Atrial Fibrillation is Associated with Worse Collaterals in Acute Stroke: Angiography in the ENDOSTROKE Registry

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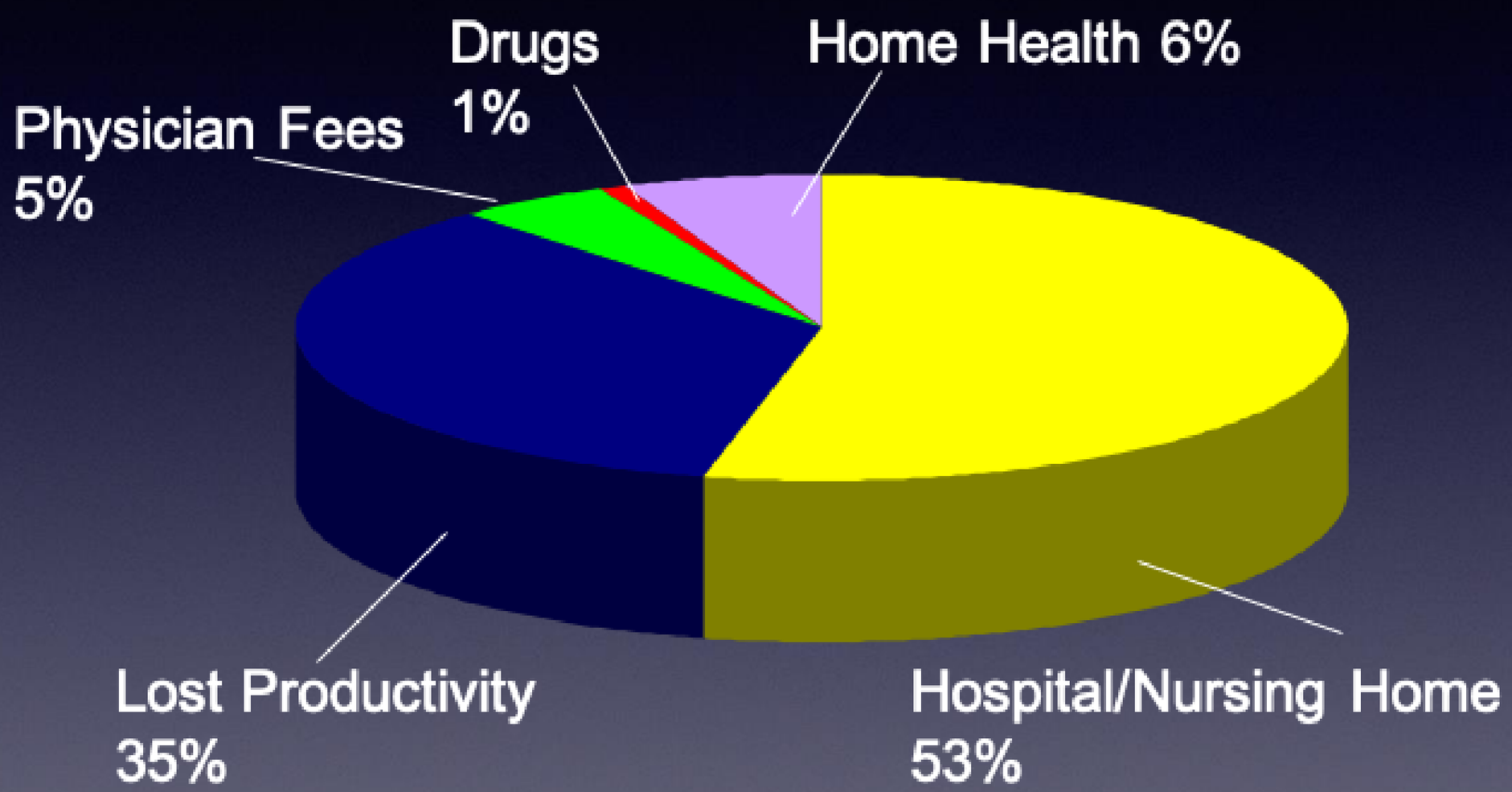
Objectives

- *Identify* patient groups who are at highest risk for acute stroke and may benefit from preventive management
- Discuss the latest *guideline* recommendations and evidence for managing acute stroke
- Describe strategies to implement *interventions* to optimize preventive and acute stroke care

Impact of Stroke



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Stroke Subtypes

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Risk & Prevention

Nonmodifiable

Age, Gender, Race, Heredity

Modifiable

Medical Conditions

- Hypertension
- Cardiac disease
- Atrial fibrillation
- Hyperlipidemia
- Diabetes mellitus
- Carotid stenosis
- Prior TIA or stroke

Behaviors

- Cigarette smoking
- Heavy alcohol use
- Physical inactivity

Recognition

- Sudden weakness or numbness
- Sudden change in vision
- Sudden difficulty speaking or understanding
- Sudden dizziness or loss of balance
- Sudden headache

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Stroke in the Young

- Common and increasingly so
- Common causes - ischemic and hemorrhagic

Imaging of Young Stroke

- Age and “stroke in the young”
  - PFO, coagulopathies, arterial dissection, moyamoya, cerebral venous thrombosis, hemorrhagic lesions
- Imaging revolution – role and evolution
- Mechanisms & pathophysiology – practical implications of precision medicine

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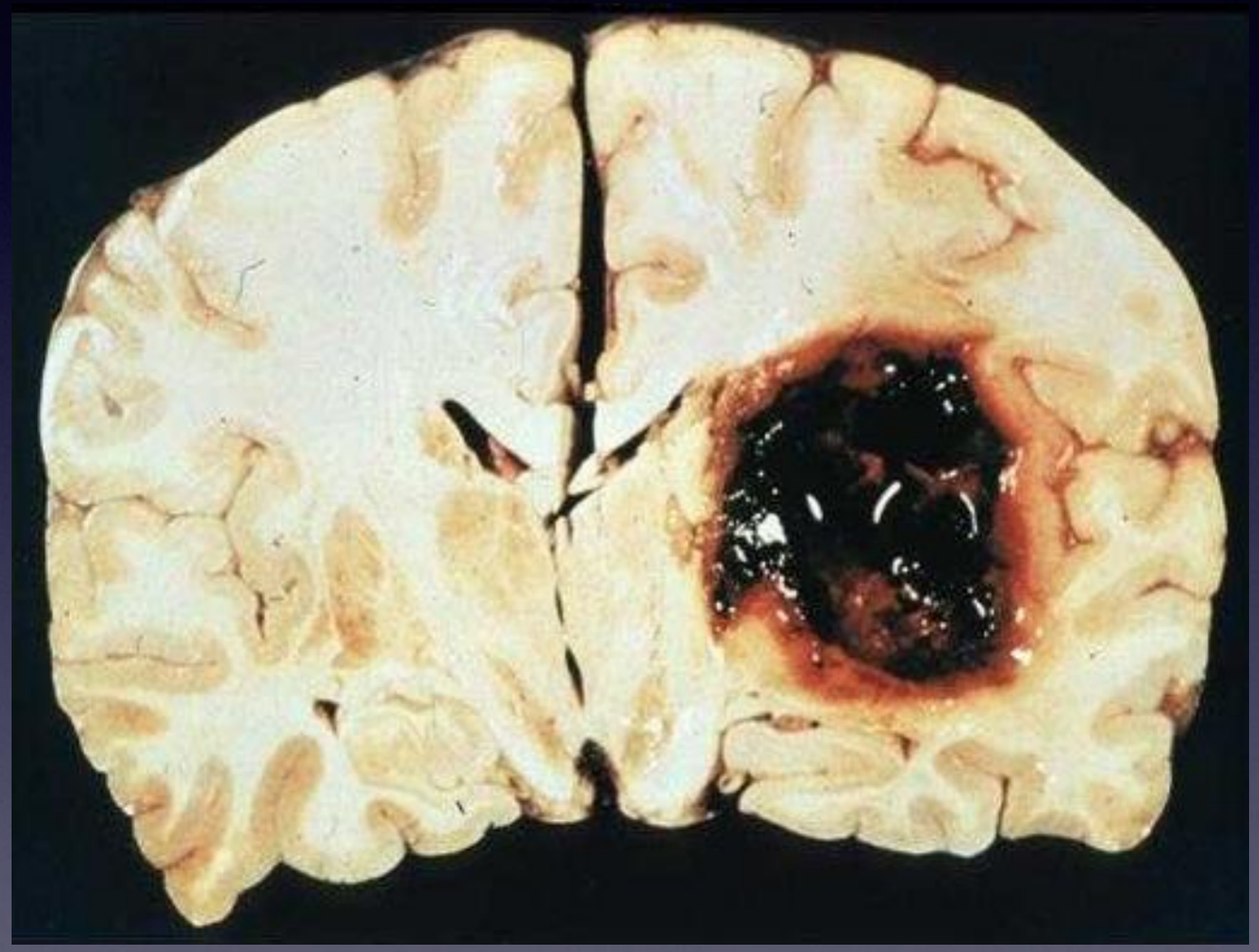
Hemorrhage



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Ischemia

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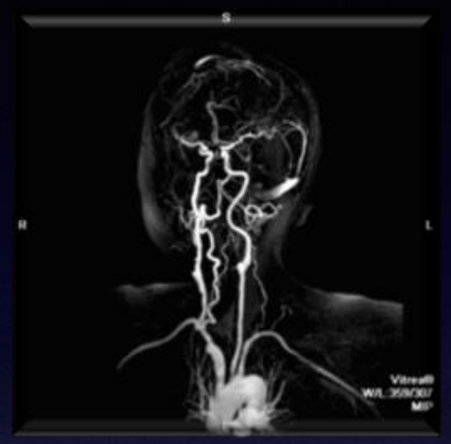
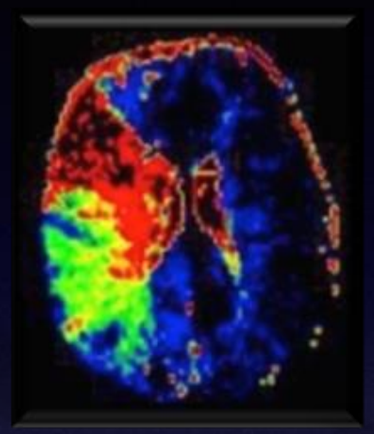
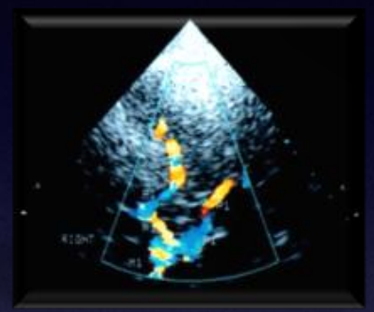
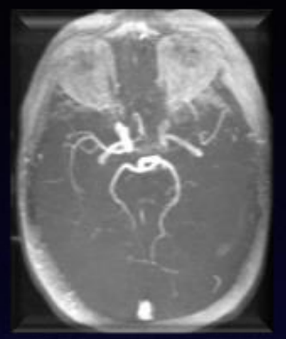
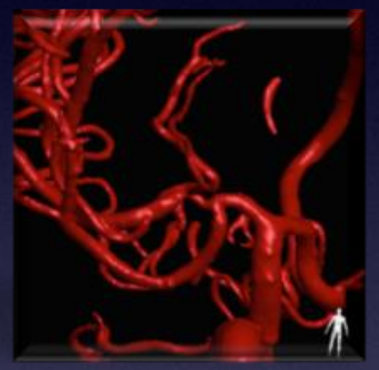
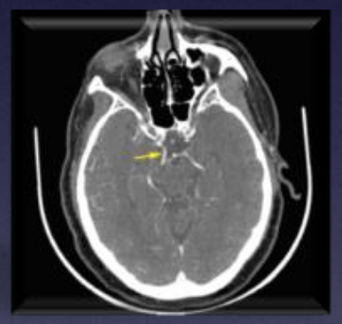
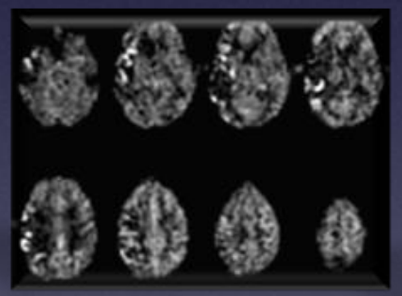
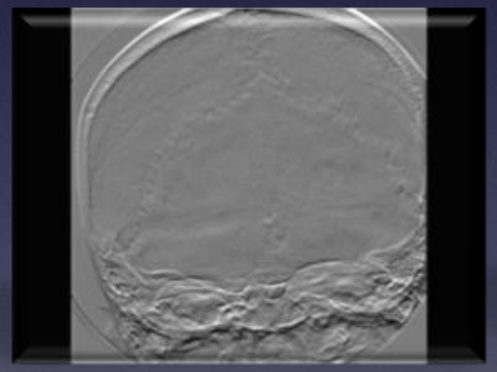
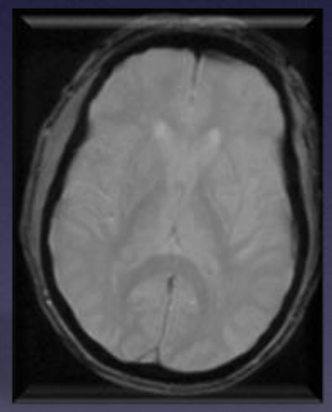
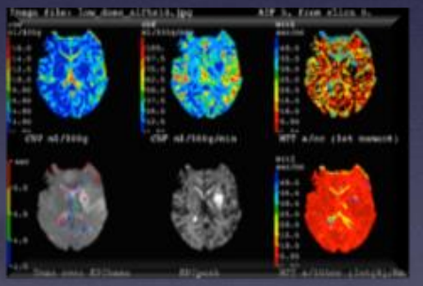
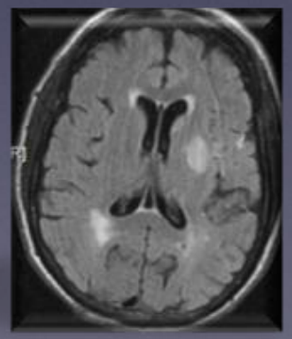
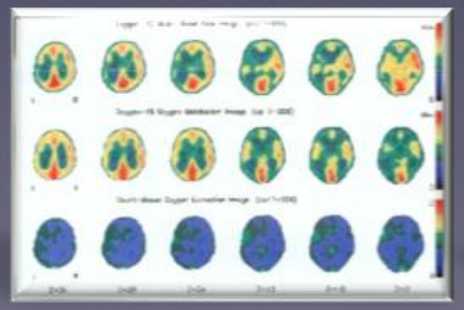
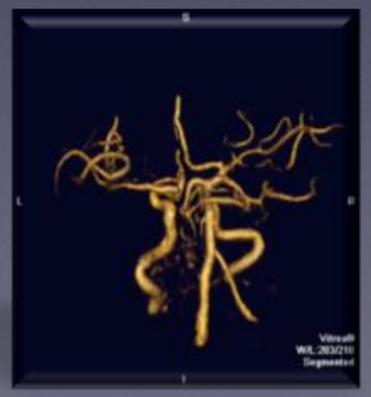
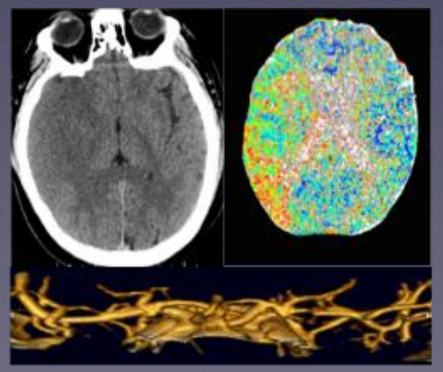
Imaging of Stroke



TIA versus Stroke

Time-Based	Tissue-Based
Indirect and arbitrary marker: time limit	Direct and biologic marker: end-organ injury
Inaccurate (in identifying infarct)	Highly accurate (in identifying infarct)
Does not add to patient/physician knowledge	Adds to patient/physician knowledge

Etiology

Ischemic Stroke (83%)

Atherothrombotic Cerebrovascular Disease (30%)

Lacunar (25%)
(small vessel disease)

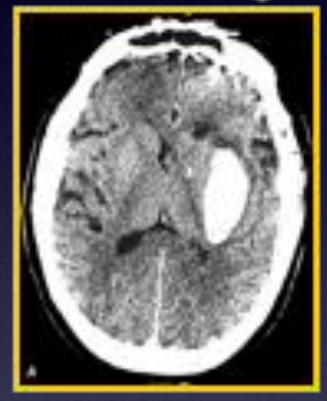
Cardioembolic (30%)

Other (vasculitiis, dissection, hypercoagulable, etc (10%)

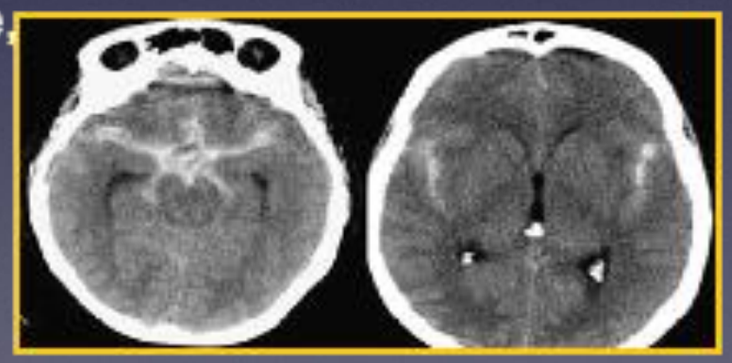
Cryptogenic (5%)

Hemorrhagic Stroke (17%)

Intracerebral Hemorrhage (70%)



Subarachnoid Hemorrhage (30%)



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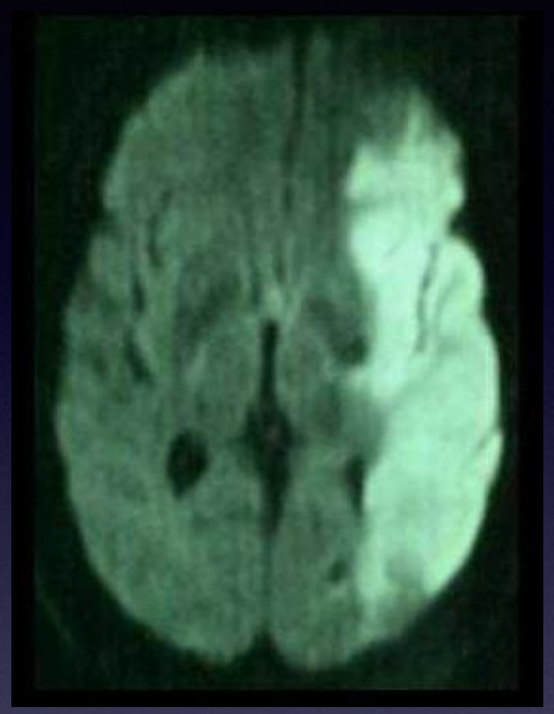
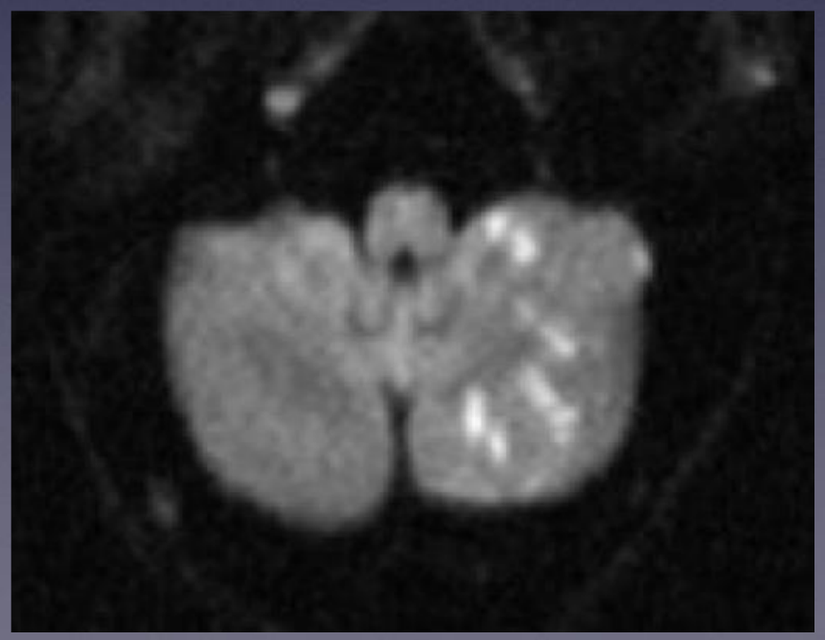
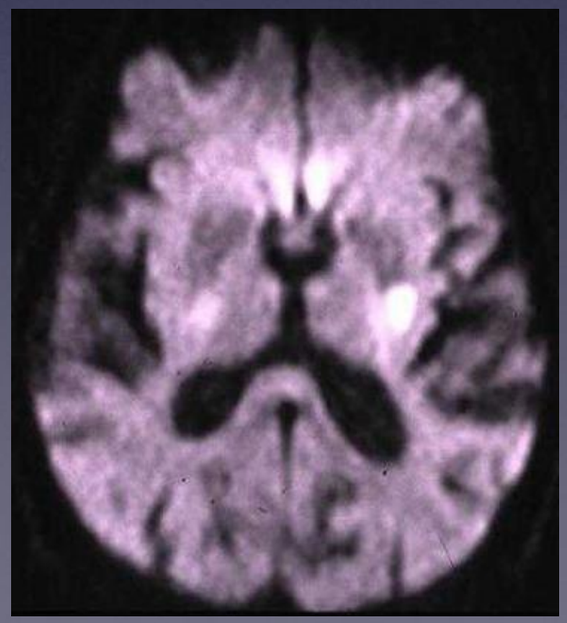
Territories







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Prevention

- Primary and secondary prevention
- Identification of risk factors
- Diagnostic evaluation is essential
- Imaging of potential vascular risks and treatment
  - PFO
  - Cardiac
  - Atherosclerosis - extracranial and intracranial
  - Small vessel disease

Prevention…

- Commonly initiated in-hospital during evaluation of potential acute stroke diagnosis
- Rational basis - determined from diagnostic studies
- Comprehensive
  - Considering all competing causes
  - Multiple concomitant strategies
- Longitudinal evaluation - importance of transitional care visits and ongoing outpatient follow up

Guidelines & Evidence for AIS

- Regulatory actions and recommendations
- Trials and practice - RCTs to RWE
- Societal guideline publications
- AHA/ASA guidelines
  - History
  - Endorsements
  - Implementation

Document Title	Publication Year	Abbreviation Used in This Document
"Recommendations for the Implementation of Telemedicine Within Stroke Systems of Care: A Policy Statement From the American Heart Association"[5]	2009	N/A
"Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association"[1]	2013	2013 AIS Guidelines
"Interactions Within Stroke Systems of Care: A Policy Statement From the American Heart Association/American Stroke Association"[6]	2013	2013 Stroke Systems of Care
"2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines"[7]	2013	2013 Cholesterol Guidelines
"2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society"[8]	2014	N/A
"Recommendations for the Management of Cerebral and Cerebellar Infarction With Swelling: A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association"[9]	2014	2014 Cerebral Edema
"Palliative and End-of-Life Care in Stroke: A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association"[10]	2014	2014 Palliative Care
"Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association"[11]	2014	2014 Secondary Prevention
"Clinical Performance Measures for Adults Hospitalized With Acute Ischemic Stroke: Performance Measures for Healthcare Professionals From the American Heart Association/American Stroke Association"[12]	2014	N/A
"Part 15: First Aid: 2015 American Heart Association and American Red Cross Guidelines Update for First Aid"[13]	2015	2015 CPR/ECC
"2015 American Heart Association/American Stroke Association Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association"[14]	2015	2015 Endovascular
"Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Alteplase in Acute Ischemic Stroke: A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association"[15]	2015	2015 IV Alteplase
"Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association"[16]	2016	2016 Rehab Guidelines

ACC indicates American College of Cardiology; AHA, American Heart Association; AIS, acute ischemic stroke; CPR, cardiopulmonary resuscitation; ECC, emergency cardiovascular care; HRS, Heart Rhythm Society; IV, intravenous; and N/A, not applicable.

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Saga of 2018 AHA/ASA Guidelines

- Process and methodology
- Presentation at ISC 2018
- Lack of endorsements
- Uproar
- Deletion - temporary and partial?

Media

News > Medscape Medical News > Neurology News

AHA Rescinds Large Sections of New Stroke Guidelines

Sue Hughes

April 27, 2018

17 Read Comments

Add to Email Alerts

In a somewhat bizarre turn of events, the American Heart Association (AHA)/American Stroke Association (ASA) has rescinded its recently released stroke guidelines, publishing a "correction" in which large parts of the document have been deleted.

A new paper, published online in *Stroke* on April 18, states: "Based on recent feedback received from the clinical stroke community...the American Heart Association/American Stroke Association has reviewed the guideline and is preparing clarifications, modifications, and/or updates to several sections in it. Currently, those sections, listed here, have been deleted from the guideline while this clarifying work is in process."

The AHA/ASA adds: "After review, a revised guideline, with consideration given to the clarifications, modifications, and/or updates of the sections noted above, will be posted over the coming weeks."

The sections that have been deleted are the following:

- Section 1.3: EMS Systems Recommendation 4
- Section 1.4: Hospital Stroke Capabilities Recommendation 1
- Section 1.6: Telemedicine Recommendation 3
- Section 2.2: Brain Imaging Recommendation 11
- Section 3.2: Blood Pressure Recommendation 3
- Section 4.3: Blood Pressure Recommendation 2
- Section 4.6: Dysphagia Recommendation 1
- Section 6.0: All subsections

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2018 Guidelines

AHA/ASA Guideline

2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke

A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

Reviewed for evidence-based integrity and endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons

Endorsed by the Society for Academic Emergency Medicine

William J. Powers, MD, FAHA, Chair; Alejandro A. Rabinstein, MD, FAHA, Vice Chair;
Teri Ackerson, BSN, RN; Opeolu M. Adeoye, MD, MS, FAHA;
Nicholas C. Bambakidis, MD, FAHA; Kyra Becker, MD, FAHA; José Biller, MD, FAHA;
Michael Brown, MD, MSc; Bart M. Demaerschalk, MD, MSc, FAHA; Brian Hoh, MD, FAHA;
Edward C. Jauch, MD, MS, FAHA; Chelsea S. Kidwell, MD, FAHA;
Thabele M. Leslie-Mazwi, MD; Bruce Ovbiagele, MD, MSc, MAS, MBA, FAHA;
Phillip A. Scott, MD, MBA, FAHA; Kevin N. Sheth, MD, FAHA;
Andrew M. Southerland, MD, MSc; Deborah V. Summers, MSN, RN, FAHA;
David L. Tirschwell, MD, MSc, FAHA; on behalf of the American Heart Association Stroke Council

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2 RCTs as evidential basis

- History of RCTs (randomized, controlled trials) and RWE (real-world evidence)
- Endovascular therapy for acute ischemic stroke
- FDA mandate for use of real-world data and RWE
- RCTs for every single variable?
  - age, low NIHSS, low ASPECTS, large CTP core, large DWI core, ICAD, distal emboli, basilar occlusions, anesthesia, blood pressure, technique…
- DAISI CRN

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DAWN & DEFUSE 3 - imaging & reperfusion

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DAWN

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 4, 2018 VOL. 378 NO. 1

Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct

R.G. Nogueira, A.P. Jadhav, D.C. Haussen, A. Bonafe, R.F. Budzik, P. Bhuva, D.R. Yavagal, M. Ribo, C. Cognard, R.A. Hanel, C.A. Sila, A.E. Hassan, M. Millan, E.I. Levy, P. Mitchell, M. Chen, J.D. English, Q.A. Shah, F.L. Silver, V.M. Pereira, B.P. Mehta, B.W. Baxter, M.G. Abraham, P. Cardona, E. Veznedaroglu, F.R. Hellinger, L. Feng, J.F. Kirmani, D.K. Lopes, B.T. Jankowitz, M.R. Frankel, V. Costalat, N.A. Vora, A.J. Yoo, A.M. Malik, A.J. Furlan, M. Rubiera, A. Aghaebrahim, J.-M. Olivot, W.G. Tekle, R. Shields, T. Graves, R.J. Lewis, W.S. Smith, D.S. Liebeskind, J.L. Saver, and T.G. Jovin, for the DAWN Trial Investigators*

ABSTRACT

BACKGROUND

The effect of endovascular thrombectomy that is performed more than 6 hours after the onset of ischemic stroke is uncertain. Patients with a clinical deficit that is disproportionately severe relative to the infarct volume may benefit from late thrombectomy.

METHODS

We enrolled patients with occlusion of the intracranial internal carotid artery or proximal middle cerebral artery who had last been known to be well 6 to 24 hours earlier and who had a mismatch between the severity of the clinical deficit and the infarct volume, with mismatch criteria defined according to age (<80 years or ≥80 years). Patients were randomly assigned to thrombectomy plus standard care (the thrombectomy group) or to standard care alone (the control group). The coprimary end points were the mean score for disability on the utility-weighted modified Rankin scale (which ranges from 0 [death] to 10 [no symptoms or disability]) and the rate of functional independence (a score of 0, 1, or 2 on the modified Rankin scale, which ranges from 0 to 6, with higher scores indicating more severe disability) at 90 days.

RESULTS

A total of 206 patients were enrolled; 107 were assigned to the thrombectomy group and 99 to the control group. At 31 months, enrollment in the trial was stopped because of the results of a prespecified interim analysis. The mean score on the utility-weighted modified Rankin scale at 90 days was 5.5 in the thrombectomy group as compared with 3.4 in the control group (adjusted difference [Bayesian analysis], 2.0 points; 95% credible interval, 1.1 to 3.0; posterior probability of superiority, >0.999), and the rate of functional independence at 90 days was 49% in the thrombectomy group as compared with 13% in the control group (adjusted difference, 33 percentage points; 95% credible interval, 24 to 44; posterior probability of superiority, >0.999). The rate of symptomatic intracranial hemorrhage did not differ significantly between the two groups (6% in the thrombectomy group and 3% in the control group, P=0.50), nor did 90-day mortality (19% and 18%, respectively; P=1.00).

CONCLUSIONS

Among patients with acute stroke who had last been known to be well 6 to 24 hours earlier and who had a mismatch between clinical deficit and infarct, outcomes for disability at 90 days were better with thrombectomy plus standard care than with standard care alone. (Funded by Stryker Neurovascular; DAWN ClinicalTrials.gov number, NCT02142283.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Jovin at the University of Pittsburgh Medical Center Stroke Institute, Department of Neurology, Presbyterian University Hospital, 200 Lothrop St., C-400, Pittsburgh, PA 15217, or at jovintg@upmc.edu.

*A complete list of sites and investigators in the DAWN trial is provided in the Supplementary Appendix, available at NEJM.org.

Drs. Nogueira and Jovin contributed equally to this article.

This article was published on November 11, 2017, at NEJM.org.

N Engl J Med 2018;378:11-21.
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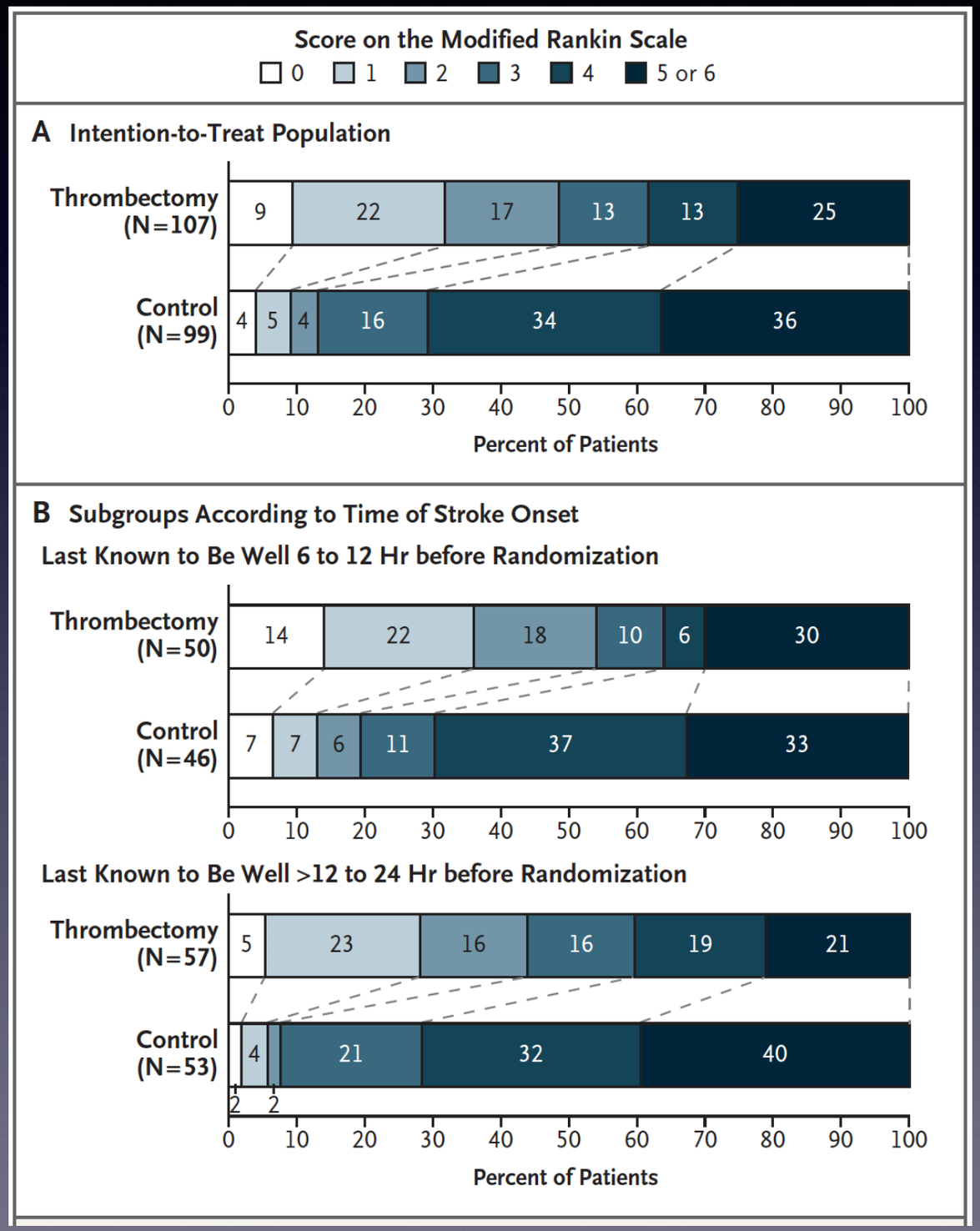
DAWN

Table 2. Efficacy Outcomes.*

Outcome	Thrombectomy Group (N = 107)	Control Group (N = 99)	Absolute Difference (95% CI)†	Adjusted Difference (95% Credible Interval)‡	Posterior Probability of Superiority
Primary end points					
Score on utility-weighted modified Rankin scale at 90 days§	5.5±3.8	3.4±3.1	2.1 (1.2–3.1)	2.0 (1.1–3.0)	>0.999
Functional independence at 90 days — no. (%)¶	52 (49)	13 (13)	36 (24–47)	33 (21–44)	>0.999
				Risk Ratio (95% CI)	**P Value**
Secondary end points					
Early response — no. (%)‖	51 (48)	19 (19)	29 (16–41)	3 (2–4)	<0.001**
Recanalization at 24 hr — no. (%)††	82 (77)	39 (39)	40 (27–52)	2 (2–4)	<0.001**
Change from baseline in infarct volume at 24 hr — ml††					0.003‡‡
Median	1	13			
Interquartile range	0–28	0–42			
Infarct volume at 24 hour — ml††					<0.001‡‡
Median	8	22			
Interquartile range	0–48	8–68			
Grade of 2b or 3 on mTICI scale — no. (%)§§	90 (84)	NA			

DAWN



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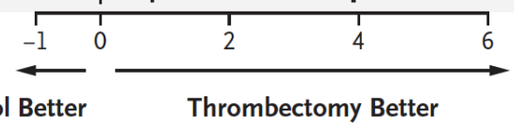
Subgroup	Adjusted Difference between Thrombectomy and Control (95% Credible Interval)	Posterior Probability: Benefit	Posterior Probability: Heterogeneity
Overall	2.0 (1.1 to 3.0)	>0.99	
Mismatch criteria			0.47
Group A	2.3 (0.3 to 4.2)	0.99	
Group B	1.8 (0.6 to 2.9)	>0.99	
Group C	2.5 (–0.6 to 5.5)	0.95	
Sex			0.14
Male	1.8 (0.2 to 3.2)	0.99	
Female	2.6 (1.3 to 4.0)	>0.99	
Age			0.42
<80 yr	1.9 (0.8 to 2.8)	>0.99	
≥80 yr	2.3 (0.3 to 4.2)	0.99	
Baseline NIHSS score			0.71
10 to 17	2.4 (1.0 to 3.7)	>0.99	
>17	1.8 (0.6 to 3.1)	>0.99	
Occlusion site			0.77
Intracranial internal carotid artery	3.0 (0.8 to 5.2)	>0.99	
First segment of the middle cerebral artery	2.0 (0.9 to 3.1)	>0.99	
Type of stroke onset			0.21
On awakening	2.3 (1.0 to 3.6)	>0.99	
Witnessed stroke	3.0 (0.5 to 5.9)	0.99	
Unwitnessed stroke	1.4 (–0.5 to 3.2)	0.93	
Interval between time that patient was last known to be well and randomization			0.22
6 to 12 hr	1.8 (0.4 to 3.4)	>0.99	
>12 to 24 hr	2.4 (1.1 to 3.6)	>0.99	
Time from first observation of symptoms to randomization			0.70
0 to 6 hr	2.0 (0.9 to 3.2)	>0.99	
>6 hr	2.4 (0.8 to 3.9)	>0.99	



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DAWN

Table 3. Safety Outcomes.*

Outcome	Thrombectomy Group (N=107)	Control Group (N=99)	Absolute Difference (95% CI)	Risk Ratio (95% CI)
	no. (%)		*percentage points*	
Stroke-related death at 90 days	17 (16)	18 (18)	–2 (–13 to 8)	1 (1 to 2)
Death from any cause at 90 days	20 (19)	18 (18)	1 (–10 to 11)	1 (1 to 2)
Symptomatic intracranial hemorrhage at 24 hr†	6 (6)	3 (3)	3 (–3 to 8)	2 (1 to 7)
Neurologic deterioration at 24 hr‡	15 (14)	26 (26)	–12 (–23 to –1)	1 (0 to 1)
Procedure-related complications	7 (7)	NA		
Distal embolization in a different territory	4 (4)	NA		
Intramural arterial dissection	2 (2)	NA		
Arterial perforation	0	NA		
Access-site complications leading to intervention	1 (1)	NA		

DEFUSE-3

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging

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*A complete list of the DEFUSE 3 investigators is provided in the Supplementary Appendix, available at NEJM.org.

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ABSTRACT

BACKGROUND

Thrombectomy is currently recommended for eligible patients with stroke who are treated within 6 hours after the onset of symptoms.

METHODS

We conducted a multicenter, randomized, open-label trial, with blinded outcome assessment, of thrombectomy in patients 6 to 16 hours after they were last known to be well and who had remaining ischemic brain tissue that was not yet infarcted. Patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion, an initial infarct size of less than 70 ml, and a ratio of the volume of ischemic tissue on perfusion imaging to infarct volume of 1.8 or more were randomly assigned to endovascular therapy (thrombectomy) plus standard medical therapy (endovascular-therapy group) or standard medical therapy alone (medical-therapy group). The primary outcome was the ordinal score on the modified Rankin scale (range, 0 to 6, with higher scores indicating greater disability) at day 90.

RESULTS

The trial was conducted at 38 U.S. centers and terminated early for efficacy after 182 patients had undergone randomization (92 to the endovascular-therapy group and 90 to the medical-therapy group). Endovascular therapy plus medical therapy, as compared with medical therapy alone, was associated with a favorable shift in the distribution of functional outcomes on the modified Rankin scale at 90 days (odds ratio, 2.77; P<0.001) and a higher percentage of patients who were functionally independent, defined as a score on the modified Rankin scale of 0 to 2 (45% vs. 17%, P<0.001). The 90-day mortality rate was 14% in the endovascular-therapy group and 26% in the medical-therapy group (P=0.05), and there was no significant between-group difference in the frequency of symptomatic intracranial hemorrhage (7% and 4%, respectively; P=0.75) or of serious adverse events (43% and 53%, respectively; P=0.18).

CONCLUSIONS

Endovascular thrombectomy for ischemic stroke 6 to 16 hours after a patient was last known to be well plus standard medical therapy resulted in better functional outcomes than standard medical therapy alone among patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion and a region of tissue that was ischemic but not yet infarcted. (Funded by the National Institute of Neurological Disorders and Stroke; DEFUSE 3 ClinicalTrials.gov number, NCT02586415.)

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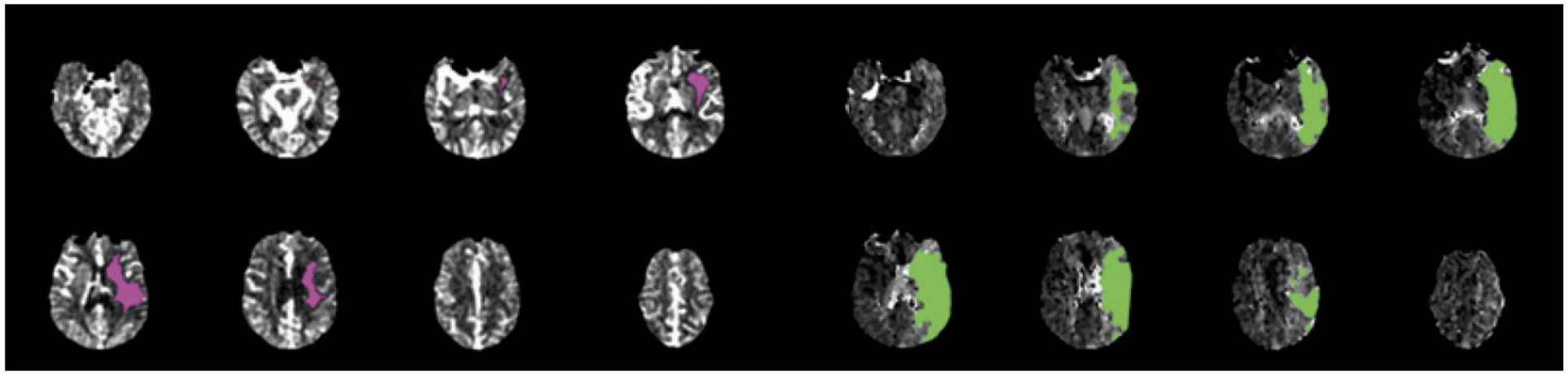
DEFUSE-3



Volume of Ischemic Core, 23 ml

Volume of Perfusion Lesion, 128 ml

Mismatch volume, 105 ml
Mismatch ratio, 5.6

Figure 1. Example of Perfusion Imaging Showing a Disproportionately Large Region of Hypoperfusion as Compared with the Size of Early Infarction.

A 59-year-old man presented with a "wake-up stroke" (having awakened with symptoms of stroke) 13 hours after he was last known to be well. The score on the National Institutes of Health Stroke Scale (NIHSS; range, 0 to 42, with higher scores indicating a greater deficit) was 23. A baseline CT perfusion scan that was obtained with the use of RAPID software shows a region of severely reduced cerebral blood flow (<30% of that in normal tissue), which represents the early infarct (ischemic core), of 23 ml (pink) and a region of perfusion delay of more than 6 seconds, which represents hypoperfused tissue, of 128 ml (green).

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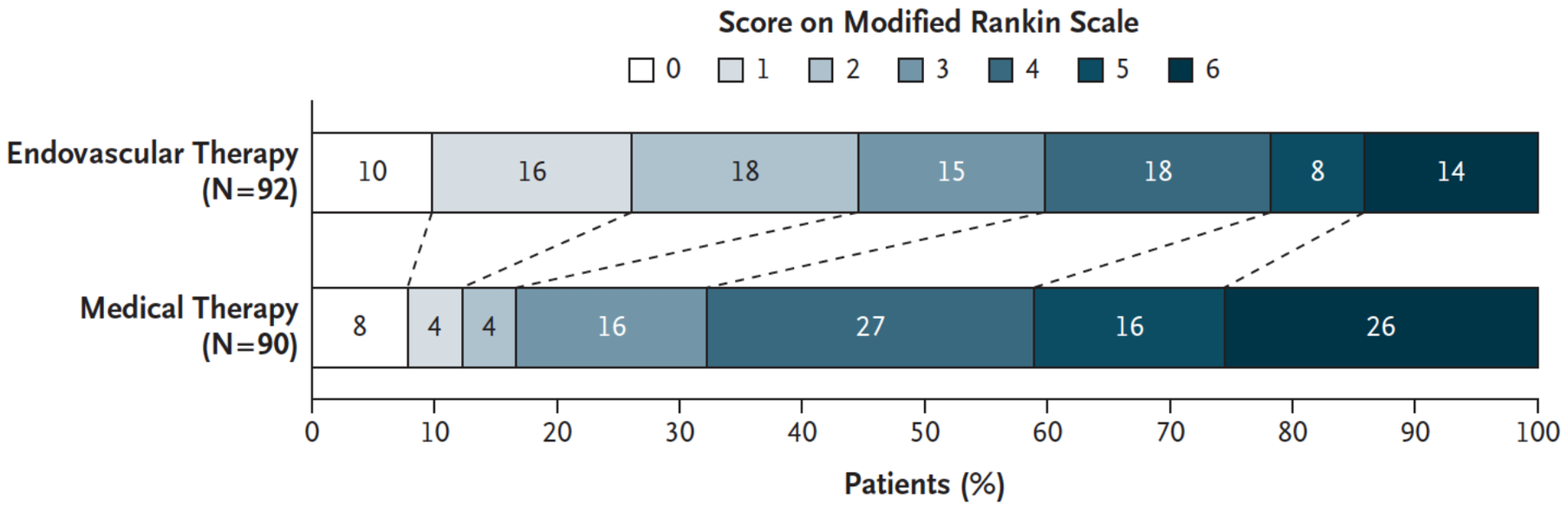

Figure 2. Scores on the Modified Rankin Scale at 90 Days.

Patients in the endovascular-therapy group received endovascular therapy plus standard medical therapy. Patients in the medical-therapy group received standard medical therapy alone. Scores on the modified Rankin scale range from 0 to 6, with 0 indicating no symptoms, 1 no clinically significant disability, 2 slight disability, 3 moderate disability, 4 moderately severe disability, 5 severe disability, and 6 death. There was a significant difference favoring the endovascular-therapy group over the medical-therapy group in the overall distribution of scores (unadjusted common odds ratio, 2.77; 95% CI, 1.63 to 4.70; P<0.001).

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Table 2. Clinical and Imaging Outcomes.

Outcome	Endovascular Therapy (N=92)*	Medical Therapy (N=90)	Odds Ratio or Risk Ratio (95% CI)†	P Value
Primary efficacy outcome: median score on modified Rankin scale at 90 days (IQR)‡	3 (1–4)	4 (3–6)	2.77 (1.63–4.70)§	<0.001
Secondary efficacy outcome: functional independence at 90 days — no. (%)¶	41 (45)	15 (17)	2.67 (1.60–4.48)	<0.001
Safety outcomes — no. (%)				
Death at 90 days	13 (14)	23 (26)	0.55 (0.30–1.02)	0.05
Symptomatic intracranial hemorrhage‖	6 (7)	4 (4)	1.47 (0.40–6.55)	0.75
Early neurologic deterioration	8 (9)	11 (12)	0.71 (0.30–1.69)	0.44
Parenchymal hematoma type 2	8 (9)	3 (3)	2.61 (0.73–14.69)	0.21
Imaging outcomes**				
Median infarct volume at 24 hr (IQR) — ml	35 (18–82)	41 (25–106)	—	0.19
Median infarct growth at 24 hr (IQR) — ml	23 (10–75)	33 (18–75)	—	0.08
Reperfusion >90% at 24 hr — no./total no. (%)	59/75 (79)	12/67 (18)	4.39 (2.60–7.43)	<0.001
Complete recanalization at 24 hr — no./total no. (%)	65/83 (78)	14/77 (18)	4.31 (2.65–7.01)	<0.001
TICI score of 2b or 3 — no./total no. (%)	69/91 (76)	—	—	

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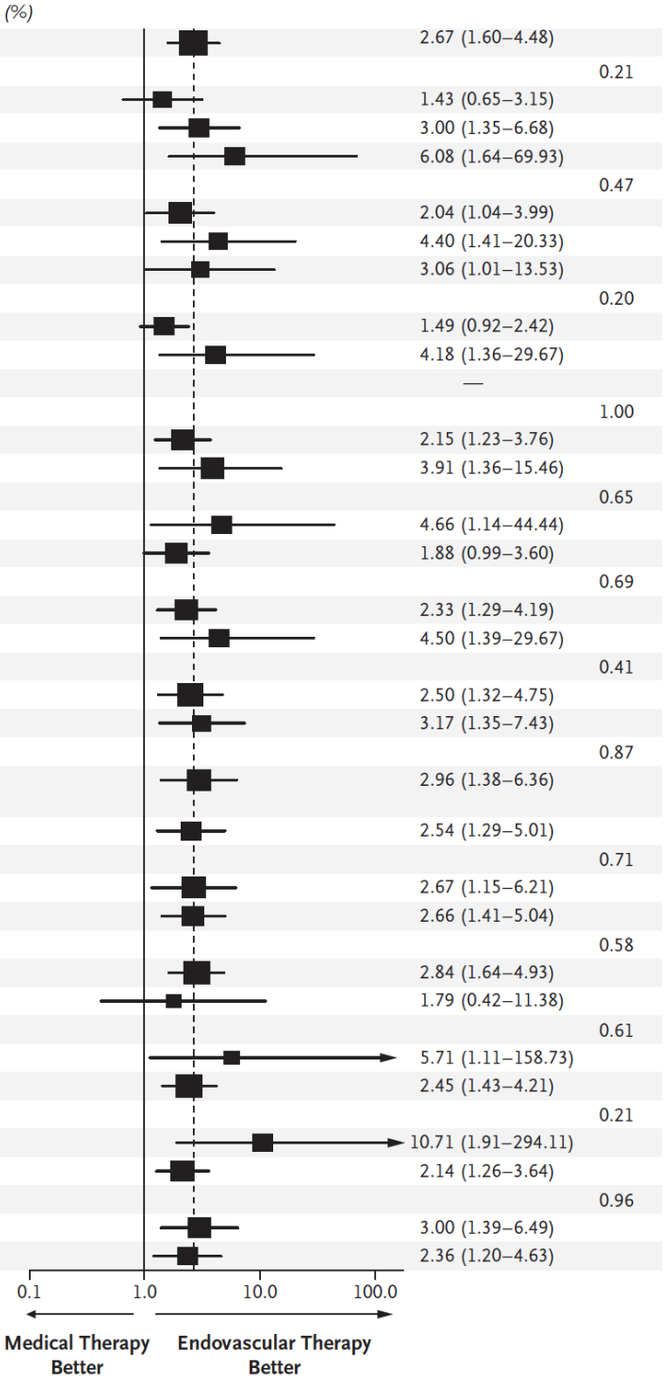
Subgroup	No. of Patients	Endovascular Therapy	Medical Therapy	Risk Ratio for Functional Independence at Day 90 (95% CI)	P Value for Interaction
		functional independence (%)			
Overall	182	45	17	2.67 (1.60–4.48)	
Time from stroke onset to randomization					0.21
<9 hr	50	40	28	1.43 (0.65–3.15)	
9–12 hr	72	50	17	3.00 (1.35–6.68)	
>12 hr	60	42	7	6.08 (1.64–69.93)	
Volume of ischemic core					0.47
<10.0 ml	92	42	20	2.04 (1.04–3.99)	
10.0–25.0 ml	44	55	13	4.40 (1.41–20.33)	
>25.0 ml	46	42	14	3.06 (1.01–13.53)	
Baseline NIHSS score					0.20
<13	55	69	46	1.49 (0.92–2.42)	
13–18	55	48	12	4.18 (1.36–29.67)	
>18	72	21	0	—	
Age					1.00
<70 yr	84	59	28	2.15 (1.23–3.76)	
≥70 yr	98	31	8	3.91 (1.36–15.46)	
ASPECTS					0.65
<8	57	32	7	4.66 (1.14–44.44)	
≥8	85	46	24	1.88 (0.99–3.60)	
Site of occlusion					0.69
Middle cerebral artery	113	48	21	2.33 (1.29–4.19)	
Internal carotid artery	68	38	8	4.50 (1.39–29.67)	
Baseline imaging method					0.41
CT	133	39	16	2.50 (1.32–4.75)	
MRI	49	61	19	3.17 (1.35–7.43)	
Determination of time of stroke					0.87
Time that patient was last known to be well	116	38	13	2.96 (1.38–6.36)	
Exact time of symptom onset	66	58	23	2.54 (1.29–5.01)	
Sex					0.71
Female	92	35	13	2.67 (1.15–6.21)	
Male	90	54	20	2.66 (1.41–5.04)	
Race					0.58
White	158	46	16	2.84 (1.64–4.93)	
Other or unknown	24	36	20	1.79 (0.42–11.38)	
Ethnic group					0.61
Hispanic	24	57	10	5.71 (1.11–158.73)	
Non-Hispanic	157	43	18	2.45 (1.43–4.21)	
Atrial fibrillation					0.21
Yes	62	38	4	10.71 (1.91–294.11)	
No	120	48	23	2.14 (1.26–3.64)	
Eligible for DAWN trial					0.96
Yes	112	38	13	3.00 (1.39–6.49)	
No	70	56	24	2.36 (1.20–4.63)	



Imaging of diagnoses

- Inseparable
  - Imaging selection and intervention
  - Clinical findings and imaging features
- Complexity of imaging in trials and integration in practice of acute stroke, defined as 24 hours after symptom onset
- Success of endovascular trial using a specific imaging diagnostic does not equate with RCT of the imaging (e.g. DWI, PWI, mCTA, CTP, non contrast CT)
- Evidence for diagnostic test performance *not* equivalent to methodology for therapeutic strategies

Key Elements

- Prehospital
- EMS
- Hospital capabilities and designations
- Telemedicine
- Data & quality improvement
- Imaging
- Other diagnostic tests
- Supportive care and stroke units
- IV tPA
- EVT - endovascular therapy (mechanical thrombectomy)
- Antiplatelets and anticoagulants
- Rehabilitation
- Complications
- Secondary prevention

CLASS (STRENGTH) OF RECOMMENDATION	LEVEL (QUALITY) OF EVIDENCE‡
CLASS I (STRONG) — Benefit >>> Risk Suggested phrases for writing recommendations: ■ Is recommended ■ Is indicated/useful/effective/beneficial ■ Should be performed/administered/other ■ Comparative-Effectiveness Phrases†: ○ Treatment/strategy A is recommended/indicated in preference to treatment B ○ Treatment A should be chosen over treatment B	**LEVEL A** ■ High-quality evidence‡ from more than 1 RCT ■ Meta-analyses of high-quality RCTs ■ One or more RCTs corroborated by high-quality registry studies
CLASS IIa (MODERATE) — Benefit >> Risk Suggested phrases for writing recommendations: ■ Is reasonable ■ Can be useful/effective/beneficial ■ Comparative-Effectiveness Phrases†: ○ Treatment/strategy A is probably recommended/indicated in preference to treatment B ○ It is reasonable to choose treatment A over treatment B	**LEVEL B-R** (Randomized) ■ Moderate-quality evidence‡ from 1 or more RCTs ■ Meta-analyses of moderate-quality RCTs
CLASS IIb (WEAK) — Benefit ≥ Risk Suggested phrases for writing recommendations: ■ May/might be reasonable ■ May/might be considered ■ Usefulness/effectiveness is unknown/unclear/uncertain or not well established	**LEVEL B-NR** (Nonrandomized) ■ Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies ■ Meta-analyses of such studies
CLASS III: No Benefit (MODERATE) — Benefit = Risk *(Generally, LOE A or B use only)* Suggested phrases for writing recommendations: ■ Is not recommended ■ Is not indicated/useful/effective/beneficial ■ Should not be performed/administered/other	**LEVEL C-LD** (Limited Data) ■ Randomized or nonrandomized observational or registry studies with limitations of design or execution ■ Meta-analyses of such studies ■ Physiological or mechanistic studies in human subjects
CLASS III: Harm (STRONG) — Risk > Benefit Suggested phrases for writing recommendations: ■ Potentially harmful ■ Causes harm ■ Associated with excess morbidity/mortality ■ Should not be performed/administered/other	**LEVEL C-EO** (Expert Opinion) Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

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AHA/ASA “guidelines”

CORRECTION

Correction to: 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

Based on recent feedback received from the clinical stroke community related to the article by Powers et al, “2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association,” which published ahead of print January 24, 2018, and appeared in the March 2018 issue of the journal (*Stroke*. 2018;49:e46–e110. DOI: 10.1161/STR.0000000000000158), the American Heart Association/American Stroke Association has reviewed the guideline and is preparing clarifications, modifications, and/or updates to several sections in it. Currently, those sections, listed here, have been deleted from the guideline while this clarifying work is in process:

Section 1.3 EMS Systems Recommendation 4
Section 1.4 Hospital Stroke Capabilities Recommendation 1
Section 1.6 Telemedicine Recommendation 3
Section 2.2 Brain Imaging Recommendation 11
Section 3.2 Blood Pressure Recommendation 3
Section 4.3 Blood Pressure Recommendation 2
Section 4.6 Dysphagia Recommendation 1
Section 6.0 All subsections (11)

We continue to support this corrected version of the guideline and its support for clinical decision-making. After review, a revised guideline, with consideration given to the clarifications, modifications, and/or updates of the sections noted above, will be posted over the coming weeks.

Ensuring our scientific guidelines reflect the best, most comprehensive scientific analysis has always been, and remains, the Association’s top priority. We appreciate the continuing commitment and dedication of our volunteer writing group, peer reviewers, and the scientific community at large, who share our devotion to the integrity and quality of guideline development.

The revised, online version of the guideline is available at http://stroke.ahajournals.org/content/49/3/e46.

1. On page e49, in Table 2, the following changes have been made:
   - The fourth row beginning “2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol…” has been deleted.
   - The eighth row beginning “Guidelines for the Prevention of Stroke in Patients with Stroke…” has been deleted.
2. On page e50, in Table 3, the entry for “TJC,” defined as “The Joint Commission,” has been deleted.
3. On page e52, in section “1.3. EMS Systems,” recommendation 4, the associated knowledge byte, and the associated references have been deleted.
4. On page e52, section “1.4. Hospital Stroke Capabilities,” recommendation 1, the associated knowledge byte, and the associated references have been deleted.
5. On page e54, in section “1.6 Telemedicine,” recommendation 3 has been deleted.
6. On page e59, in section “2.2 Brain Imaging,” recommendation 11, the associated knowledge byte, and the associated references have been deleted.
7. On page e61 (previously page e62), in section “3.2 Blood Pressure,” recommendation 3, the associated knowledge byte, and the associated references have been deleted.
8. On page e78 (previously page e79), in section “4.3 Blood Pressure,” recommendation 2, the associated knowledge byte, and the associated references have been deleted.
9. On page e80 (previously page e81), in section “4.6 Dysphagia Screening,” recommendation 1, the associated knowledge byte, and the associated references have been deleted.
10. On pages e87 through e93 in the previous version, section “6. In-Hospital Institution of Secondary Prevention: Evaluation” (recommendations, associated knowledge bytes, and references) has been deleted.
11. On page e87 (previously page e93), the following sentence was updated to include references 202, 216, 217, 220, 221, 224, 226, 227, 229, 322, 323, 325, and 326: “Additional reference support for this guideline is provided in online Data Supplement 1.[200,202,216,217,220,221,224,226,227,229,322,323,325,326,336-402,404-421],,
12. On pages e88 through e99 (previously pages e96 through e110), the following references have been deleted: 7, 11, 24-31, 33, 34, 230-234, 258-321, 324, and 327-335.
13. In Data Supplement 1, the following changes have been made:
    - Table V, Table VI, Table LI, Table LII, Tables LXI-LXXVI, and Tables LXXVIII-LXXXII have been deleted.
    - In Table LXXXIII, the original wording of text for the following has been deleted:
      - 1.4 Rec 1
      - 6.4. Rec 1
      - 6.6. Recs 1, 2, 3, 4, and 5
      - 6.7. Recs 1, 4, and 5
      - 6.10. Recs 1 and 6
    - References 7, 11, 24-31, 33, 34, 230-234, 258-321, 324, and 327-335 have been deleted.
14. In Data Supplement 2, the following changes have been made:
    - All references to Data Supplement 1 Table V, Table LI, Tables LXI-LXXVI, and Tables LXXVIII-LXXXII have been deleted.
    - Because of these deletions, the following literature search sections have been removed:
      - ASA Failure
      - Statins
      - Smoking
      - Carotid Endarterectomy and Carotid Artery Stenting Timing
      - Complications After Acute Carotid Endarterectomy or Stenting
      - Guidelines for Treatment of Blood Cholesterol for Secondary Stroke Prevention
      - Cost-Effectiveness of Echocardiography in Acute Stroke
      - Prolonged Cardiac Monitoring for Secondary Stroke Prevention
      - Symptomatic Carotid Stenosis and Early Recurrent Stroke
      - Risk of Early Carotid Intervention
      - Routine Screening of Patients With Recent Ischemic Stroke for Obstructive Sleep Apnea
      - MRA Intracranial, Non-Invasive Imaging Intracranial
      - CTA Intracranial, Non-Invasive Imaging
      - Association of AMIMCC With Stroke Etiologic Classification
      - Infarct Topography and Detection of AF By Long Term Monitoring
      - Evolocumab and Secondary Stroke Prevention
      - Dysphagia Screening

The pagination of this article has changed from e46–e110 to e46–e99. This has been updated in the citations on pages e46 and e47 and in the issue’s online table of contents.

***Stroke* is available at http://stroke.ahajournals.org**

DOI: 10.1161/STR.0000000000000172

Stroke
Journal of the American Heart Association

American Heart Association | American Stroke Association

Correction to: 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

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Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/early/2018/04/17/STR.0000000000000172.citation

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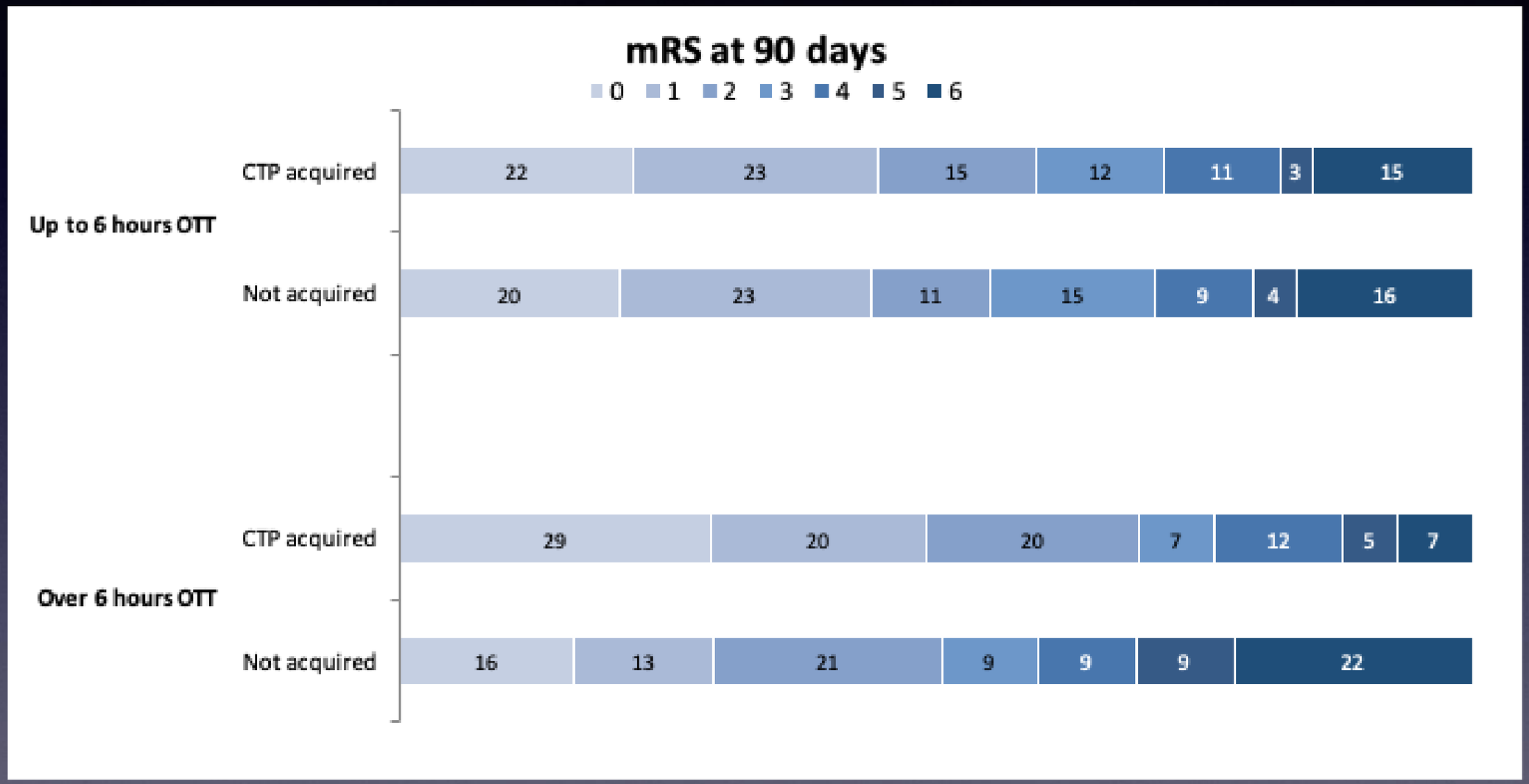
6 hours? RWE - STRATIS, TRV & DAISI…



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Optimize Interventions for Treatment & Prevention


Symptoms


911


EMS

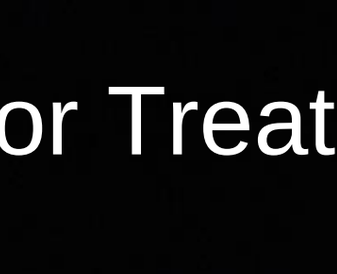

Neuroprotectants

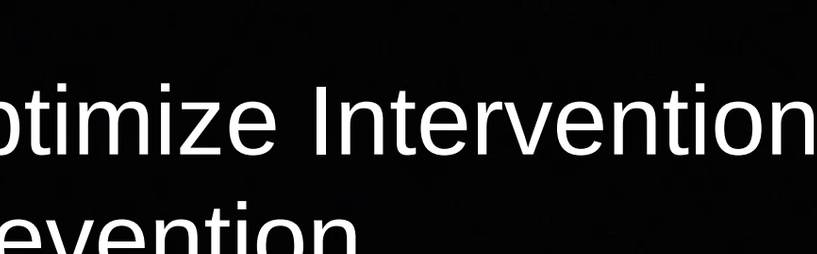

Primary Stroke Center


Imaging

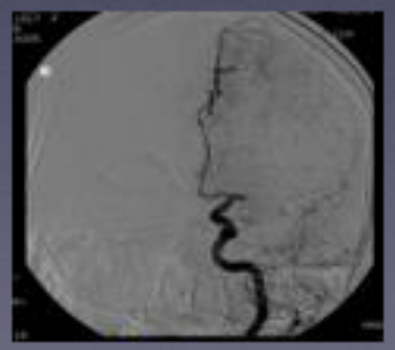

IV Lytic


EMS


Comp Stroke Center


Imaging


Cath Lab


Angiogram


IA Mechanical or Lytic


Neuroprotectants


Stroke Unit

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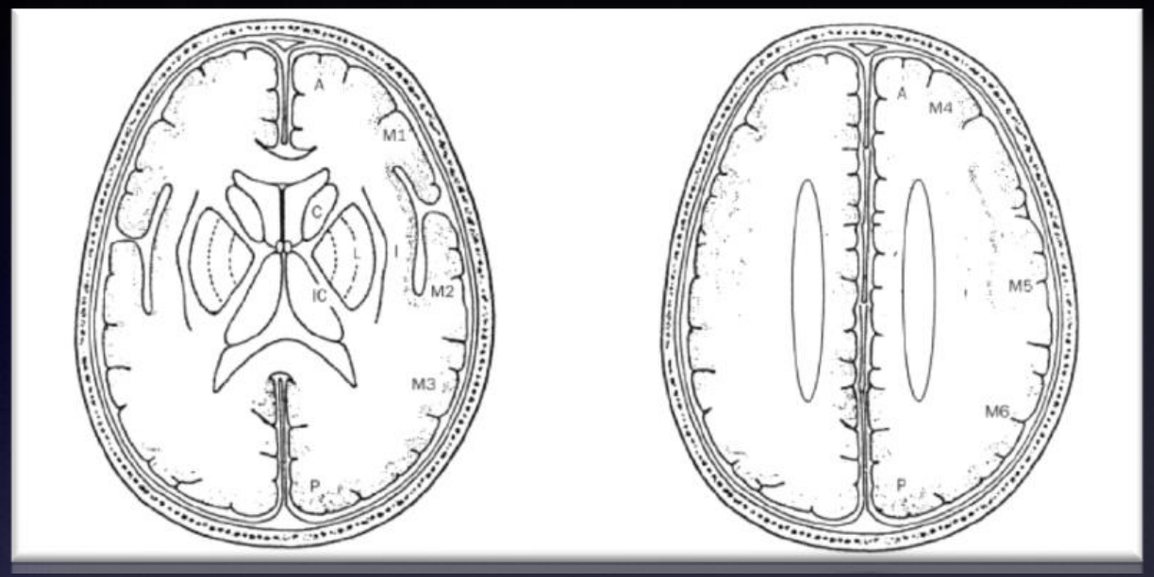
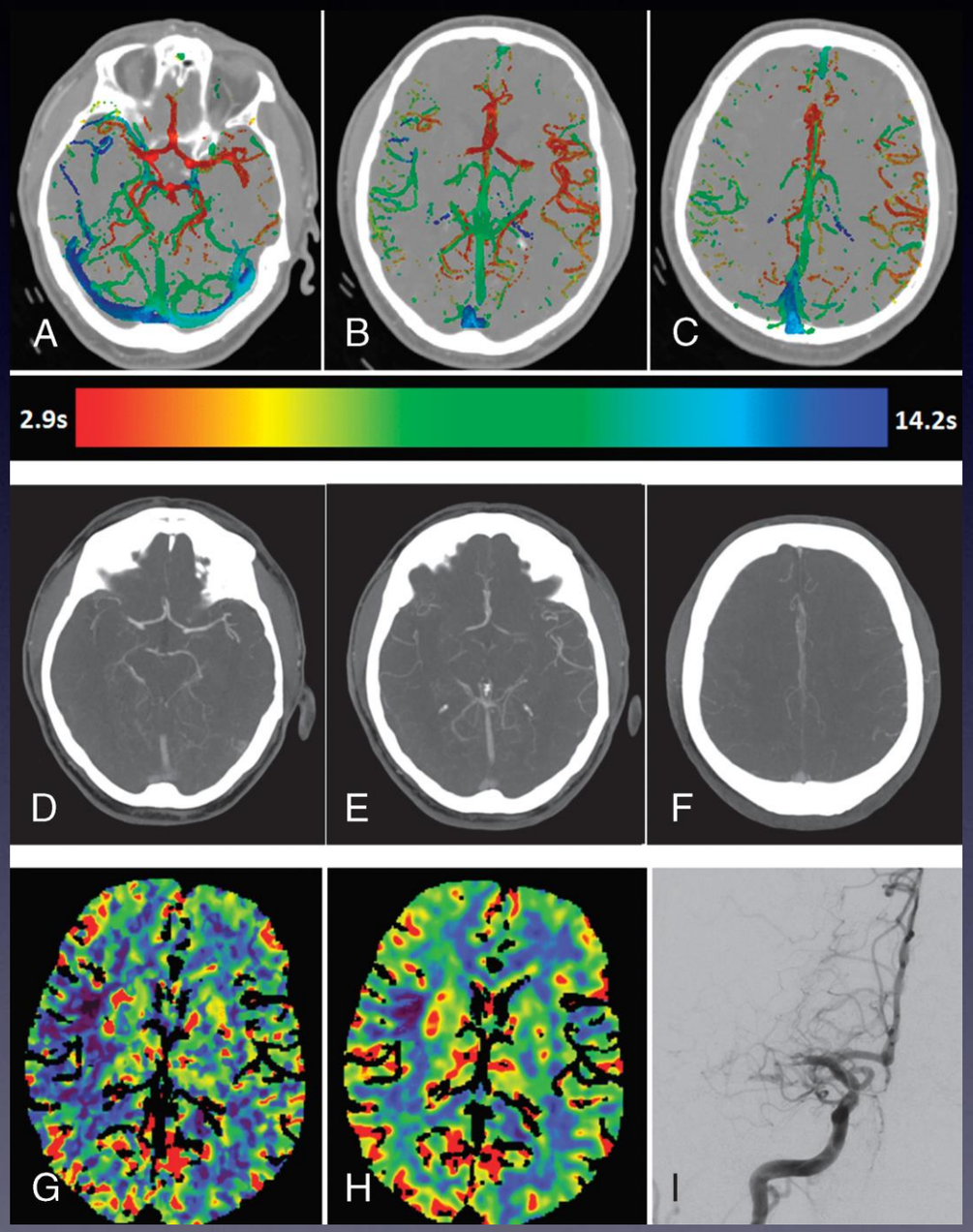
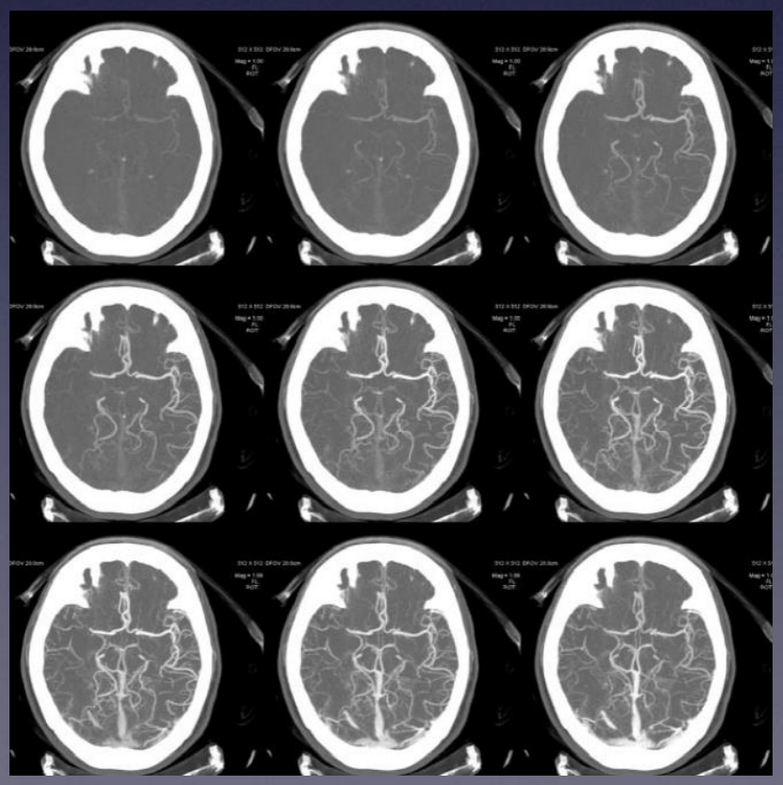
Multimodal CT







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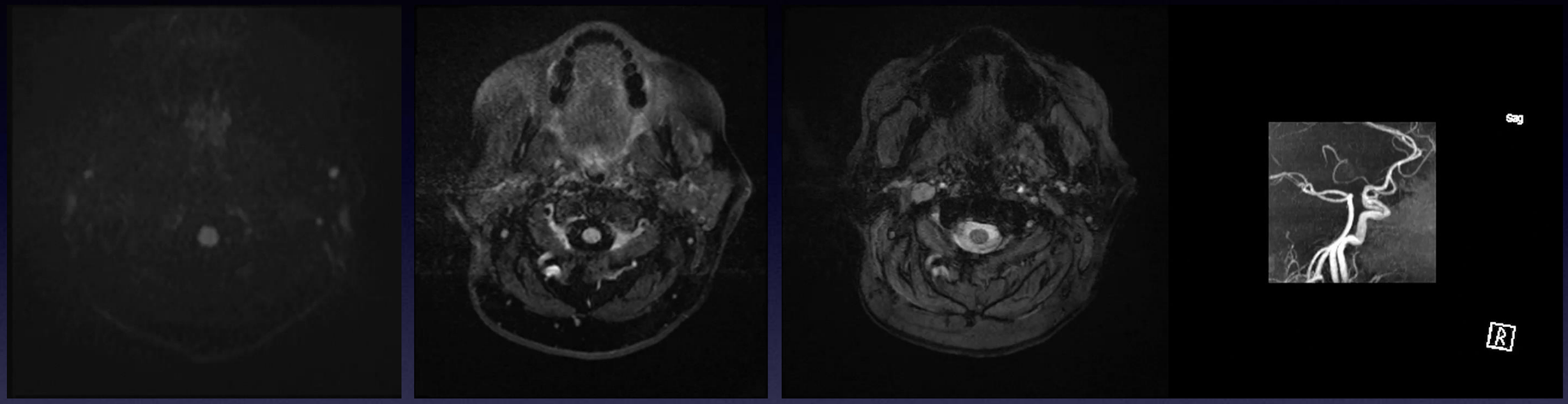
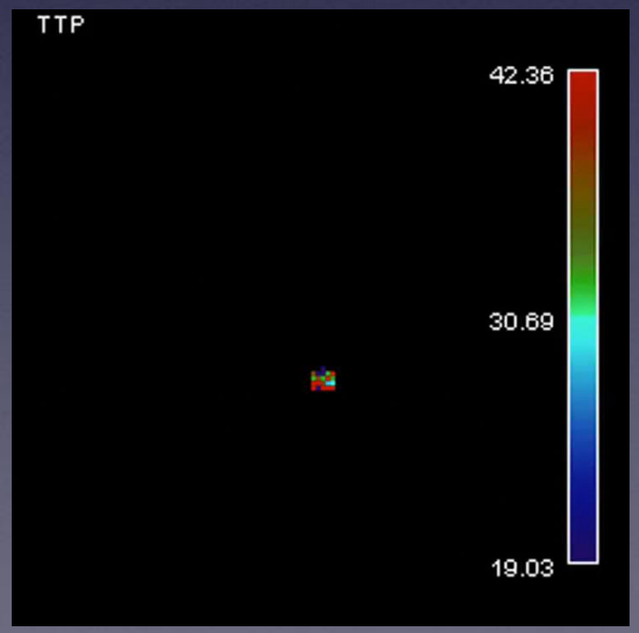
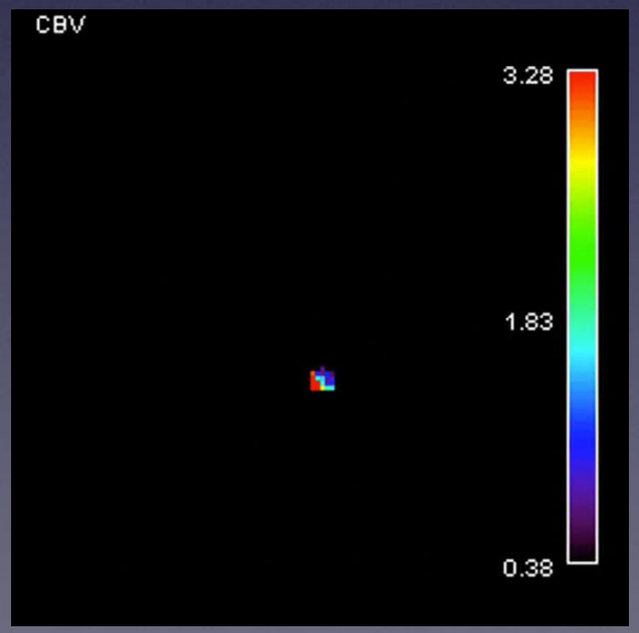
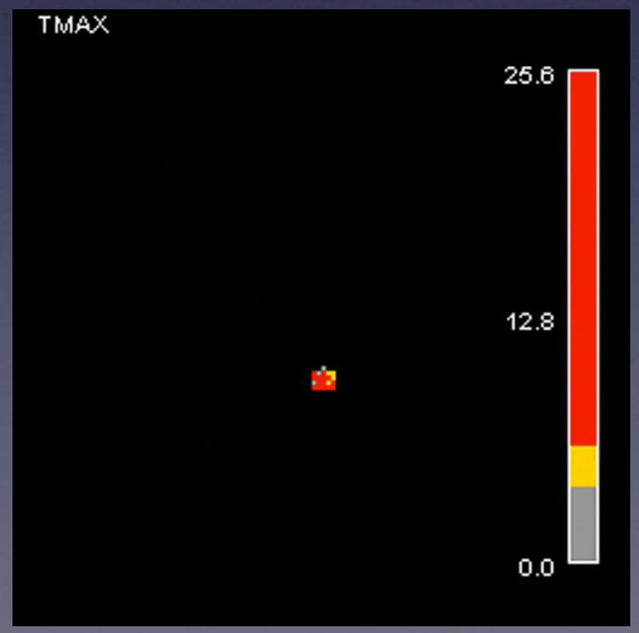
Multimodal MRI









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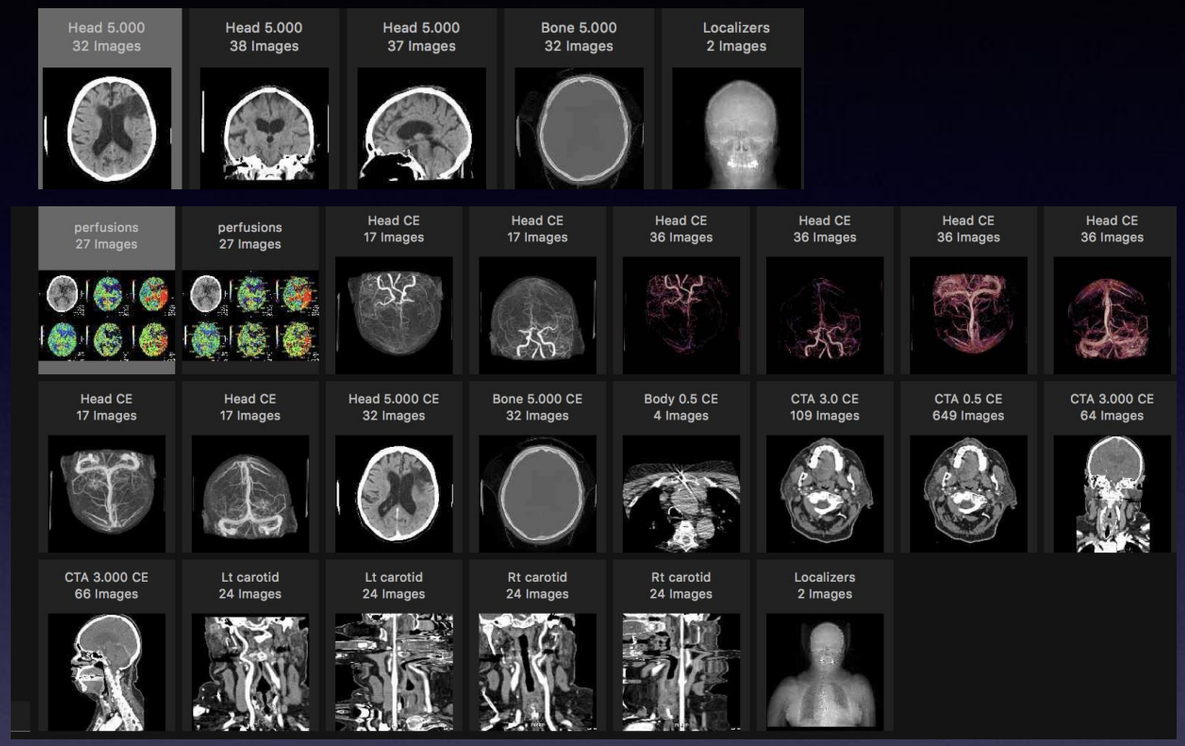
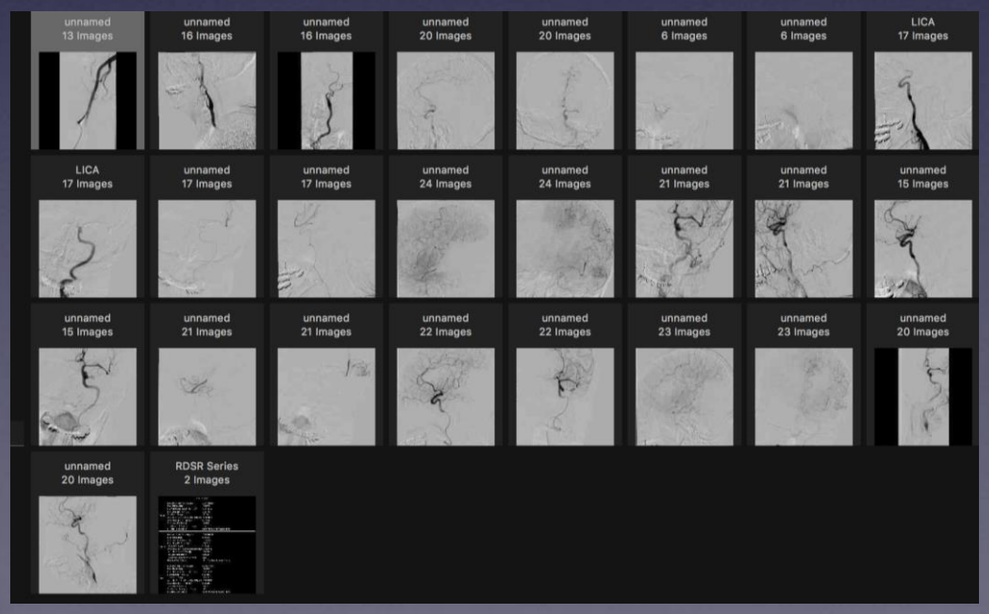
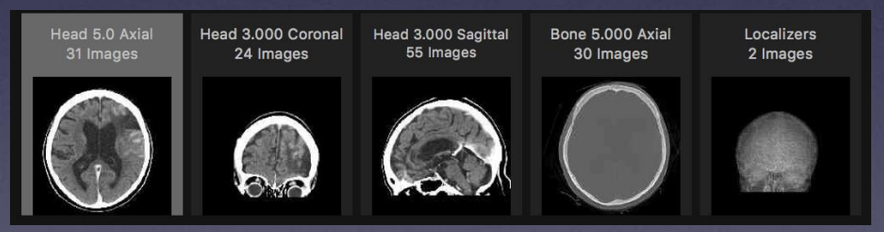
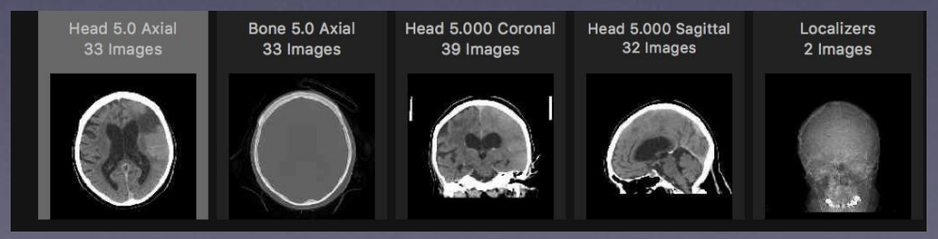
Typical sequence of imaging

- CT (CT/CTA/CTP)
- DSA
- 24 hr CT
- AE









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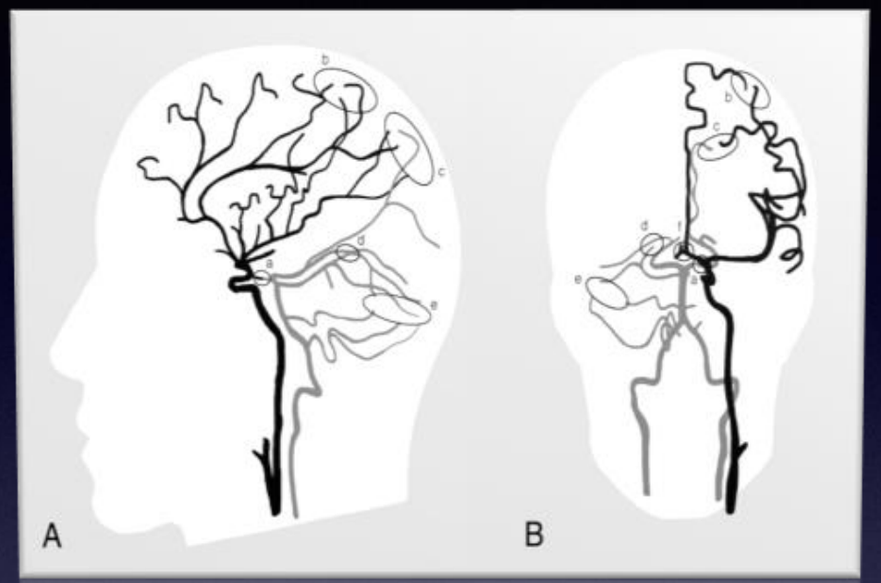
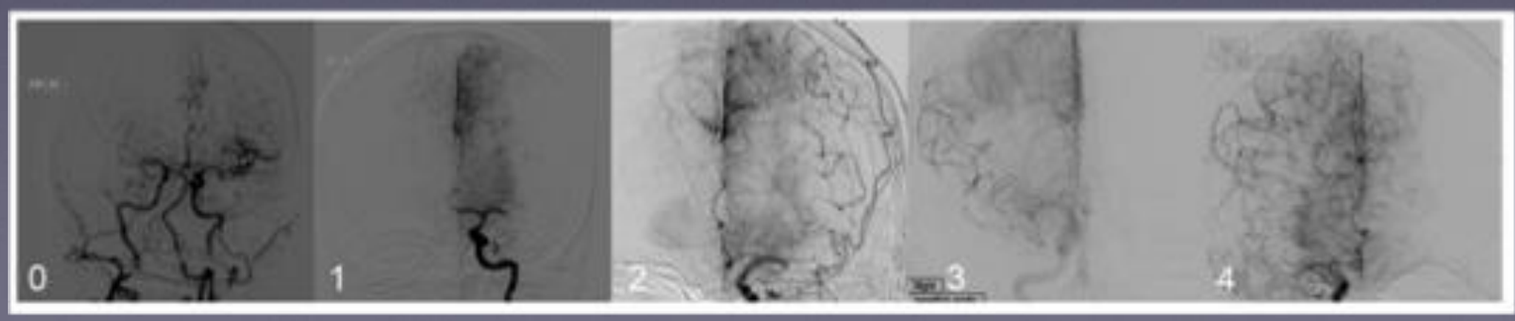
Collaterals



- Collateral evidence for benefit and reduced risk:
  - recanalization
  - reperfusion
  - hemorrhagic transformation
  - subsequent neurological outcomes after stroke

Collateral Flow Grade Definitions

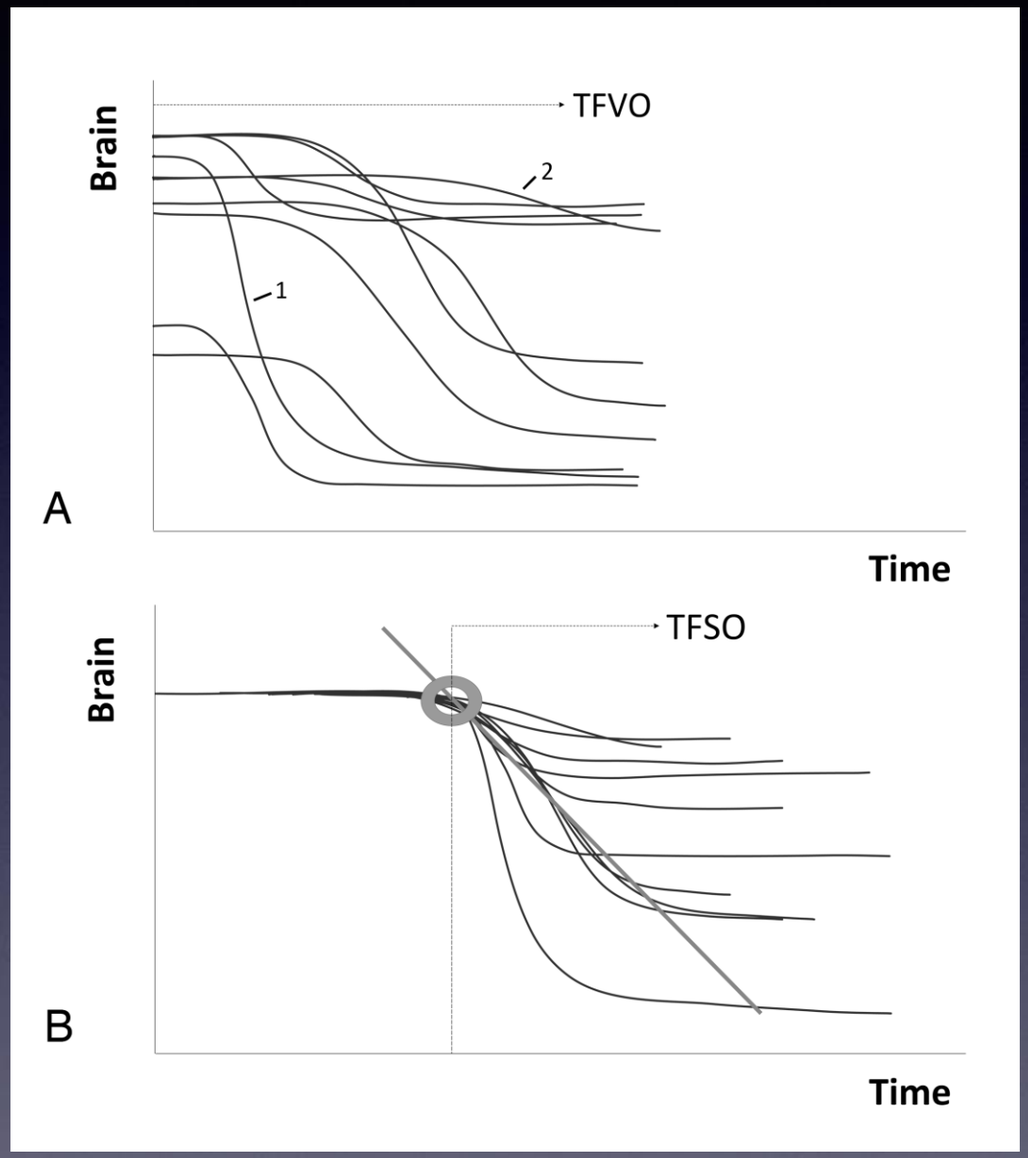
Grade 0: No collaterals visible to the ischemic site
Grade 1: Slow collaterals to the periphery of the ischemic site with persistence of some of the defect
Grade 2: Rapid collaterals to the periphery of ischemic site with persistence of some of the defect and to only a portion of the ischemic territory
Grade 3: Collaterals with slow but complete angiographic blood flow of the ischemic bed by the late venous phase
Grade 4: Complete and rapid collateral blood flow to the vascular bed in the entire ischemic territory by retrograde perfusion
N/A: not applicable based on territory or injections available



Neurovascular Imaging Research Core at **UCLA**

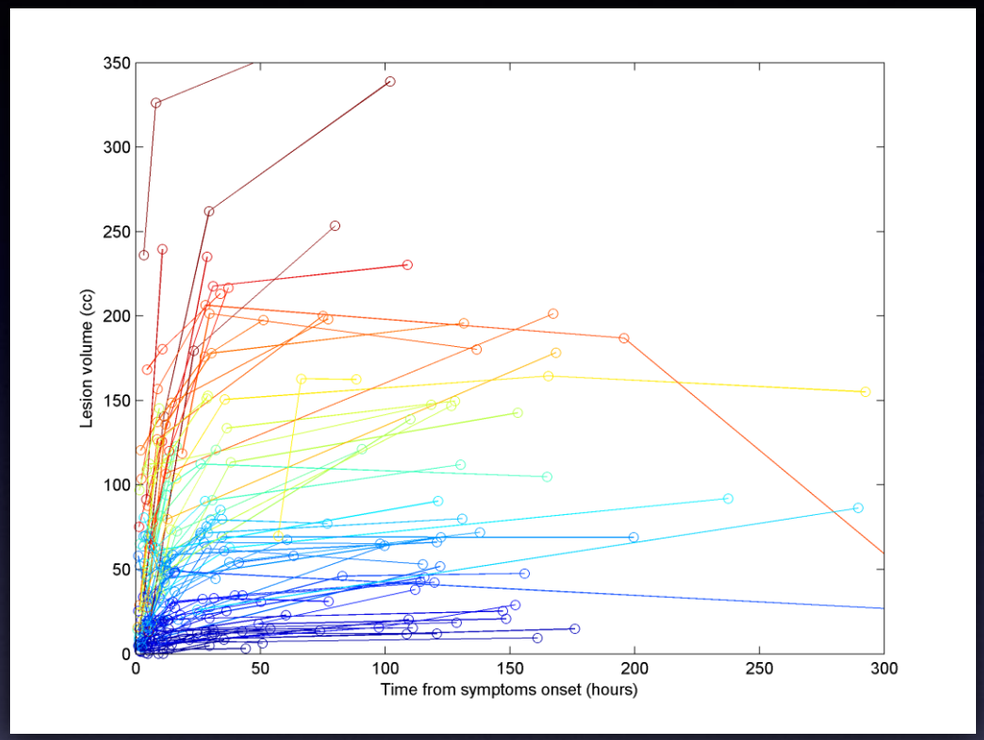
Flow Determines Time and Outcomes

- If collaterals compensate for arterial occlusion or stenosis, symptoms are negligible or absent
- Pace of collateral recruitment influences timeline of symptom progression
- Poor collaterals predispose to impaired reperfusion
  - no reflow
  - reperfusion injury or hemorrhagic transformation



Role of Collaterals

- Why collaterals?
  - Age
  - Severity - NIHSS, ASPECTS
  - Time
  - Sex
  - Co-morbidities
- How are we using collateral status?
  - Imaging definitions
  - Avoid absolute reductionism in traditional RCT mindset of thresholds (e.g. age, low ASPECTS, large perfusion core, TFSO) or cutoffs for variables
  - Adaptive nature of platform trials, in real-world evidence of phase 4, after graduation from phase 3
- Collaterals as basis of precision medicine in acute stroke treatment

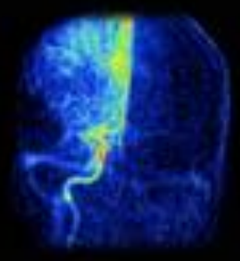


Neurovascular Imaging Research Core at UCLA

5th International Symposium on Collaterals to the Brain

Collaterals 2018

co-chairs David S Liebeskind, MD & Ashfaq Shuaib, MD



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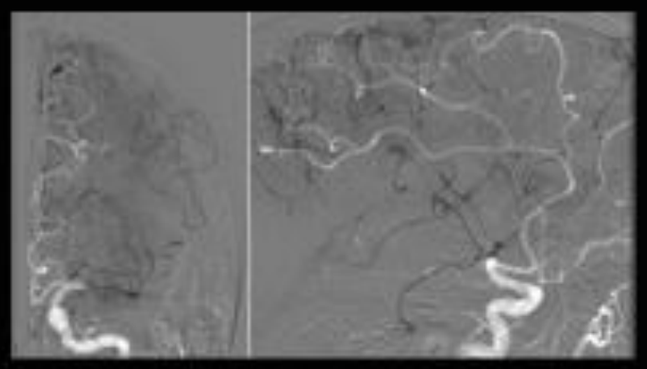
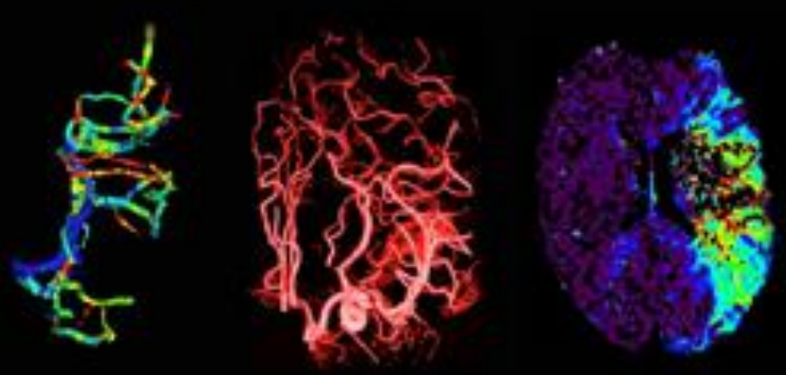
- acute ischemic stroke, intracranial atherosclerosis, hemodynamics & endovascular therapies





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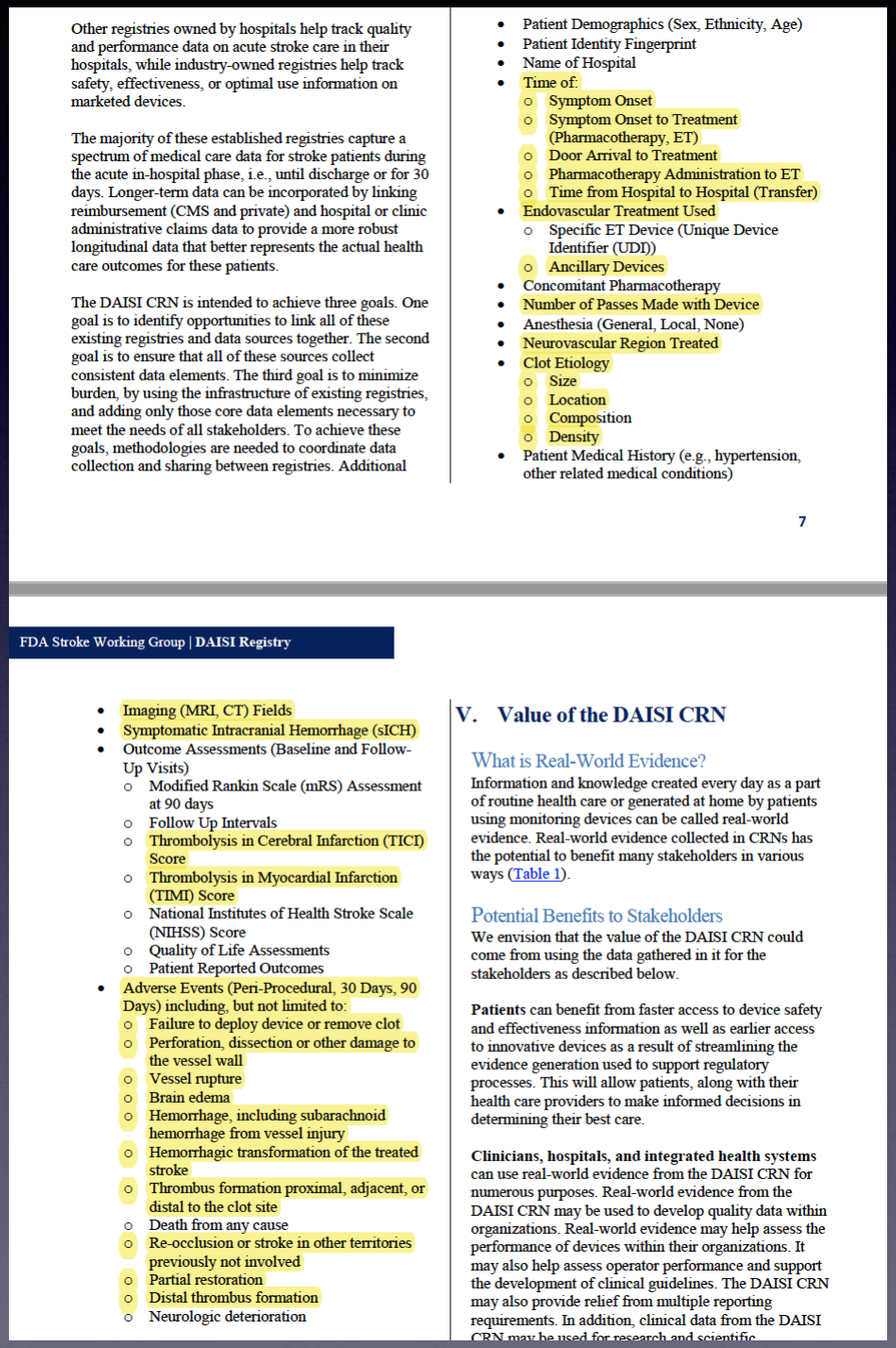
Registries and the DAISI CRN

- Need generalizability on a very large scale
- Imaging triage and management - OH or MSU and beyond
- What is most valuable data variable in a clinical study? Added value?
- Imaging and angiography at top of hierarchy of list – before novel markers, prehospital, discharge or rehab variables or economic costs
- Imaging before genomic infatuation
- Quality of data is essential
- Digitally preserved, can be verified, automated, must have expertise



Other registries owned by hospitals help track quality and performance data on acute stroke care in their hospitals, while industry-owned registries help track safety, effectiveness, or optimal use information on marketed devices.

The majority of these established registries capture a spectrum of medical care data for stroke patients during the acute in-hospital phase, i.e., until discharge or for 30 days. Longer-term data can be incorporated by linking reimbursement (CMS and private) and hospital or clinic administrative claims data to provide a more robust longitudinal data that better represents the actual health care outcomes for these patients.

The DAISI CRN is intended to achieve three goals. One goal is to identify opportunities to link all of these existing registries and data sources together. The second goal is to ensure that all of these sources collect consistent data elements. The third goal is to minimize burden, by using the infrastructure of existing registries, and adding only those core data elements necessary to meet the needs of all stakeholders. To achieve these goals, methodologies are needed to coordinate data collection and sharing between registries. Additional

- Patient Demographics (Sex, Ethnicity, Age)
- Patient Identity Fingerprint
- Name of Hospital
- Time of:
  - Symptom Onset
  - Symptom Onset to Treatment (Pharmacotherapy, ET)
  - Door Arrival to Treatment
  - Pharmacotherapy Administration to ET
  - Time from Hospital to Hospital (Transfer)
- Endovascular Treatment Used
  - Specific ET Device (Unique Device Identifier (UDI))
  - Ancillary Devices
- Concomitant Pharmacotherapy
- Number of Passes Made with Device
- Anesthesia (General, Local, None)
- Neurovascular Region Treated
- Clot Etiology
  - Size
  - Location
  - Composition
  - Density
- Patient Medical History (e.g., hypertension, other related medical conditions)

7

FDA Stroke Working Group | **DAISI Registry**

- Imaging (MRI, CT) Fields
- Symptomatic Intracranial Hemorrhage (sICH)
- Outcome Assessments (Baseline and Follow-Up Visits)
  - Modified Rankin Scale (mRS) Assessment at 90 days
  - Follow Up Intervals
  - Thrombolysis in Cerebral Infarction (TICI) Score
  - Thrombolysis in Myocardial Infarction (TIMI) Score
  - National Institutes of Health Stroke Scale (NIHSS) Score
  - Quality of Life Assessments
  - Patient Reported Outcomes
- Adverse Events (Peri-Procedural, 30 Days, 90 Days) including, but not limited to:
  - Failure to deploy device or remove clot
  - Perforation, dissection or other damage to the vessel wall
  - Vessel rupture
  - Brain edema
  - Hemorrhage, including subarachnoid hemorrhage from vessel injury
  - Hemorrhagic transformation of the treated stroke
  - Thrombus formation proximal, adjacent, or distal to the clot site
  - Death from any cause
  - Re-occlusion or stroke in other territories previously not involved
  - Partial restoration
  - Distal thrombus formation
  - Neurologic deterioration

V. Value of the DAISI CRN

What is Real-World Evidence?

Information and knowledge created every day as a part of routine health care or generated at home by patients using monitoring devices can be called real-world evidence. Real-world evidence collected in CRNs has the potential to benefit many stakeholders in various ways (Table 1).

Potential Benefits to Stakeholders

We envision that the value of the DAISI CRN could come from using the data gathered in it for the stakeholders as described below.

Patients can benefit from faster access to device safety and effectiveness information as well as earlier access to innovative devices as a result of streamlining the evidence generation used to support regulatory processes. This will allow patients, along with their health care providers to make informed decisions in determining their best care.

Clinicians, hospitals, and integrated health systems can use real-world evidence from the DAISI CRN for numerous purposes. Real-world evidence from the DAISI CRN may be used to develop quality data within organizations. Real-world evidence may help assess the performance of devices within their organizations. It may also help assess operator performance and support the development of clinical guidelines. The DAISI CRN may also provide relief from multiple reporting requirements. In addition, clinical data from the DAISI CRN may be used for research and scientific

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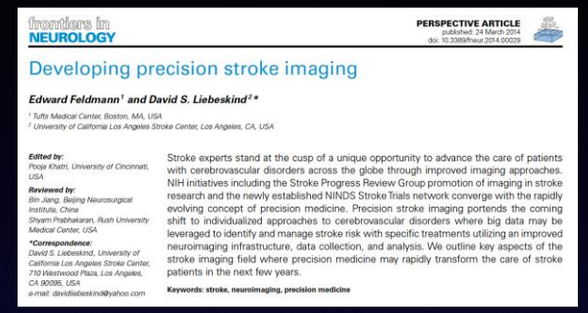
Optimize Interventions for Treatment & Prevention

- Diagnosis drives therapy and subsequent prognoses
- Systematic diagnostic evaluation is crucial
- Cost effective is not “bare minimum”
- Even guideline authors emphasize the need to think and carefully consider cause and management of each stroke

Neurovascular Imaging Research Core at UCLA

Real World of Precision Medicine in Stroke

- Prospective diagnostic and therapeutic strategy, based on clinical manifestations
- Focus on optimizing outcomes of entire, affected population
- Theranostics
  - integrated diagnostic & therapeutic strategy for individual
  - right treatment, right patient at right time
  - basis of precision medicine, leveraging unique role of collateral status
- *Not* retrospective, reductionist approach of traditional RCTs


frontiers in NEUROLOGY

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Developing precision stroke imaging

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Stroke experts stand at the cusp of a unique opportunity to advance the care of patients with cerebrovascular disorders across the globe through improved imaging approaches. NIH initiatives including the Stroke Progress Review Group promotion of imaging in stroke research and the newly established NINDS Stroke Trials network converge with the rapidly evolving concept of precision medicine. Precision stroke imaging portends the coming shift to individualized approaches to cerebrovascular disorders where big data may be leveraged to identify and manage stroke risk with specific treatments utilizing an improved neuroimaging infrastructure, data collection, and analysis. We outline key aspects of the stroke imaging field where precision medicine may rapidly transform the care of stroke patients in the next few years.

Keywords: stroke, neuroimaging, precision medicine


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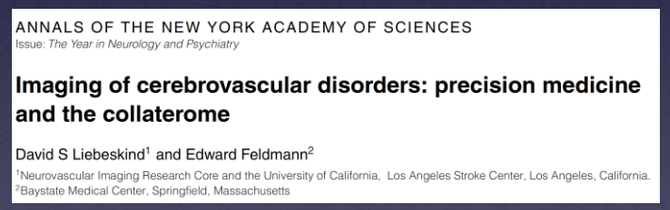
Review

Innovative Interventional and Imaging Registries: Precision Medicine in Cerebrovascular Disorders

David S. Liebeskind

Neurovascular Imaging Research Core, University of California, Los Angeles, and Comprehensive Stroke Center and Department of Neurology, Geffen School of Medicine at the University of California, Los Angeles, Los Angeles, Calif., USA


ANNALS OF THE NEW YORK ACADEMY OF SCIENCES
Issue: *The Year in Neurology and Psychiatry*

Imaging of cerebrovascular disorders: precision medicine and the collaterome

David S Liebeskind[1] and Edward Feldmann[2]

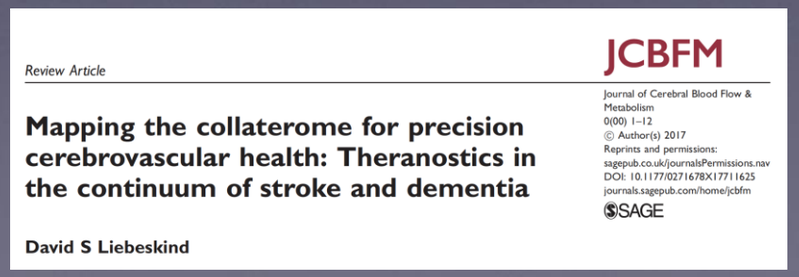
[1]Neurovascular Imaging Research Core and the University of California, Los Angeles Stroke Center, Los Angeles, California. [2]Baystate Medical Center, Springfield, Massachusetts


Cerebrovascular disease

REVIEW

Principles of precision medicine in stroke

Jason D Hinman,[1] Natalia S Rost,[2] Thomas W Leung,[3] Joan Montaner,[4] Keith W Muir,[5] Scott Brown,[6] Juan F Arenillas,[7] Edward Feldmann,[8] David S Liebeskind[1]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Mapping the collaterome for precision cerebrovascular health: Theranostics in the continuum of stroke and dementia

David S Liebeskind

Neurovascular Imaging Research Core at UCLA

Conclusions

- Optimal prevention and treatment of acute stroke hinges on recognition and proper diagnostic evaluation
- Guidelines provide suggestions for routine clinical practice, RWE to guide future stroke management
- Acute stroke (up to 24 hours after symptom onset) is a common and key public health priority worldwide