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Selection circa 2012

CT and MRI

MGH Acute Stroke Imaging Algorithm



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Selection Protocol

Patient selection

ORIGINAL RESEARCH

Implementation of a patient selection protocol for intra-arterial therapy increases treatment rates in patients with acute ischemic stroke

Natalia S Rost,¹ Eric E Smith,² Raul G Nogueira,³ Kaitlin M Fitzpatrick,¹
Albert J Yoo,⁴ Joshua A Hirsch,⁴ Lee H Schwamm¹

Of 1348 subjects identified, 118 (8.7%) met the criteria for LTB and 62 (52%) underwent IAT. There was a significant increase in rates of IAT among LTB patients after protocol implementation (61% vs 40%, $p < 0.02$).

These data provide evidence that a uniform approach to patient selection for open-label or compassionate use of IAT may improve the rates of patient inclusion for intervention as well as the homogeneity of the patient cohort.



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Reasons for not performing IAT in the LTB group

1. Late presentation in the intervention window (21.4%)
2. Rapid improvement (16.1%)
3. Family refusal (14.3%)
4. Neuroimaging features of limited tissue at risk (11%)
5. Extensive clot burden identified by endovascular team (7.2%)
6. Reason unclear/unrecorded (7.2%)
7. Advanced age (5.3%)
8. Technical challenge identified by endovascular team (5.3%)
9. Carotid dissection (4%)
10. Advanced directives (4%)
11. Hemorrhagic conversion (1.7%)
12. Trial enrollment (1.7%).



Powerful New Data

The NEW ENGLAND JOURNAL of MEDICINE
 ESTABLISHED IN 1812 VOL. 372 NO. 1
 JANUARY 1, 2015

A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke

O.A. Berkhemer, P.S.S. Fransen, D. Beumer, L.A. van den Berg, H.F. Lingsma, A.J. Yoo, W.J. Schonewille, J.A. Vos, P.J. Nederkoorn, M.J.H. Wermer, M.A.A. van Walderveen, J. Staals, J. Hofmeijer, J.A. van Oostayen, G.J. Lycklama à Nijeholt, J. Boiten, P.A. Brouwer, B.J. Emmer, S.F. de Bruijn, L.C. van Dijk, L.J. Kappelle, R.H. Lo, R.J. Dallinga, M.C. Visser, J.C.J. Bot, P.C. Vroomen, O. Eshghi, T.H.C.M.L. Schreuder, R.J.J. Heijboer, K. Keizer, A.V. Tialbeek, H.M. den Hertog, D.G. Gerrits, R.M. van den Berg-Vos, G.B. Karas, E.W. Steygerberg, H.Z. Flach, H.A. Marquering, M.E.S. Sprengers, S.F.M. Jenniskens, L.F.M. Beenen, R. van den Berg, P.J. Koudstaal, W.H. van Zwam, Y.B.W.E.M. Roos, A. van der Lugt, R.J. van Oostenbrugge, C.B.L.M. Majoie, and D.W.J. Dippel, for the MR CLEAN Investigators*

ABSTRACT

BACKGROUND In patients with acute ischemic stroke caused by a proximal intracranial arterial occlusion, intraarterial treatment is highly effective for emergency revascularization. However, proof of a beneficial effect on functional outcome is lacking.

METHODS We randomly assigned eligible patients to either intraarterial treatment plus usual care or usual care alone. Eligible patients had a proximal arterial occlusion in the anterior cerebral circulation that was confirmed on vessel imaging and that could be treated intraarterially within 6 hours after symptom onset. The primary outcome was the modified Rankin scale score at 90 days; this categorical scale measures functional outcome, with scores ranging from 0 (no symptoms) to 6 (death). The treatment effect was estimated with ordinal logistic regression as a common odds ratio, adjusted for prespecified prognostic factors. The adjusted common odds ratio measured the likelihood that intraarterial treatment would lead to lower modified Rankin scores, as compared with usual care alone (shift analysis).

RESULTS We enrolled 500 patients at 16 medical centers in the Netherlands (233 assigned to intraarterial treatment and 267 to usual care alone). The mean age was 65 years (range, 23 to 96), and 445 patients (89.0%) were treated with intravenous alteplase before intraarterial treatment. Retrievable stents were used in 190 of the 233 patients (81.5%) assigned to intraarterial treatment. The adjusted common odds ratio was 1.67 (95% confidence interval [CI], 1.21 to 2.30). There was an absolute difference of 13.5 percentage points (95% CI, 5.9 to 21.2) in the rate of functional independence (modified Rankin score, 0 to 2) in favor of the intervention (32.6% vs. 19.1%). There were no significant differences in mortality or the occurrence of symptomatic intracerebral hemorrhage.

CONCLUSIONS In patients with acute ischemic stroke caused by a proximal intracranial occlusion of the anterior circulation, intraarterial treatment administered within 6 hours after stroke onset was effective and safe. (Funded by the Dutch Heart Foundation and others; MR CLEAN Netherlands Trial Registry number, NTR1804, and Current Controlled Trials number, ISRCTN10888758.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Dippel at the Department of Neurology (MR CLEAN) at the Erasmus MC University Medical Center, PO Box 2040, Rotterdam 3000 CA, the Netherlands, or at d.dippel@erasmusmc.nl.

Drs. Berkhemer, Fransen, and Beumer and Drs. van Zwam, Roos, van der Lugt, van Oostenbrugge, Majoie, and Dippel contributed equally to this article.

*A complete list of investigators in the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN) is provided in the Supplementary Appendix, available at NEJM.org.

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JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombectomy within 8 Hours after Ischemic Stroke

A. de Miquel, C.A. Molina, A. Rovira, Ribó, M. Millán, X. Urra, P. Cardona, Estañó, J. Blasco, L. Aja, L. Dorado, Iz-Pérez, M. Goyal, A.M. Demchuk, for the REVASCAT Trial Investigators*

ABSTRACT

BACKGROUND Thrombectomy for the treatment of large-vessel occlusion-based stroke reperfusion registry.

RESULTS In Valencia, Spain, we randomly assigned patients after the onset of symptoms of acute ischemic stroke to either thrombectomy (intervention group) or intravenous alteplase (control group). All patients had a proximal large-vessel occlusion in the anterior, middle, or posterior cerebral circulation. The primary outcome was the modified Rankin scale score at 90 days. Secondary outcomes included the proportion of patients with functional independence (modified Rankin score, 0 to 2) and the proportion of patients with functional independence who were discharged to home. The primary outcome was significantly better in the intervention group (32.6% vs. 19.1%, P=0.001). Secondary outcomes were also significantly better in the intervention group (P<0.001).

CONCLUSIONS Thrombectomy within 8 hours after acute ischemic stroke caused by a proximal large-vessel occlusion was effective and safe. (Funded by the Spanish Ministry of Health and others; REVASCAT Trial Registry number, NTR1804, and Current Controlled Trials number, ISRCTN10888758.)

JOURNAL of MEDICINE

ORIGINAL ARTICLE

Endovascular Treatment of Rapid Onset of Ischemic Stroke

Menon, M. Eesa, J.L. Rempel, J. Thornton, D. Roy, Sapkota, D. Dowlatshahi, D.F. Frei, N.R. Kamal, J. Ryckborst, F.L. Silver, A. Shuaib, D. Tampieri, W. Baxter, P.A. Burns, H. Choe, J.-H. Heo, M. Kelly, G. Linares, J.L. Mandzia, J. Shankar, S.B. Coutts, E.E. Smith, W.F. Morrish, A.P. Mitha, J.H. Wong, M.W. Lowerison, for the ESCAPE Trial Investigators*

ABSTRACT

BACKGROUND Rapid onset of ischemic stroke in the anterior circulation, 60 to 80% of cases, is associated with a small infarct core, a large penumbra, and a high potential for functional recovery. Endovascular treatment of rapid onset of ischemic stroke with a small infarct core and moderate-to-good collateral circulation.

RESULTS We randomly assigned patients to either endovascular treatment (intervention group) or standard care (control group) or standard care (control group) or standard care (control group). The primary outcome was the modified Rankin scale score at 90 days. Secondary outcomes included the proportion of patients with functional independence (modified Rankin score, 0 to 2) and the proportion of patients with functional independence who were discharged to home. The primary outcome was significantly better in the intervention group (32.6% vs. 19.1%, P=0.001). Secondary outcomes were also significantly better in the intervention group (P<0.001).

CONCLUSIONS Endovascular treatment of rapid onset of ischemic stroke was effective and safe. (Funded by the National Institutes of Health and others; ESCAPE Trial Registry number, NTR1804, and Current Controlled Trials number, ISRCTN10888758.)

JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombectomy after Intravenous Alteplase in Stroke

Al, M.D., Alain Bonafe, M.D., J. Levy, M.D., Vitor M. Pereira, M.D., M.D., Ph.D., David J. Cohen, M.D., M.D., Ph.D., Tudor G. Jovin, M.D., D., Thomas H. Siddiqui, M.D., Ph.D., Thomas G. Devlin, M.D., Ph.D., Richard du Mesnil de Rochemont, M.D., for the SWIFT PRIME Investigators*

ABSTRACT

BACKGROUND Thrombectomy after intravenous alteplase (tPA) increases reperfusion in the proximal anterior cerebral artery (ACA) alone. Thrombectomy after intravenous tPA, increases reperfusion in the proximal anterior cerebral artery (ACA) alone. Thrombectomy after intravenous tPA, increases reperfusion in the proximal anterior cerebral artery (ACA) alone.

RESULTS We randomly assigned patients to either thrombectomy after intravenous alteplase (intervention group) or intravenous alteplase alone (control group). The primary outcome was the modified Rankin scale score at 90 days. Secondary outcomes included the proportion of patients with functional independence (modified Rankin score, 0 to 2) and the proportion of patients with functional independence who were discharged to home. The primary outcome was significantly better in the intervention group (32.6% vs. 19.1%, P=0.001). Secondary outcomes were also significantly better in the intervention group (P<0.001).

CONCLUSIONS Thrombectomy after intravenous alteplase was effective and safe. (Funded by the National Institutes of Health and others; SWIFT PRIME Trial Registry number, NTR1804, and Current Controlled Trials number, ISRCTN10888758.)

JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombectomy for Ischemic Stroke with Proximal Arterial Occlusion: Imaging Selection

J. Kleinig, H.M. Dewey, L. Churilov, N. Yassi, M. Krause, T.J. Oxley, T.Y. Wu, M. Brooks, P.B. R. Scroop, P.A. Barber, B. McGuinness, P. Chandra, C.F. Bladin, M. Badier, H. Rice, M.D., G.A. Donnan, and S.M. Davis, for the MR CLEAN Investigators*

ABSTRACT

BACKGROUND Thrombectomy for ischemic stroke with proximal arterial occlusion: imaging selection.

RESULTS We randomly assigned patients to either thrombectomy (intervention group) or intravenous alteplase (control group). The primary outcome was the modified Rankin scale score at 90 days. Secondary outcomes included the proportion of patients with functional independence (modified Rankin score, 0 to 2) and the proportion of patients with functional independence who were discharged to home. The primary outcome was significantly better in the intervention group (32.6% vs. 19.1%, P=0.001). Secondary outcomes were also significantly better in the intervention group (P<0.001).

CONCLUSIONS Thrombectomy for ischemic stroke with proximal arterial occlusion was effective and safe. (Funded by the Australian National Health and Medical Research Council and others; MR CLEAN Trial Registry number, NTR1804, and Current Controlled Trials number, ISRCTN10888758.)

**MR CLEAN
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 EXTEND-IA
 SWIFT PRIME
 REVASCAT
 THRACE
 THERAPY**

Selection circa 2016

Goals

- Modify our MGH approach based on the available new Class 1 Level A data
- Increase autonomy and consistency for cases with proven benefit
- Expand to capture cases that we think are probable to benefit



Endovascular Screening Criteria

For **ALL** patients with

NIHSS ≥ 4

LSW < 24 hrs

Assess the following:

Clinical

Age

Last seen well

Premorbid baseline mRS (and dementia)

Candidacy for IV tPA

Radiological

Hemorrhage excluded

Evidence of ischemic stroke

Presence of LVO (ICA, M1, M2, BA)

Core infarct volume (ASPECTS or DWI)

Quality of collaterals

Using these screening criteria classify patients as

Proven

Uncertain

Unlikely

to benefit from endovascular therapy.

Page Neuroendovascular fellow
33722 immediately for all cases.

Evaluate for enrollment in active clinical trials.



Endovascular Criteria

Treatment process for all cases initiated by Stroke and Endovascular Fellows

Clinical (must meet all)

NIHSS ≥ 6

Time ≤ 6 hours from LSW to expected groin puncture

Age 18-85 years

Premorbid condition

-mRS ≤ 1

-Life expectancy > 12 months

Radiological (must meet all)

Intracranial ICA or MCA M1 occlusion

Small established infarct core volume by either imaging modality

if by CT criteria: visual estimation of ASPECTS ≥ 6 on NCCT

: symmetric collaterals on CTA

if by MRI criteria: ≤ 70 cc DWI by ABC/2 measurement

Endovascular Criteria

Treatment only if both Stroke and Endovascular Attendings agree

Clinical (must meet all)

NIHSS ≥ 4

Time: ≤ 16 hours anterior circulation; ≤ 24 hours posterior circulation

Premorbid condition

-mRS ≤ 3

-Life expectancy > 12 months

Radiological (must meet all)

Anterior circulation

Proximal arterial occlusion (ICA, M1, M2)

Small established infarct core volume by either imaging modality

if by MRI criteria: ≤ 70 cc DWI by ABC/2 measurement

if needed, by CT criteria: visual estimation of ASPECTS ≥ 5 on NCCT

: excellent collaterals on CTA

Posterior circulation

Proximal arterial occlusion (basilar, dominant vertebral)

$\leq 50\%$ infarction of pons, midbrain or thalamus



Endovascular Criteria

No endovascular treatment offered

Clinical (if meets any)

NIHSS <4

Time: >16 hr from LSW for Anterior circulation; >24 hr Posterior circulation

Premorbid condition

- mRS \geq 4
- major medical co-morbidity
- Life expectancy of <12 months

Radiological (if meets any)

Anterior circulation

Large established core by either imaging modality

by CT criteria: ASPECTS \leq 4 on NCCT (or)

: malignant collateral pattern

by MRI criteria: infarct core >100cc DWI by ABC/2 measurement

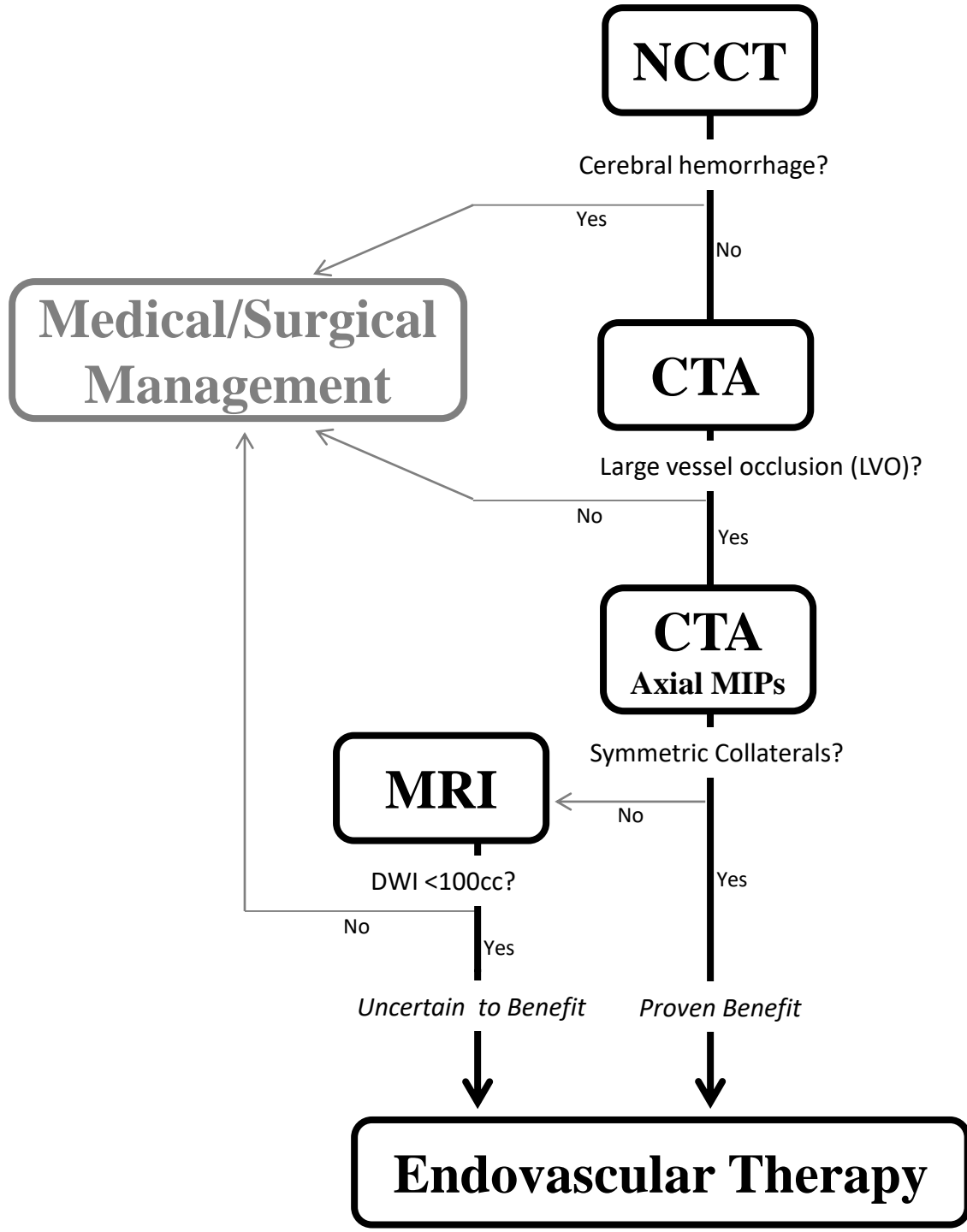
Distal arterial occlusion (M3, M4, A2)

Posterior circulation

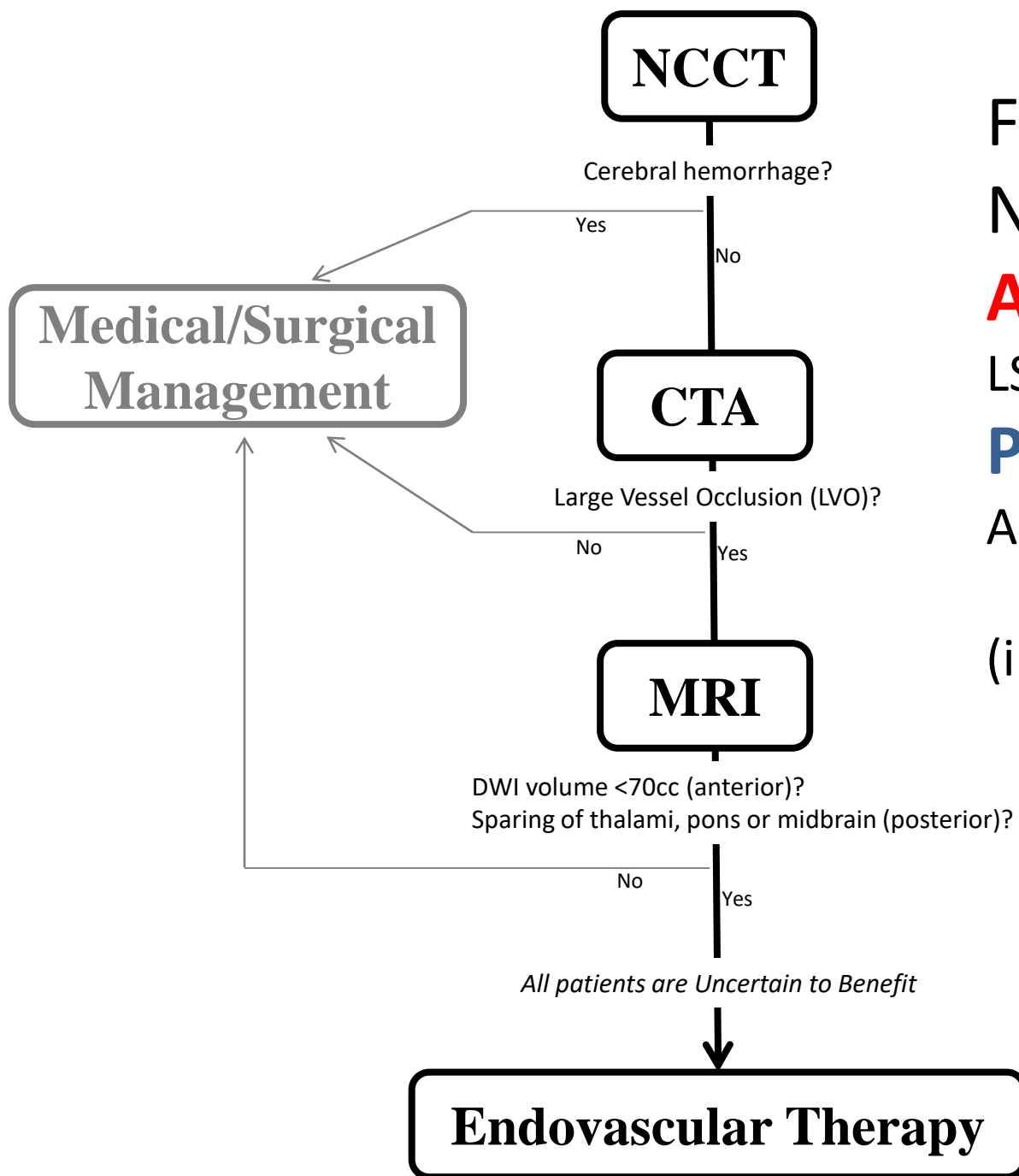
>50% infarction of pons, midbrain or thalamus

Distal arterial occlusion (e.g. isolated PCA)





For patients with
NIHSS ≥ 6 :
Anterior Circulation
LSW < 6 hrs



For patients with
NIHSS ≥ 6 :

Anterior Circulation

LSW 6-16hrs

Posterior Circulation

All patients <24hrs

(includes wake-up strokes)

Note, this imaging approach may vary for patients enrolled in a research trial

The Near Horizon: Time Window Expansion



16 hours, larger volume inclusion



24 hours\smaller volume inclusion



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Selection 2017/2018: Proposed



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Endovascular Criteria

Treatment process for all cases initiated by Stroke and Endovascular Fellows

•Clinical (must meet all)

–NIHSS ≥ 6

–Time ≤ 24 hours from LSW to expected groin puncture

–Age 18-95 years

–Premorbid condition

•mRS ≤ 2

•Life expectancy >12 months

•Radiological (must meet all)

– ≤ 6 hours from LSW to expected groin puncture

•Intracranial ICA or MCA M1 occlusion

–6-24hrs from LSW to expected groin puncture

•Intracranial ICA or MCA M1 occlusion

•Small established infarct core volume by either imaging modality

– if by CT criteria: ASPECTS ≥ 7 on NCCT

» Adequate collateral pattern on CTA

– if by MRI criteria: ≤ 70 cc DWI by ABC/2 measurement



Endovascular Criteria

Treatment only if both Stroke and Endovascular Attendings agree

Clinical (must meet all)

- NIHSS ≥ 4
- Time: ≤ 24 hours from LSW to expected groin puncture
- Premorbid condition
 - mRS ≤ 4
 - Adequate life expectancy

Radiological (must meet all)

Anterior circulation

Proximal arterial occlusion (ICA, M1, M2)

Small established infarct core volume by either imaging modality

if by MRI criteria: ≤ 120 cc DWI by ABC/2 measurement

if needed, by CT criteria: visual estimation of ASPECTS ≥ 5 on NCCT
: non malignant collaterals on CTA

Posterior circulation

Proximal arterial occlusion (basilar, dominant vertebral)

$\leq 70\%$ infarction of pons, midbrain or thalamus

Endovascular Criteria

No endovascular treatment offered

Clinical (if meets any)

NIHSS <4

Time: >24 hr from LSW for Anterior circulation; >24 hr Posterior circulation

Premorbid condition

- mRS \geq 4
- major medical co-morbidity
- Life expectancy

Radiological (if meets any)

Anterior circulation

Large established core by either imaging modality

by CT criteria: ASPECTS \leq 4 on NCCT (or)

: malignant collateral pattern

by MRI criteria: infarct core >120cc DWI by ABC/2 measurement

Distal arterial occlusion (M3, M4, A2)

Posterior circulation

>70% infarction of pons, midbrain or thalamus

Distal arterial occlusion (e.g. isolated PCA)

Conclusions

- Key to have institutional protocols – increases patient treatment
- Work-flow protocols unrelated to patient characteristics are important
- Decisions cannot be made based on whims, personal opinions, timing, holidays, vacation schedules
- Review data and results
- Re-evaluate established protocols altering data
- Imaging criteria are important



Thank you.



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