Therapy for Acute Stroke

and

Systems of Care for TIA

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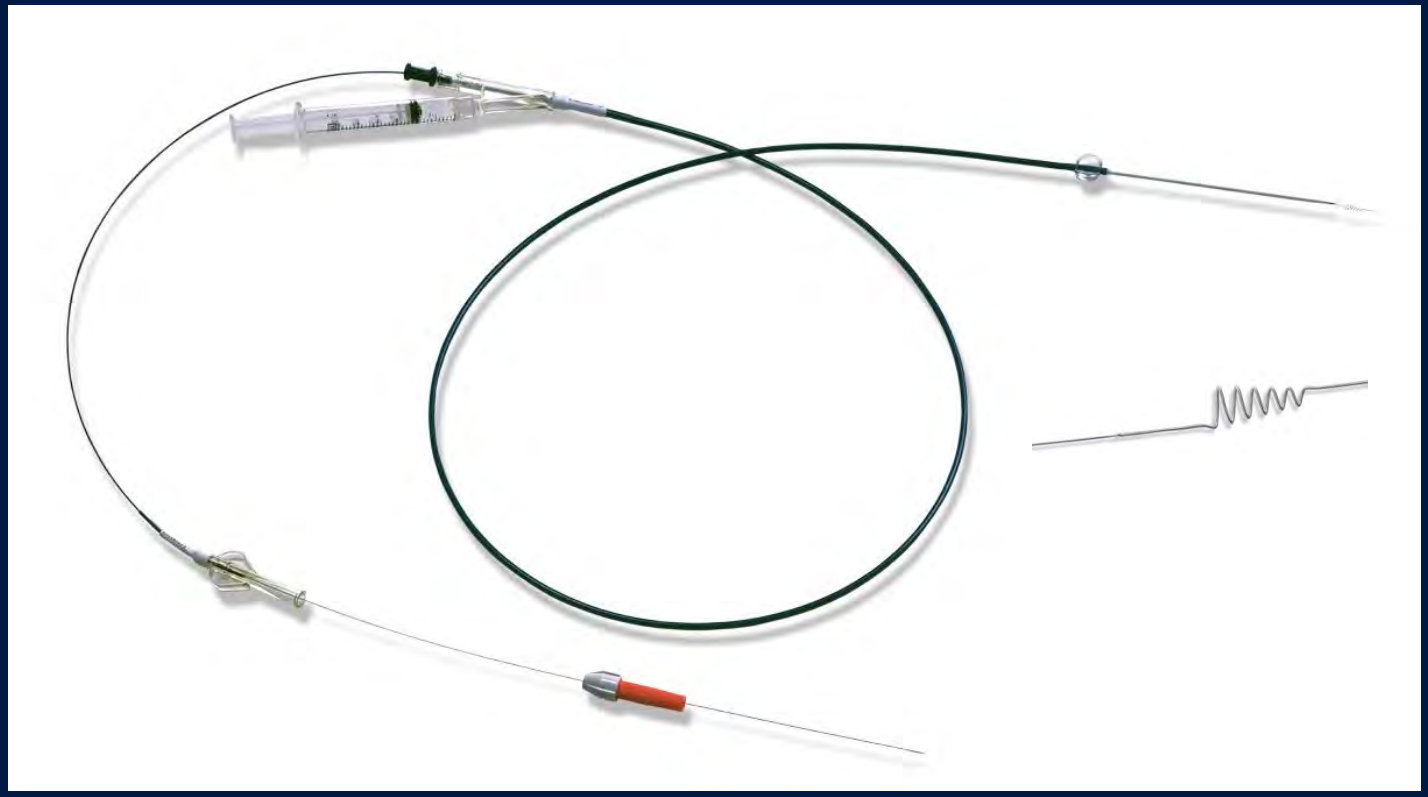
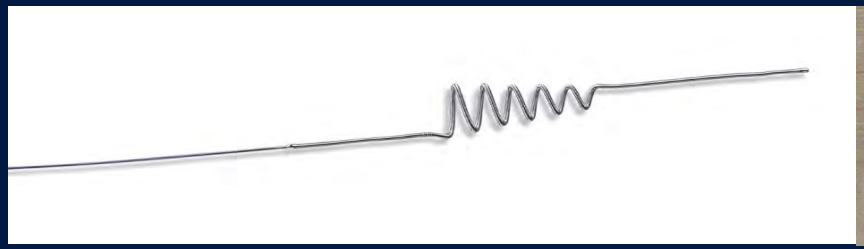
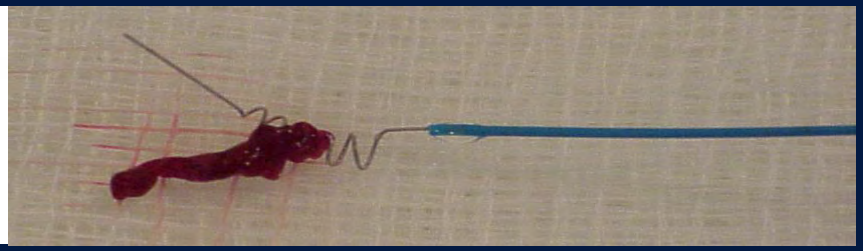
Acute Stroke Therapy

- Intravenous tPA
  - FDA approved in 1996 (3 hour window)
  - Cost-effective
  - Better efficacy with earlier treatment
  - Treatment rates vary from <1%-20%

MERCI® Retrieval System







Acute Stroke Therapy

- Endovascular therapy
  - Several thrombectomy devices with FDA 510K clearance
  - Encouraging cohort study data
  - CMS reimbursement
  - Randomized trials required to establish efficacy
  - No data on cost-effectivness

DRG Reimbursement for Acute Stroke Therapy

- Standard medical therapy - about 6K
- IV tPA - about 12K
- Endovascular therapy - >20K

Randomize Trials of Endovascular Stroke Therapy

Your loved one is in the ER with a large stroke:

MD: “There is a large blood clot in the brain, we have an FDA cleared device (Merci) that can probably pull out the clot. That could be a good option or we can enroll in a clinical trial: 50% get the device, 50% do not.

So, what will it be? Merci or No Merci?

Endovascular Stroke Therapy

- Randomized Trials
  - Lack of equipoise made clinical trials very challenging
  - Selection bias, extremely slow recruitment
  - All 3 randomized trials failed to establish efficacy of thrombectomy devices

Audience Response Question:

Should there be changes in reimbursement?

A. Suspend all reimbursement for thrombectomy
B. Reimburse only if enrolled in a randomized trial
C. No changes yet; let's wait for more data

October 26, 2013 10 am: Stroke Code in ER

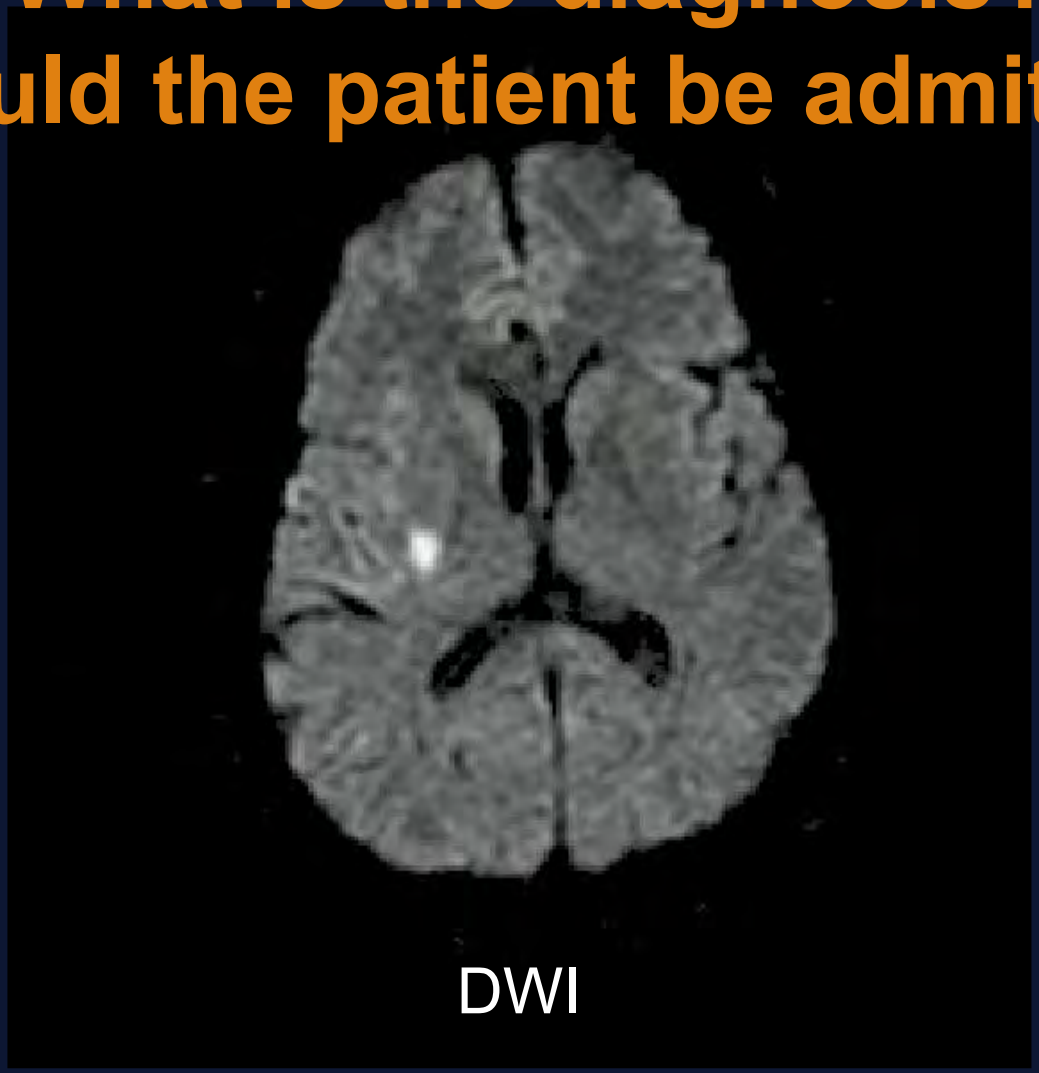
61yo female, healthy but recent stressors; 2 hr episode of L sided weakness; BP 160/90, neuro exam now nl, routine labs ok, non-con CT nl

Resident calls attending: Attending asks "do you think she had a TIA?"

Resident: "I have no idea."

Attending sees patient obtains more history, "some features are atypical, but $ABCD^2$ score is 4; I think it might be a TIA, but maybe not. Let's get an MRI"

What is the diagnosis?
Should the patient be admitted?



DWI

MRI / MRA negative except for:

How Should TIA Be Defined?

In 2002 the TIA Working Group proposed a new definition:

"A brief episode of neurological dysfunction caused by focal brain or retinal ischemia with clinical symptoms … without evidence of acute infarction"

Albers GW, Caplan LR, Easton JD, et al for the TIA Working Group. *N Engl J Med.* 2002;347(21):1713-1716 .

TIA: New technology triggers a change in terminology to emphasize tissue status, rather than time

New AHA endorsed definition of TIA:

A transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction

AHA Guidelines: *Stroke.* 2009;40(6):2276-2293.

Stroke Risk After TIA: ABCD^2 Score

Score points for each of the following:

- Age ≥60 (1)
- Blood pressure ≥140/90 on initial evaluation (1)
- Clinical:
  - Focal weakness (2)
  - Speech impairment without weakness (1)
- Duration
  - ≥60 min (2)
  - 10-59 min (1)
- Diabetes (1)

Final Score 0-7

Johnston, Rothwell, et al, Lancet, 369:283, 2007

ABCD^2 Score and Stroke Risks

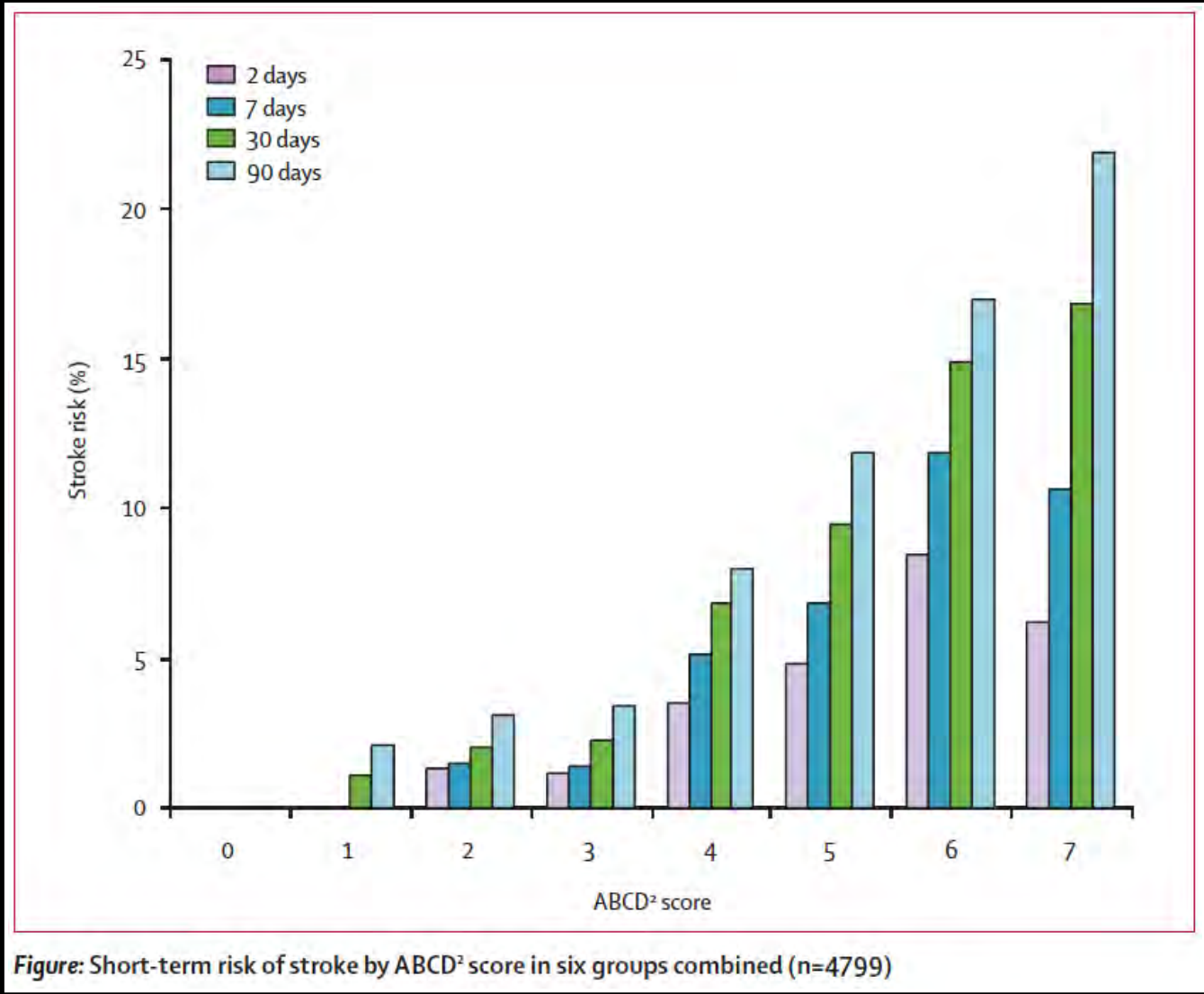


Figure: Short-term risk of stroke by ABCD² score in six groups combined (n=4799)

Johnston, Rothwell, et al, Lancet, 369:283, 2007

Stroke
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Stroke Association
A Division of American Heart Association

Addition of Brain Infarction to the ABCD2 Score (ABCD2I): A Collaborative Analysis of Unpublished Data on 4574 Patients

After adjustment for $ABCD^2$ score, patients with acute infarction had substantially higher 7 day stroke risk:

OR for positive DWI: 14.9 (7.4- 30.2)

Incorporation of imaging evidence of infarction into $ABCD^2$ improved predictive power: optimal weighing of 3 points

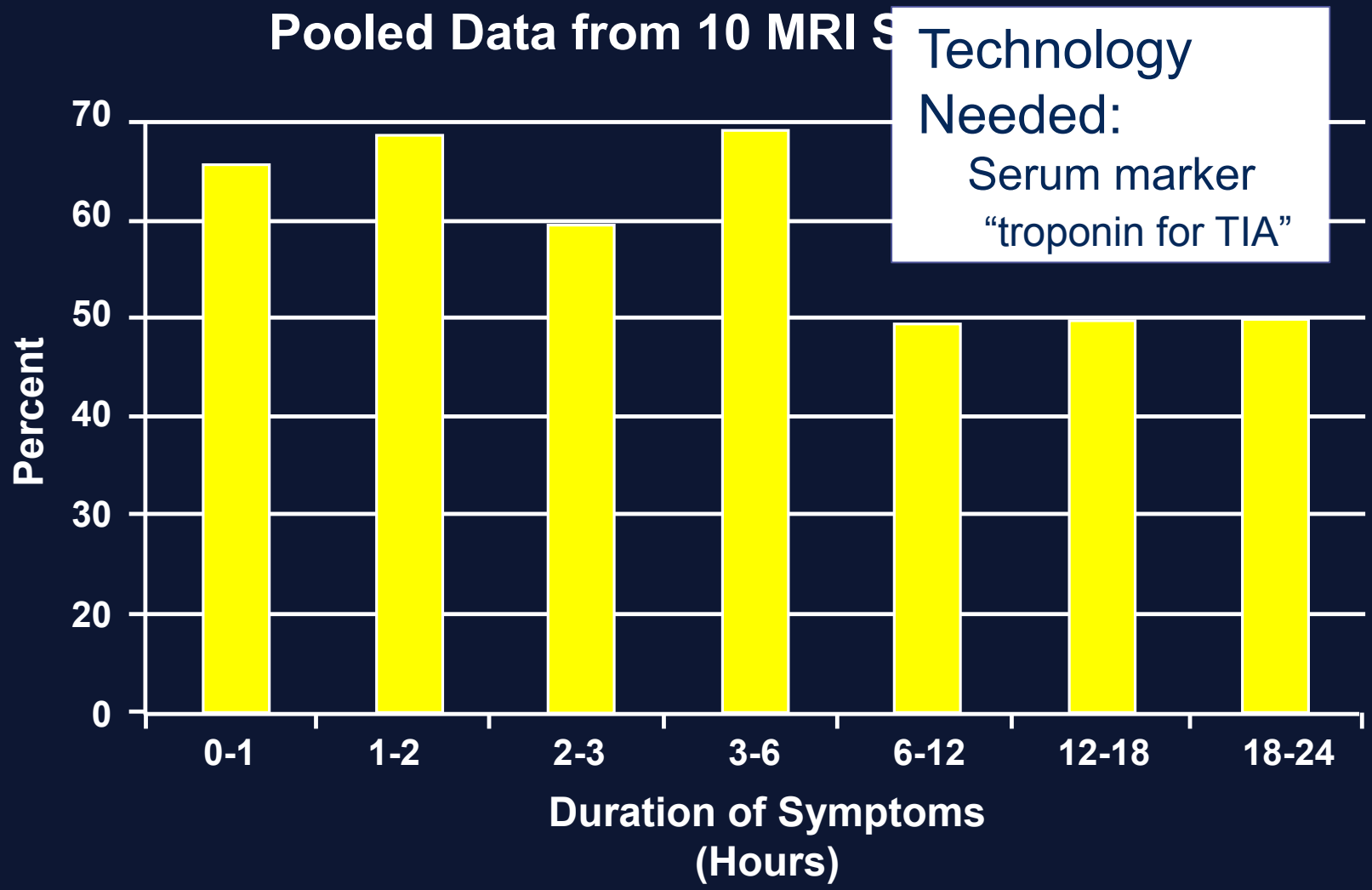
Giles MF, Albers GW, Amarenco P, et al Stroke. 2010 Sep;41(9):1907-13.

Stroke Risk at 7 days

$ABCD^2$	N	DWI positive	N	DWI negative
≤1	20	0.0 (0.0- 0.0)	225	0.0 (0.0- 0.0)
2	68	1.5 (0.0- 8.2)	329	0.0 (0.0- 0.0)
3	135	2.2 (0.5- 6.5)	469	0.2 (0.0- 1.2)
4	228	5.3 (2.7- 9.2)	577	0.7 (0.2- 1.8)
5	241	9.5 (6.0- 14.3)	454	0.7 (0.1- 1.9)
≥6	192	12.5 (8.0- 18.6)	268	0.4 (0.0- 2.1)
Total	884	7.1 (5.5- 9.1)	2322	0.4 (0.2- 0.7)

Giles MF, Albers GW, Amarenco P, et al. Neurology, 2011;77(13):1222-8.

Duration of Transient Symptoms and Proportion with Negative DWI



Easton JD, Saver JL, Albers GW, et al. *Stroke.* 2009;40(6):2276-2293.

NSA Recommendations for Systems of Care for TIA

- **Goal: identify dedicated models of care for TIA that assure the best possible patient outcomes in diverse healthcare settings.**

Johnston SC, Albers GW, Gorelick PB, et al. Ann Neuro 2011;69:872-877

Factors Influencing Systems of Care for TIA

- Regional and institutional differences have a major impact:
  - Limited inpatient bed availability
  - ED overcrowding
  - Presence of a stroke unit
  - Payer mix
  - Availability of stroke experts
  - Availability of brain/vascular imaging

NSA Recommendations: Triage

Healthcare systems should establish a routine TIA triage process including:

- **Urgent evaluation recommended if TIA within the last 24 hours**
- **TIA admission policy established by representative physicians**
- **TIA patients who are not hospitalized should be evaluated within 24 to 48 hours by a physician with expertise in TIA**

Recommendations: TIA Evaluation

Healthcare systems should establish a routine TIA evaluation protocol including:

- **Description of recommended lab testing**
- **Protocols for head imaging, by MRI (optimal) or CT performed within 24 hrs**
- **Protocols for carotid imaging (MRA, CTA, or Doppler), preferably within 24 hrs**
- **Protocols for cardiac monitoring and/or echocardiography in appropriate patients**

NSA 2011 Systems of Care for TIA Examples: STANFORD TWO ACES

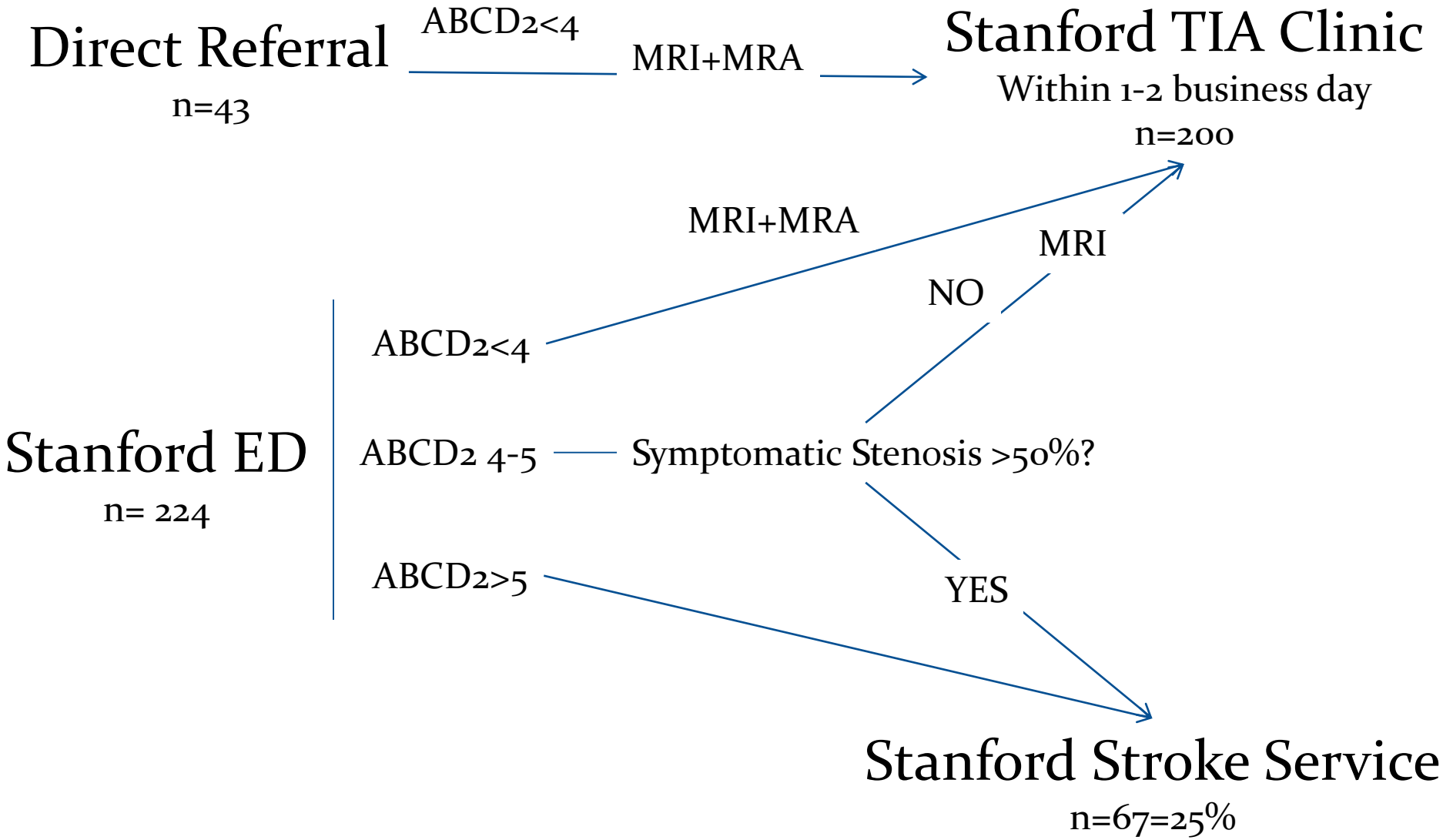
TWO ACES

Transient Ischemic Attack Work-Up as Outpatient Assessment of Clinical Evaluation and Safety

Jean-Marc Olivot, MD, PhD; Connie Wolford, NP; James Castle, MD; Michael Mlynash, MD, MS; Neil E. Schwartz, MD, PhD; Maarten G. Lansberg, MD, PhD; Stephanie Kemp, BS; Gregory W. Albers, MD

Stroke 2011; 42:1839-1843

Triage protocol



Methods

- Final diagnosis defined by stroke neurologist:

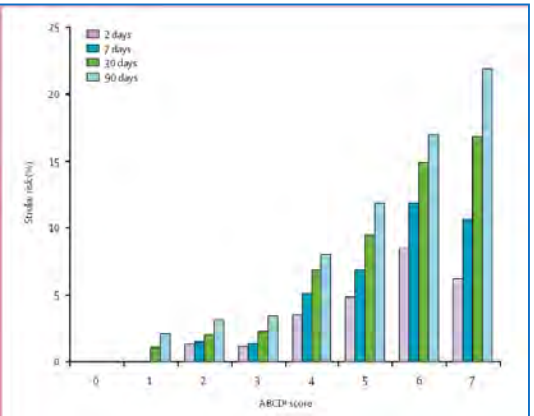
  Probable TIA/Possible TIA/Unlikely TIA

- Follow up Stroke/MI/Vascular Death at 7, 30 and 90 days.

Hypotheses

1- Patients will have a low rate of stroke recurrence <2% at 1 week and <5% at 90 days

2- Both groups will have lower risk than predicted based on ABCD2 score *



*Johnston et al, Lancet 2007.

Outcome: Stroke/MI/Vasc Death

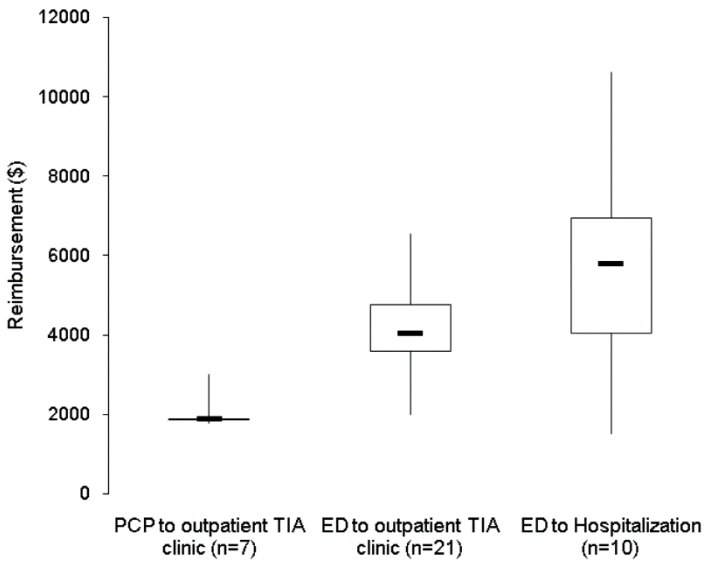
	% events at 7 and 90 days	% expected risk at 7 days*	p	% expected risk at 90 days*	p
All patients** (n=265)	0.7 (0.2-2.7)	4.0	0.015	7.0	<0.001
Final Dx TIA/stroke (n=108)	1.8 (0.5-6.5)	4.9	0.44	8.2	0.032
TIA Clinic Patients (n=199)	0.5 (0.9-2.8)	2.5	0.215	6.2	0.002

* Johnston et al. Lancet 2007

** 2 patients were lost of follow-up before 7 days

- The median (IQR) Medicare cost per patient was*:
  - $1,884 ($1,866-$1,897) for direct referrals to the TIA clinic;
  - $4,049 ($3,594-$4,756) for ED to the TIA clinic;
  - $5,804 ($4,027-$7,173) for ED to hospitalization.

- The median Medicare cost for a hospitalized patient was greater by*:
  - $3,587 (95% CI $1,450 – 5,396, p=0.006)
  - compared to the cost for a direct referral
  - to the TIA clinic;
  - $1,427 (95% CI -$326 - $3,088, p=0.108)
  - compared to the cost for an ED to the
  - TIA clinic referral.



*based on a representative 15% sample of Medicare reimbursed patients from each group in the TWOACES study

Conclusion: ABCD2 based Outpatient TIA Clinic Triage Protocol

- Safe: <2% stroke/MI/vasc death rate at 90 days
- Stroke rates lower than predicted based on ABCD2
- Reduced hospitalization rate: 25% vs. prior to TWO ACES protocol, about 75%.
- Cost savings compared to routine hospital admission

Limitations:

- Small sample size, selected population, some patients did not return to clinic, insurance issues

Alternative Model: CDA triage

Direct Referral
ABCD2<4 symptoms > 48 hrs

Selective MRI+MRA

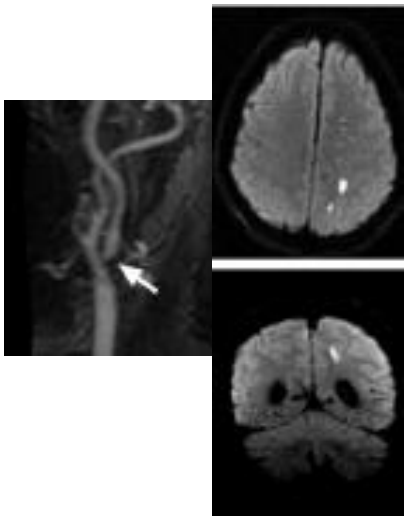
Stanford TIA Clinic
within 1 week

NO

Stanford ED

Clinical Decision Area*

Positive DWI or Symptomatic Stenosis >50% ?



YES

Hospital Admission

***ED Observation unit <24 hr stay**

- Clinical monitoring
- MRI/MRA within 6 hrs
- Labs/EKG/Other evaluations

Call to Action

- Expand adoption of TIA Clinics
  - More cost-effective than hospital admission
  - Hospitalization reserved for high risk patients
  - Further research efforts to clarify high risk subgroups and differentiate events due to brain ischemia from non-ischemic mimics