Who should perform acute stroke intervention and What training is needed?

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TOSHIBA STROKE & VASCULAR RESEARCH CENTER

Kaleida Health
Building a healthier future

University at Buffalo
State University of New York

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Cardiovascular Research Foundation

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
	• Toshiba – Honorarium • Medtronic - Honorarium

United States Workforce Status NOT World workforce

- 800 practicing Neurointerventionists in the US in 2012

Number of people training/year (2012)

- 80-100 new fellows graduating each year
  - From ~83 Active US Fellowship Programs
    - Some with >2 per year
    - More programs every year

Number of people training/year (2012)

- 80-100 new fellows graduating each year
  - Most "senior" NIs are <10 years into their career
  - No appreciable attrition rate to retirement

Point of Reference

- 100 Neurosurgery programs graduate about 160 new Neurosurgeons per year
  - Much more prevalent and varied diseases treated
  - Older age of practicing physicians

US AIS Treatment

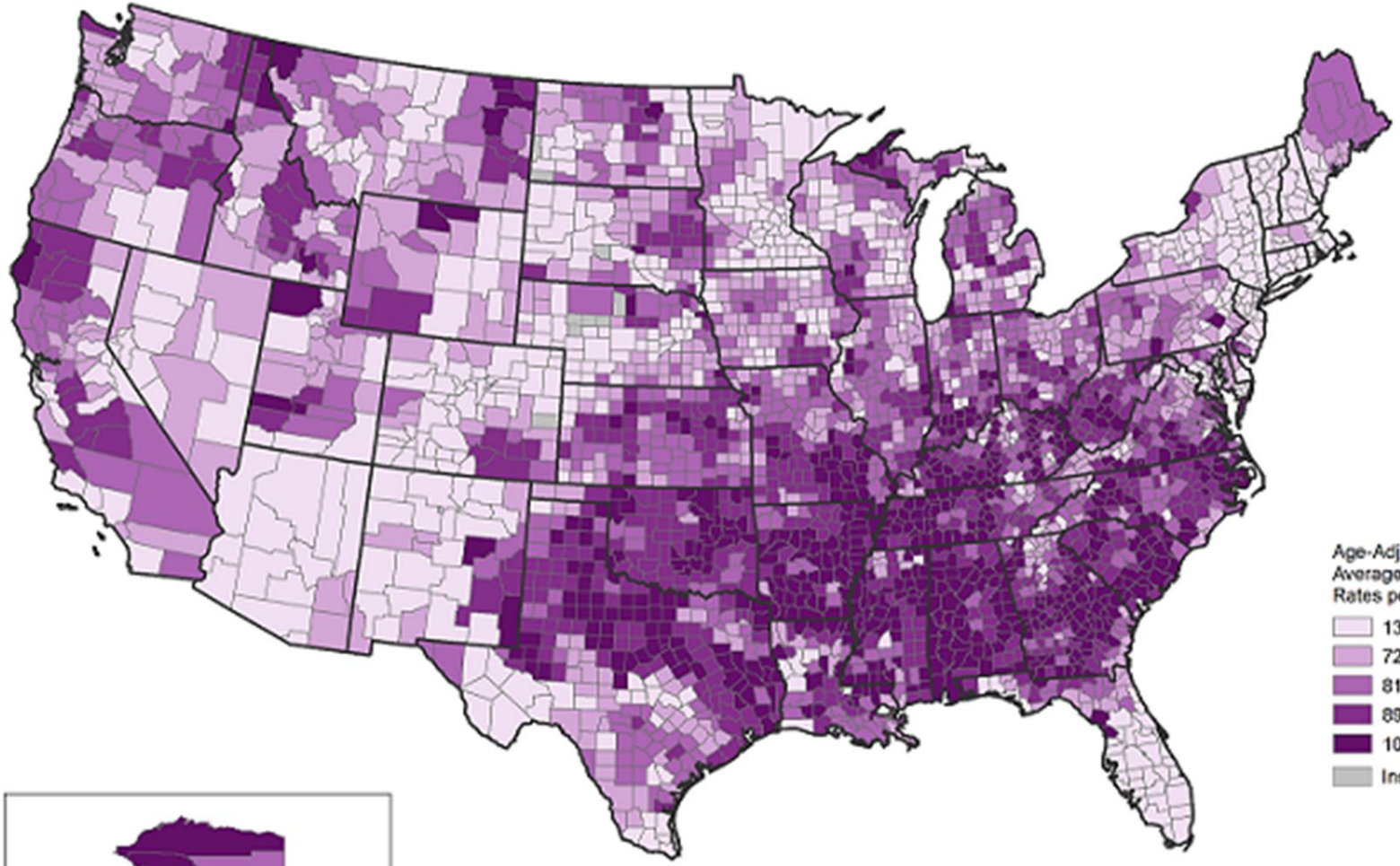
9 –12K 2014

Growth to what number??

Stroke Cases per NI

- 9 – 12K
- 12K Stroke Cases/800 MD/yr
  - 15/NI/year
    - ~1 every month

Stroke Death Rates, 2008-2010
Adults, Ages 35+, by County



Age-Adjusted
Average Annual
Rates per 100,000

- 13.5 - 72.7
- 72.8 - 81.2
- 81.3 - 88.9
- 89.0 - 100.1
- 100.2 - 300.1
- Insufficient Data

Rates are spatially smoothed to enhance the stability of rates in counties with small populations.

Data Source:
National Vital Statistics System
National Center for Health Statistics

CDC

Neurology®

Demand-supply of neurointerventionalists for endovascular ischemic stroke therapy

Osama O. Zaidat, Marc Lazzaro, Emily McGinley, et al.

Neurology 2012;79;S35-S41
DOI 10.1212/WNL.0b013e31826957ef

Figure US maps depicting density of acute ischemic stroke patients eligible for endovascular ischemic stroke therapy, a reflection of the population density, and hospitals' ability to perform intra-arterial therapy

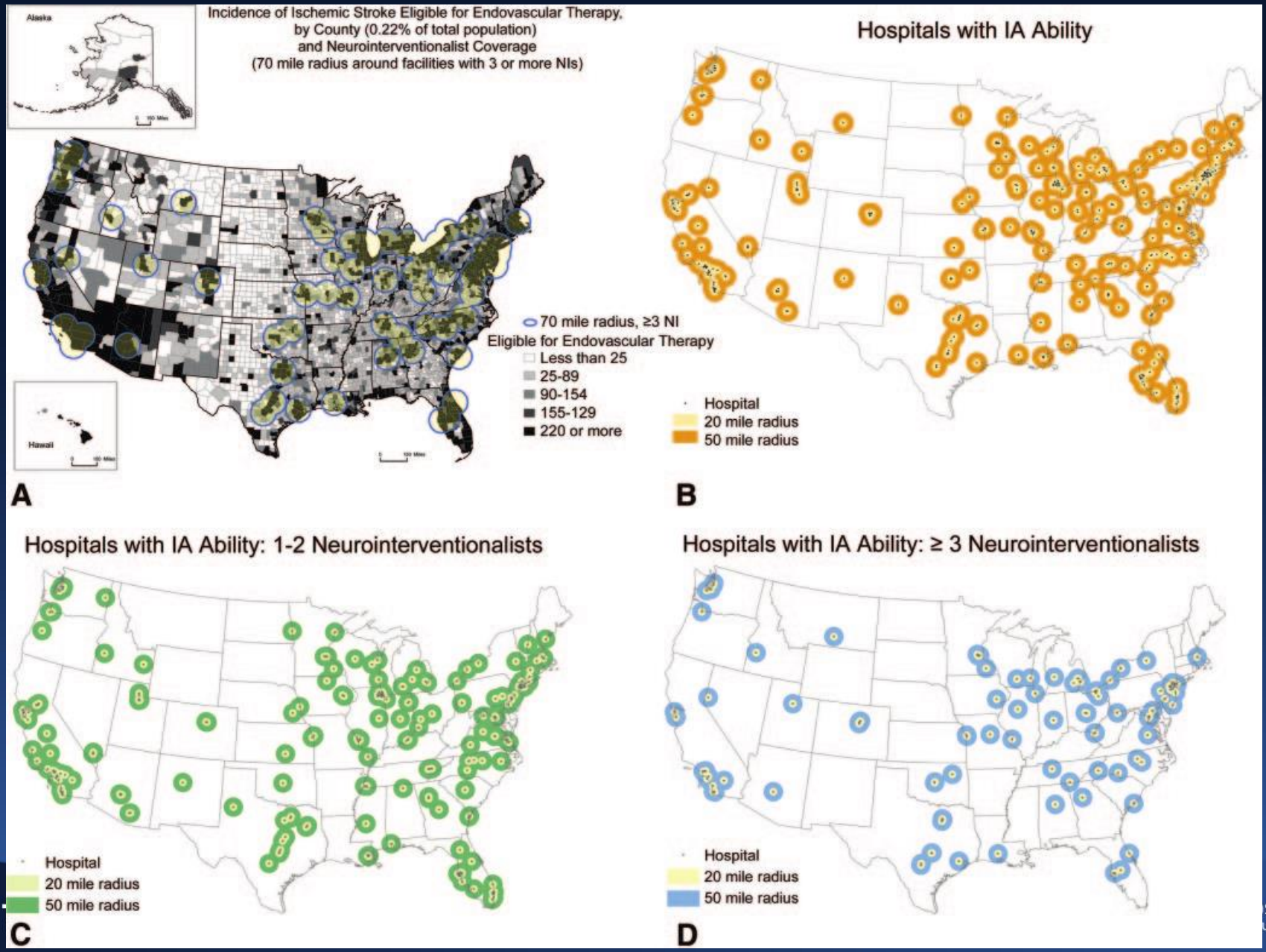


Table 2 Summary of estimated numbers of ischemic strokes eligible for endovascular therapy

Basis for estimation of endovascular AIS annual case volume estimates	Percentage of all AIS cases, range	Lower-end no. (SD)	Upper-end no. (SD)
US population-based, large-vessel disease	9 to 27	60,750	18,2250
Prospective endovascular AIS trial screening data, screened vs enrolled	1.5 to 10.7	11,000	75,000
Regional and hospital registry based, large-vessel disease and severe stroke	5 to 13	34,000	87,750
Hirsch et al. (2009), 500 hospitals performing at MG or St. Luke center[a] volume[25]	1.5 to 6.2	10,400	41,500
Cloft et al. (2009) [24]	3 to 18.7	20,000	120,000
National Inpatient Sample Database 2008[31]	2	14,000	
Medical College of Wisconsin (3 NIs, 2005 = 24/540 to 2009 = 64/630)	4.4 to 10.2	30,000	68,571
Mean (SD)			
Lower range	3.6 (2.6)[b]	25,736 (17,960)	96,845 (50,133)
Upper range	14.3 (7.4)[c]		
No. of cases/y per NI, assuming NI total is			
800		32 (25,736/800)	121 (96,845/800)
1,000		26 (25,736/1,000)	97 (96,845/1,000)
1,200		22 (25,736/1,200)	81 (96,845/1,200)

Geographic Coverage: 2011

- **95%** of the US population lives within 50 miles of an interventional CV center w 24/7 coverage

Zaidat et al., Neurology 201

Incidence of Emergency Department Visits for ST-Elevation Myocardial Infarction in a Recent 6-Year Period in the United States

Michael J. Ward, MD, MBA[1,*], Sunil Kripalani, MD, MSc[1], Yuwei Zhu, MD, MS[1], Alan B. Storrow, MD[1], Robert S. Dittus, MD, MPH[1,2], Frank E. Harrell Jr., PhD[1], and Wesley H. Self, MD, MPH[1]

[1]Vanderbilt University School of Medicine

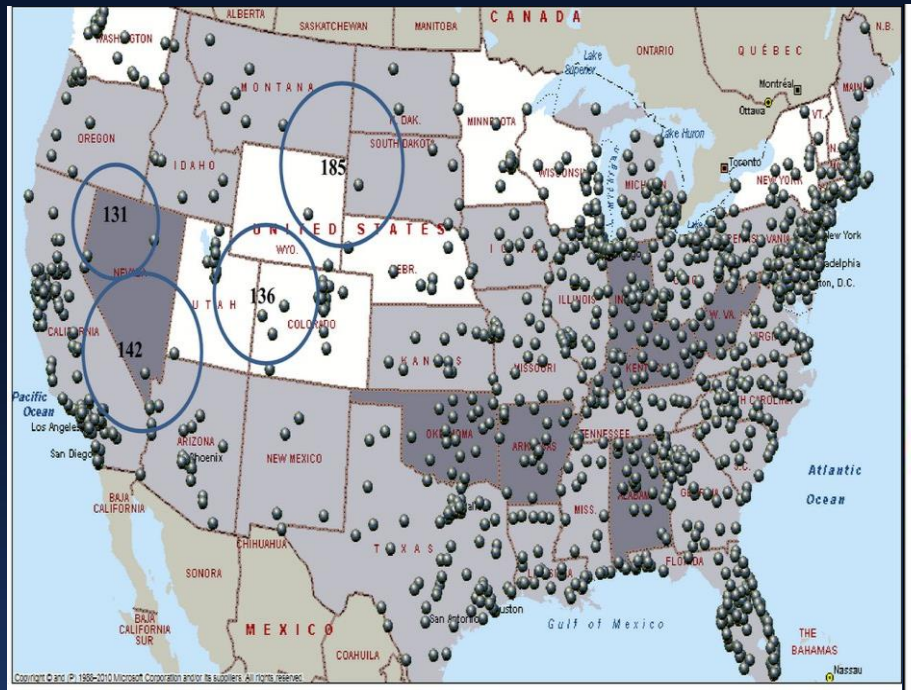
[2]VA Tennessee Valley Healthcare System

2006–2011, there was a mean of 258,106 STEMIs presenting to EDs per year

Number of PCI centers in US 1975

140 STEMI per PCI center per year

PCI Centers vs Stroke centers



Zaidat et al 2012

ORIGINAL RESEARCH

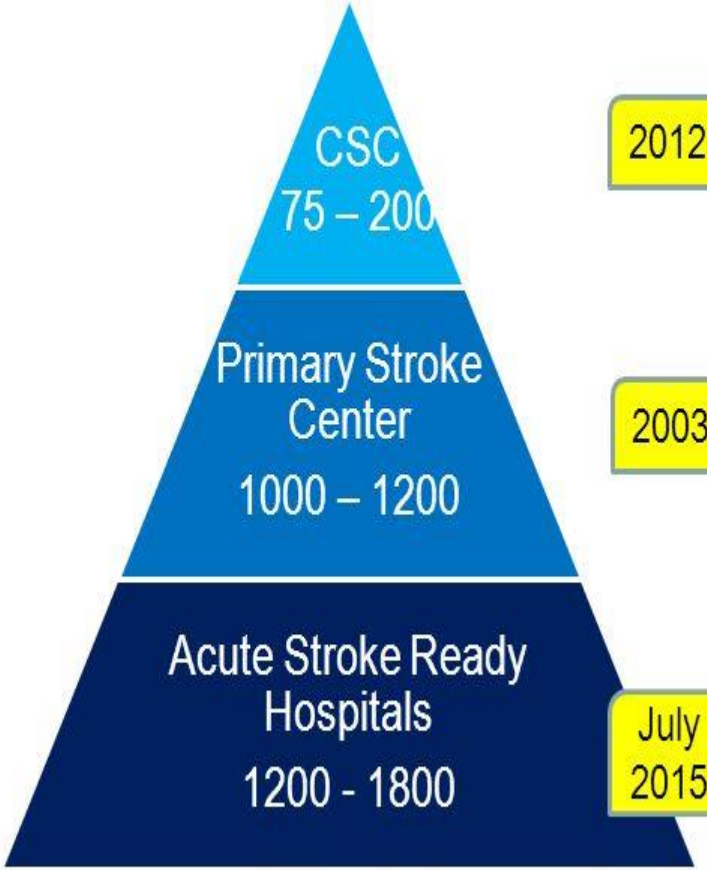
American Heart Association | American Stroke Association

Growth in Percutaneous Coronary Intervention Capacity Relative to Population and Disease Prevalence

James R. Langabeer, II, PhD; Timothy D. Henry, MD; Dean J. Kereiakes, MD; Jami DelliFraine, PhD; Jamie Emert, MPH; Zheng Wang, MA; Leilani Stuart, RN, BSN; Richard King, PhD; Wendy Segrest, MS; Peter Moyer, MD; James G. Jollis, MD

2013

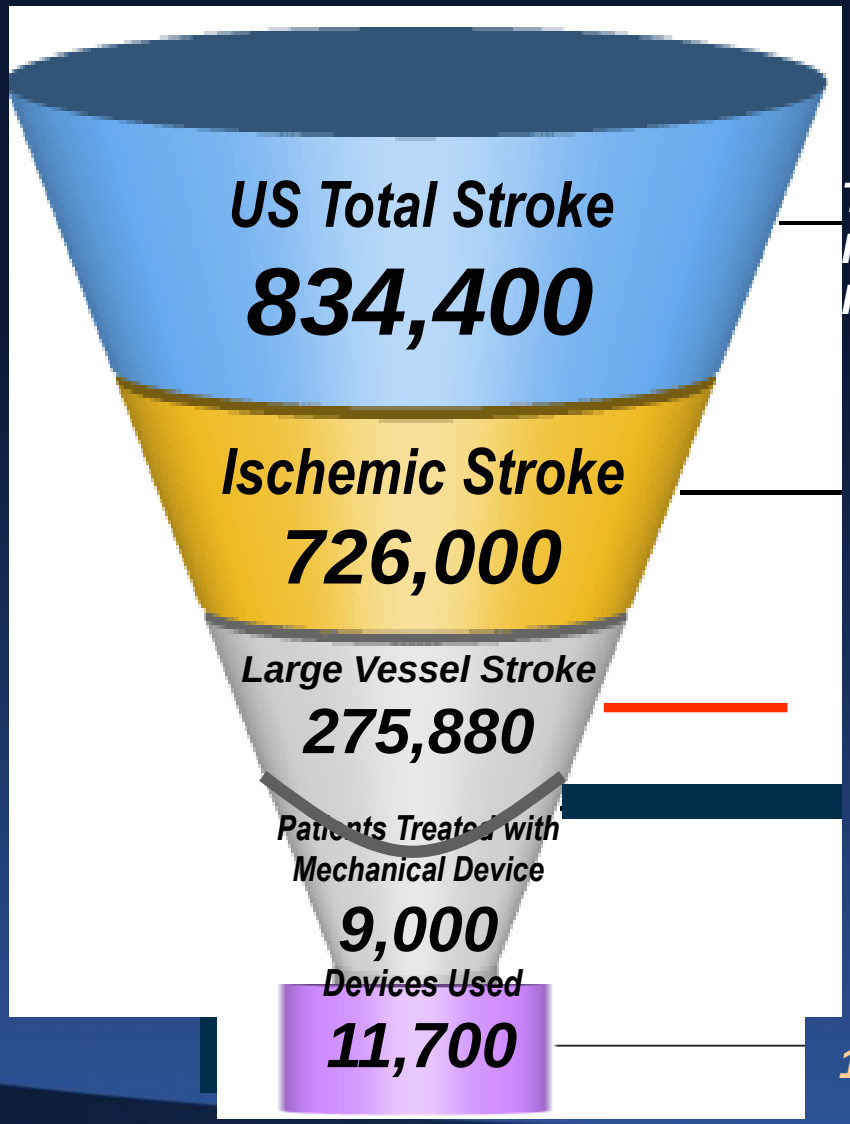
Models of Stroke Care



2012	Academic medical center, tertiary care facility
2003	Wide range of hospitals; standard stroke care; stroke unit; uses tPA
July 2015	Rural hospitals; basic care; drip and ship; use tele-technologies

The Joint Commission
Certification
Disease-Specific Care

Endovascular Treatment Population



Total Stroke: Ischemic and Hemorrhagic

87% of Strokes are Ischemic

38% of Ischemic Strokes are Large Vessel Occlusions (LVOs) (28-46%)

Untreated LVO strokes typically result in moderate to severe symptoms

Only 3% pts. treated

1.3 devices used / patient

Improved stroke networks, logistics, public awareness, positive level 1 data & more effective endovascular device options will increase # of patients treated

ORIGINAL RESEARCH

A population-based incidence of acute large vessel occlusions and thrombectomy eligible patients indicates significant potential for growth of endovascular stroke therapy in the USA

Ansaar T Rai,[1] Aaron E Seldon,[1] SoHyun Boo,[1] Paul S Link,[2] Jennifer R Domico,[1] Abdul R Tarabishy,[3] Noelle Lucke-Wold,[1] Jeffrey S Carpenter[1]

1157 patients were discharged from the hospital's PSA, of whom 129 (11.1%, 95% CI 9.5%
to 13.1%) had an LVO. This translated into an LVO incidence of 24 per 100 000 people per year (95% CI 20 to 28).

These rates yield 77 569 (95% CI 65 835 to 91 091) new LVOs per year in the USA. An estimated 10 284 mechanical thrombectomy procedures were performed in 2015.

Unclear number of LVOs

- 700-750K strokes per year
  - 14% bleeds
  - 4% TIAs
  - 1% Late effects of CV disease
- 645K ischemic strokes
  - ~20% NIHSS > 10

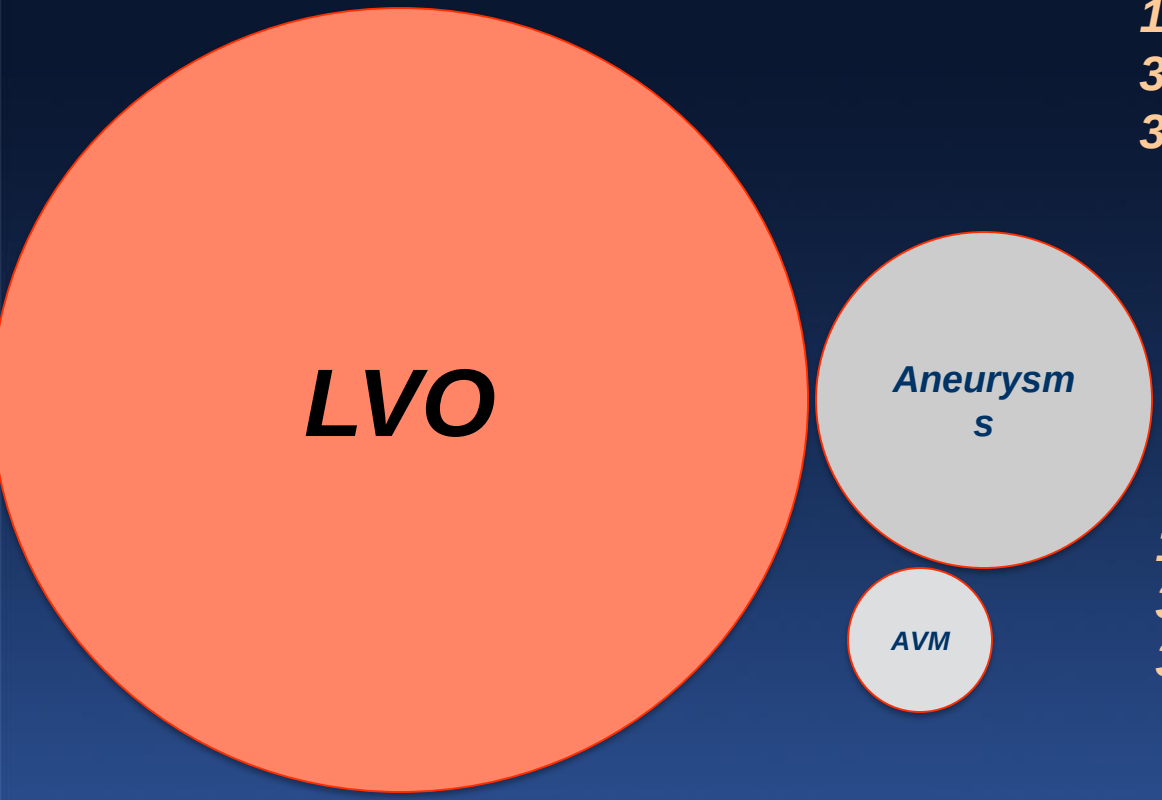
Cloft et al., AJNR 2009

Unclear number of LVOs

- **126K Potential IAT Cases**
  - **Imaging exclusion**
    - **Completed stroke**
    - **Out of “window”**
  - **No LVO**
  - **IV tPA successes**

Cloft et al., AJNR 2009

This is where we are heading….



800 NIs

100,000 LVO ~ 125/per NI/year
30,000 aneurysms ~ 38/NI/year
3,000 AVMs ~ 4/NI/year

We will double in 5 years

1600 NIs

100,000 LVO ~ 62/per NI/year
30,000 aneurysms ~ 19/NI/year
3,000 AVMs ~ 2/NI/year

On one hand there is clear association of improved outcomes with increased volume

Hospital volume and stroke outcome

Does it matter?

- **Ischemic Stroke Outcomes at High Volume Hospitals vs. Low Volume Hospitals**
  - **Lower 7-day mortality**
  - **Lower discharge mortality**

Saposnik et al., Neurology 2007

ORIGINAL RESEARCH

Higher volume endovascular stroke centers have faster times to treatment, higher reperfusion rates and higher rates of good clinical outcomes

Rishi Gupta,[1] Anat Horev,[2] Thanh Nguyen,[3] Dheeraj Gandhi,[4] Dolora Wisco,[5] Brenda A Glenn,[1] Ashis H Tayal,[6] Bryan Ludwig,[7] John B Terry,[7] Muhammad Shazam Hussain,[5] Raphael Y Gershon,[8] Tudor Jovin,[2] Paul F Clemmons,[9] Michael R Frankel,[1] Carolyn A Cronin,[10] Melissa Tian,[6] Kevin N Sheth,[10] Raul G Nogueira,[1] Aaron M Anderson,[1] Samir R Belagaje[1]

- **High Volume Hospitals**
  - **Shorter times from CT to groin puncture**
  - **Shorter procedure times**
  - **More likely to have good outcomes**
  - **More likely to achieve successful reperfusion**

On the other hand there is clear decline in outcomes with delayed revascularization

Transfer a patient to a Primary stroke center or Comprehensive stroke center?

Impact of transfer status on hospitalization cost and discharge disposition for acute ischemic stroke across the US

Ashish Sonig, MD, MS, MCh,[1,5] Ning Lin, MD,[1,5] Chandan Krishna, MD,[1,5]
Sabareesh K. Natarajan, MD, MS,[1,5] Maxim Mokin, MD, PhD,[1,5] L. Nelson Hopkins, MD,[1,2,4–6]
Kenneth V. Snyder, MD, PhD,[1–5] Elad I. Levy, MD, MBA,[1,2,4,5] and Adnan H. Siddiqui, MD, PhD[1,2,4–6]

Departments of [1]Neurosurgery, [2]Radiology, and [3]Neurology, School of Medicine and Biomedical Sciences; and [4]Toshiba Stroke and Vascular Research Center, University at Buffalo, State University of New York; [5]Department of Neurosurgery, Gates Vascular Institute at Kaleida Health; and [6]Jacobs Institute, Buffalo, New York

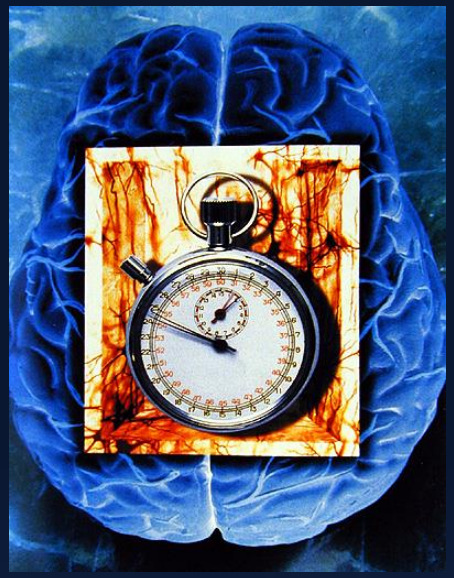
J Neurosurg - April 8, 2015

- We analyzed United States Nation-wide in patient Data sample 2008-2010
- NIS contains data from approximately 1,000 hospitals sampled to approximate a 20% stratified sample of U.S. community hospitals
- We compared the outcome of patients who had mechanical thrombectomy performed as a direct admission or after being referred from another hospital

- **Our study showed that the cost incurred by a hospital for acute stroke intervention is significantly higher for a transferred patient than for a direct admission.**

- **The frequency of worse discharge disposition was significantly higher among transferred patients compared with direct admissions.**

- **Future strategies should focus on the means and ways of transporting the patient appropriately and directly to a comprehensive stroke center.**



Time is Brain

Meaning What??

In each minute we lose:

-1.9 million neurons,

-14 billion synapses (connections)

-12 km (7.5 miles) of nerve fibers

New Data: Subgroup analysis of 2015 trials

If we can reopen a blocked brain artery ...

Within 2 hours:

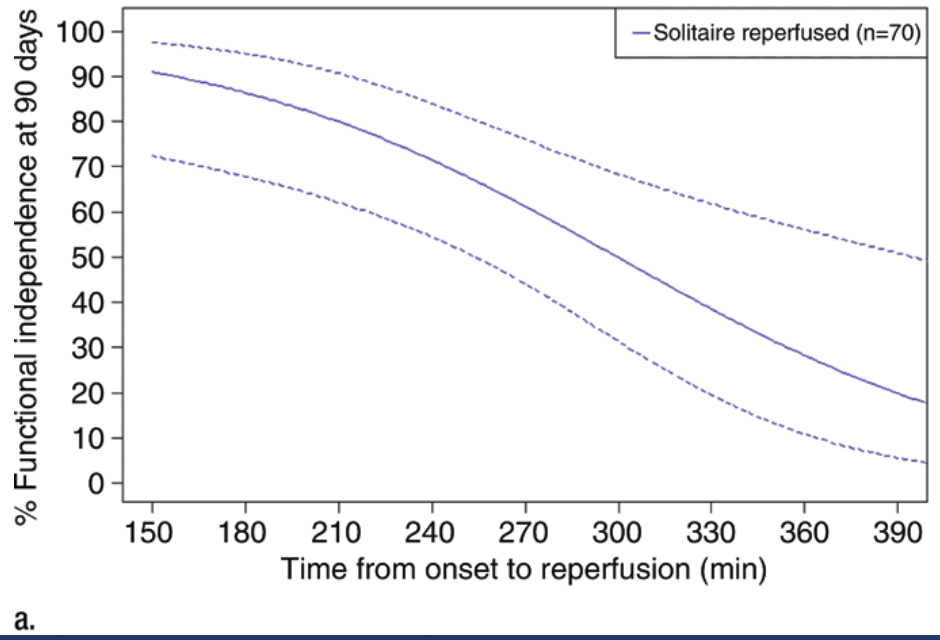
-Recovery rate is 90% !!

After 6 hours:

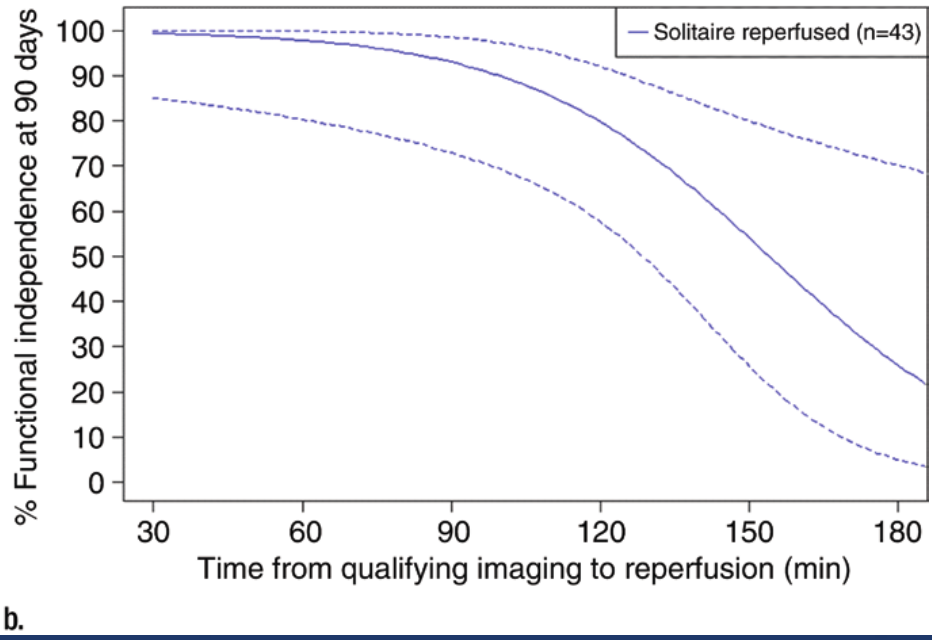
-Recovery rate is 20-30% !!!!

Analysis of Workflow and Time to Treatment and the Effects on Outcome in Endovascular Treatment of Acute Ischemic Stroke: Results from the SWIFT PRIME Randomized Controlled Trial[1]

Figure 3


Solitaire reperfused (n=70)
% Functional independence at 90 days
100
90
80
70
60
50
40
30
20
10
0
150
180
210
240
270
300
330
360
390
Time from onset to reperfusion (min)

a.


Solitaire reperfused (n=43)
% Functional independence at 90 days
100
90
80
70
60
50
40
30
20
10
0
30
60
90
120
150
180
Time from qualifying imaging to reperfusion (min)

b.

Impact of Onset-to-Reperfusion Time on Stroke Mortality

A Collaborative Pooled Analysis

Mikael Mazighi, MD, PhD; Saqib A. Chaudhry, MD; Marc Ribo, MD; Pooja Khatri, MD, MSc; David Skoloudik, MD; Maxim Mokin, MD; Julien Labreuche, BST; Elena Meseguer, MD; Sharon D. Yeatts, PhD; Adnan H. Siddiqui, MD; Joseph Broderick, MD; Carlos A. Molina, MD; Adnan I. Qureshi, MD; Pierre Amarenco, MD

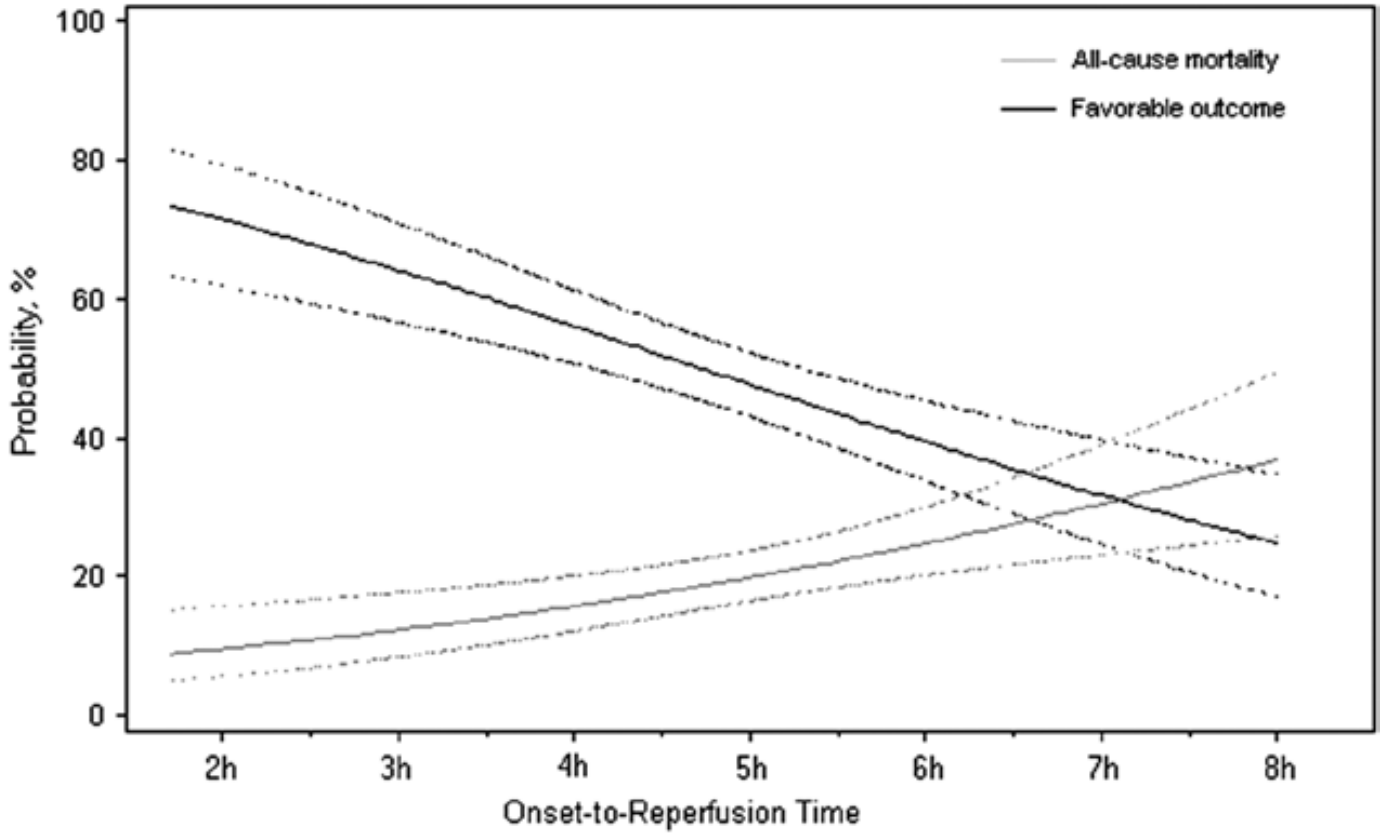
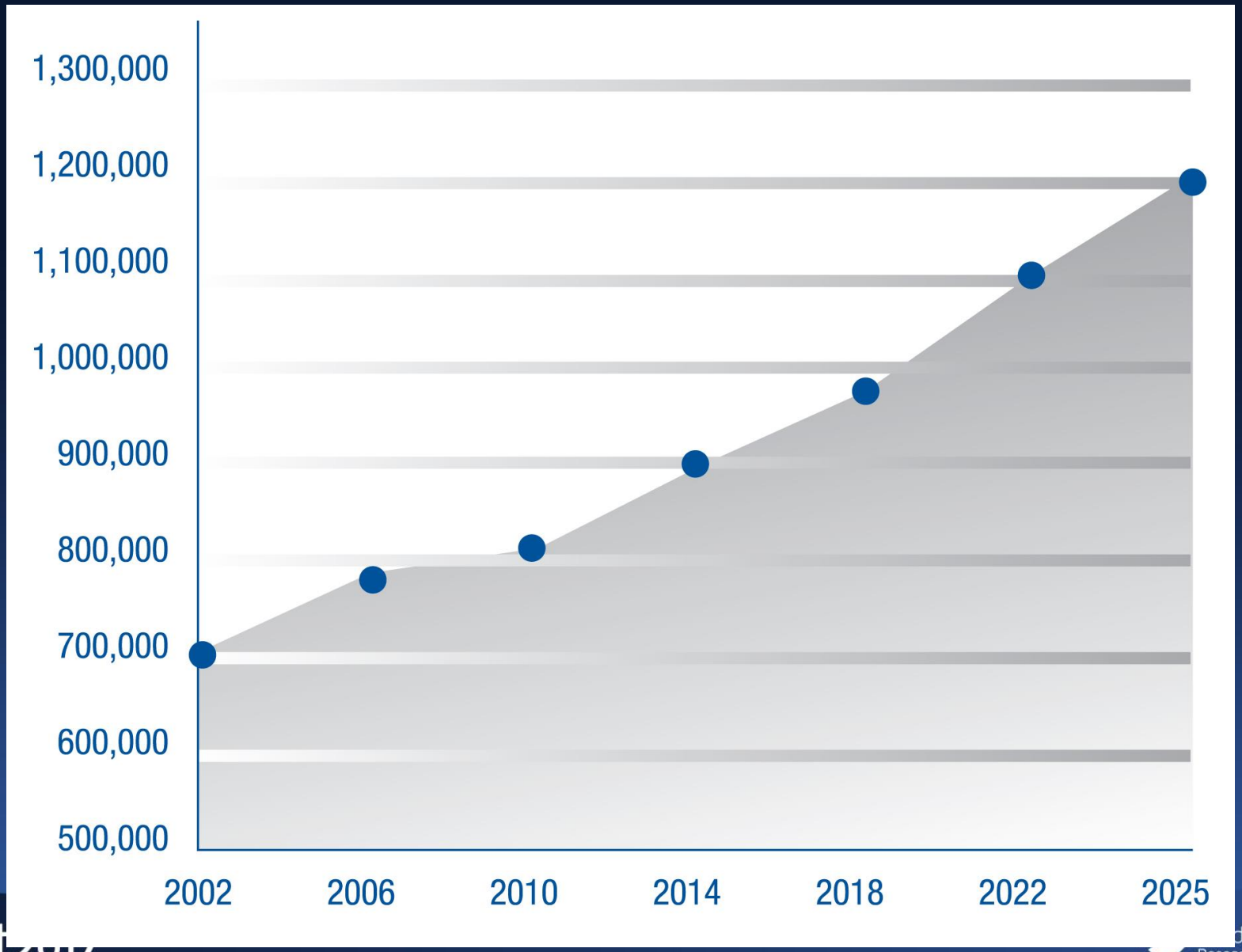
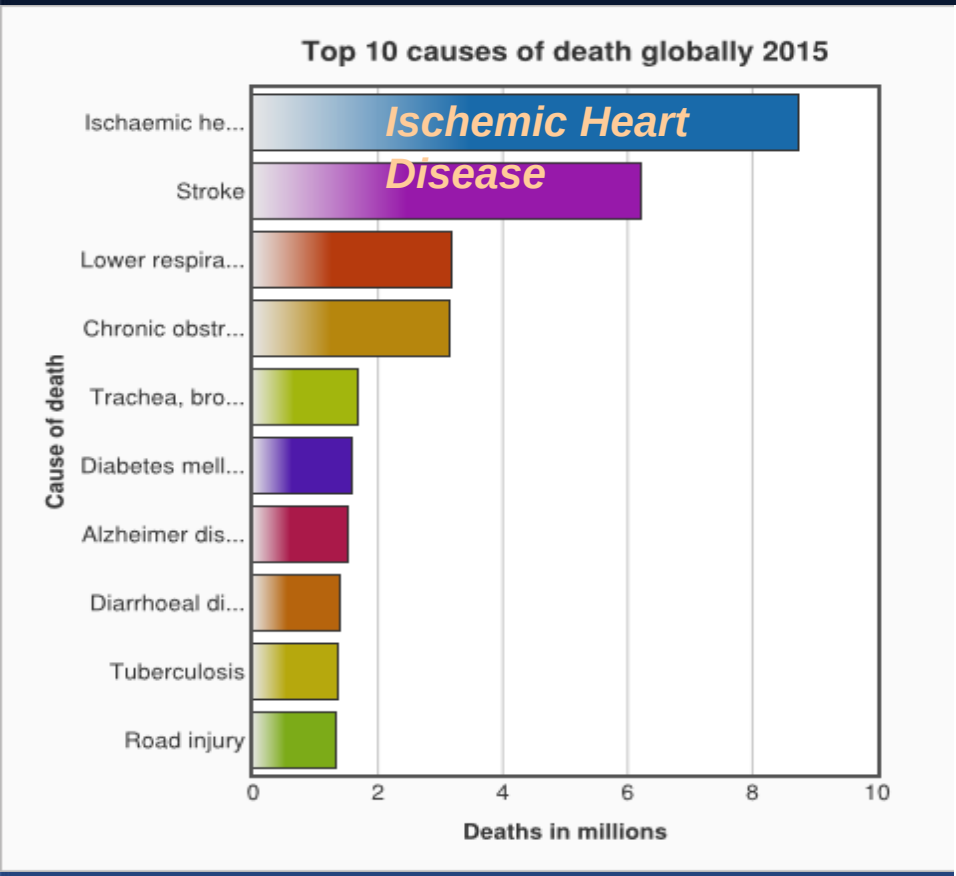


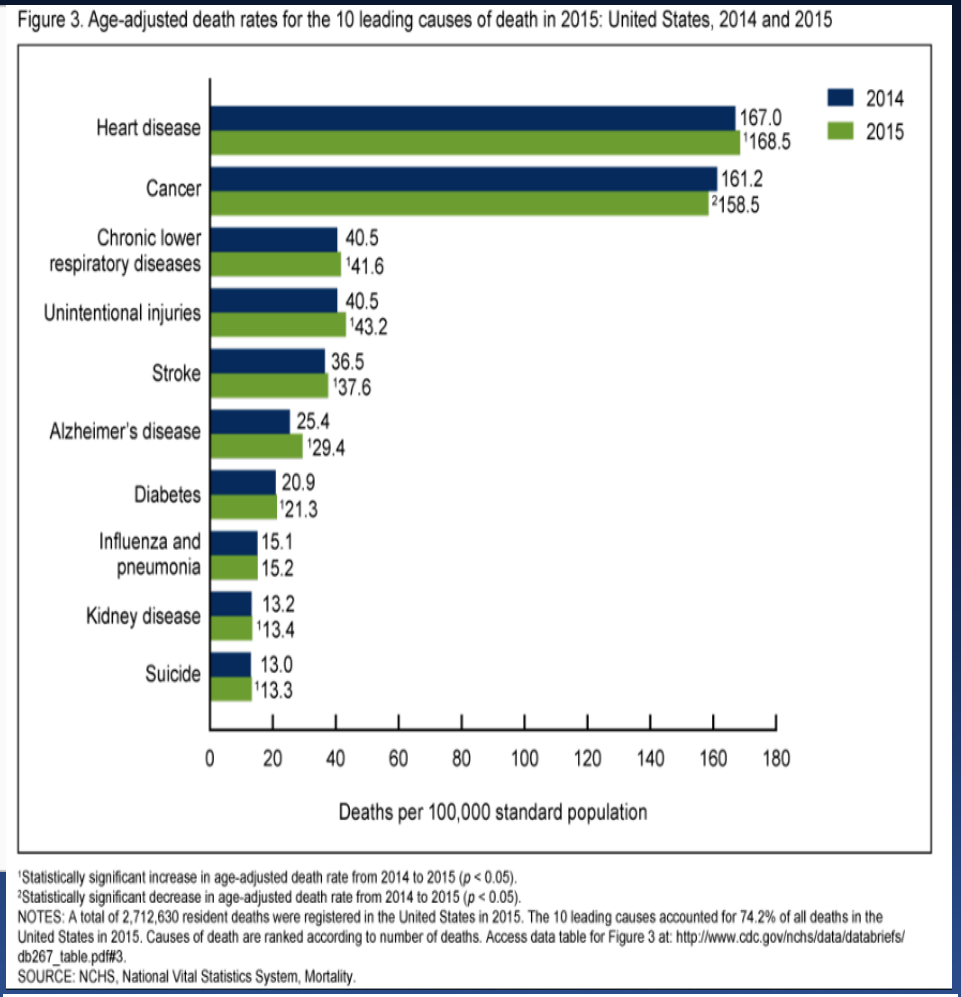
Figure 1. Unadjusted predicted probability of mortality and favorable outcome at 90 days by onset-to-reperfusion time. Solid lines represents the probability of outcome (gray, all-cause mortality; black, favorable outcome) over onset-to-reperfusion time (ORT) as predicted by unadjusted logistic regression model with ORT used as a continuous variable. Dashed lines show the 95% confidence intervals.

A clear need!


1,300,000
1,200,000
1,100,000
1,000,000
900,000
800,000
700,000
600,000
500,000
2002
2006
2010
2014
2018
2022
2025

Worldwide Mortality Impact





World Health Organization

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Preamble

- We don’t know the numbers 90,000-300,000
- Without question the number is going to be far greater than intracranial aneurysms, AVMs and AVFs combined
- Perhaps we need to be proactive about a palatable solution which allows us to preserve the expertise required to treat hemorrhagic disease while delivering 24/7 emergent care for acute ischemic stroke as close to the patient as is reasonable????

Challenges of Acute Stroke Intervention

- *Complex 3D anatomy*
- *Appreciation of unique end organ physiology*
- *Subtleties which are hard to convey*
- *Litigation*
- *Increasing expectations of societies*
- *Public/Payer focus on cost reduction and pay for performance*

NI Societies

- CAST (Committee on Advanced Subspeciality Training) – Responsible for certifying subspeciality fellowship training programs for Society of Neurological Surgery (SNS)
  - 21 programs in US in Neuroendovascular Surgery
- NESAC (Neuroendovascular Surgery Advisory Council) – Neurosurgeons, Neurologists, Neuro-radiologists, 9 members + chair

Program & Individual requirements for Accreditation & Certification through CAST for Fellowship in Neuroendovascular Surgery

Special Reports

Training Standards in Neuroendovascular Surgery

Program Accreditation and Practitioner Certification

Arthur L. Day, MD; Adnan H. Siddiqui, MD, PhD; Philip M. Meyers, MD; Tudor G. Jovin, MD; Colin P. Derdeyn, MD; Brian L. Hoh, MD; Howard Riina, MD; Italo Linfante, MD; Osama Zaidat, MD; Aquilla Turk, DO; Jay U. Howington, MD; J. Mocco, MD, MS; Andrew J. Ringer, MD; Erol Veznedaroglu, MD; Alexander A. Khalessi, MD, MS; Elad I. Levy, MD, MBA; Henry Woo, MD; Robert Harbaugh, MD; Steven Giannotta, MD

(*Stroke*. 2017;48:00-00. DOI: 10.1161/STROKEAHA.117.016560.)

Published July 2017

CAST NES certification:
NES Advisory Council (NESAC)

1. Agreement to represent all neurologic specialties

and neuroendovascular surgery organizations to certify programs and individuals in NES

2. Jointly develop and publish training and certification guidelines

3. NES written exam (currently ABNS)

4. Practice review

5. Leapfrog interactions

Editorial

Endovascular Thrombectomy and Stroke Physicians
Equity, Access, and Standards

Stephen M. Davis, MD, FRACP; Bruce C.V. Campbell, PhD, FRACP; Geoffrey A. Donnan, MD, FRACP

Comments and Opinions

Rethinking Training and Distribution of Vascular Neurology Interventionists in the Era of Thrombectomy

James C. Grotta, MD; Patrick Lyden, MD; Thomas Brott, MD

Comments and Opinions

Amartya Sen and the Organization of Endovascular Stroke Treatment

Mayank Goyal, MD, FRCPC; Alexis T. Wilson, BSc; Noreen Kamal, PhD; Ryan A. McTaggart, MD; Mahesh V. Jayaraman, MD; Marc Fisher, MD; Michael D. Hill, MSc, MD, FRCPC

Definition

- **Acute Ischemic Stroke Intervention (AISI) is a subspecialty that uses pharmacologic and minimally invasive catheter-based technology, radiological imaging, and clinical expertise to diagnose and treat Acute Ischemic Stroke. The unique clinical and invasive nature of this subspecialty requires special training and skills.**

Institutions

- **Programs for advanced training in AISI must exist within an advanced NES training center.**

Specialty Curriculum- Prerequisite

- Qualifying prerequisite: 100 diagnostic cerebral angiograms
- Qualifying prerequisite: 20 carotid / vertebral stents

Specialty Curriculum- Specialty pathway

- Any applicants interested in pursuing AISI intervention must have completed prior clinical residency training to be Board Certified or Board eligible in any of the following fields
  - Neurosurgery, Neurology, Radiology, Cardiology, Surgery

AISI Fellowship Training

- **Fellowship training in AISI should consist of a period of 12 continuous dedicated months during which the trainee has the opportunity to perform a large number of diagnostic cerebral angiograms and administer pharmacologic and endovascular therapies for acute ischemic stroke.**

AISI Fellowship Training

- **Basic arterial and venous angiographic anatomy of the brain, spinal cord, head, neck and spine** including collateral anastomoses, anatomic variants and modifications induced by disease processes.
- **Cerebral and spinal blood flow and its physiology.**
- **Pharmacologic agents**
  - Contrast materials
  - Sedatives and anesthetics
  - Analgesics
  - Thrombolytics
  - Antiplatelet agents
  - Antithrombotics
  - Vasoactive agents including vasopressors and vasodilators

AISI Fellowship Training

- **The technical aspects of AISI including:**
  - Arterial and venous access techniques
  - Catheter systems, nomenclature, and selection
  - Treatment of acute cerebral ischemia
  - Complications of endovascular AIS procedures and their management
  - Extra and Intracranial revascularization for atherosclerotic disease or dissection encountered during AISI
  - Administration of intravenous thrombolytic therapy

AISI Fellowship Training

- Periprocedural follow-up
- Patient evaluation and decision making
- Neurointensive Care
- Long-term follow-up

AISI Fellowship Training
Core Competency Requirements

- A minimum of 100 ‘interventional’ procedures as primary operator

Advanced NES Fellowship Training
Core Competency Requirements

- 25 extracranial stent placements
- 30 acute ischemic stroke treatments
- 10 intracranial infusions (e.g. vasospasm, stroke)
- If a candidate is unable to complete the required 100 interventions during the 12 months, there training must be extended to accomplish this requirement (Opportunity for collaboration between different institutions to accommodate these requirements).

Conclusion

- We don’t know the numbers 90,000-300,000
- Without question the number is going to be far greater than intracranial aneurysms, AVMs and AVFs combined
- Perhaps we need to be proactive about a palatable solution which allows us to preserve the expertise required to treat hemorrhagic disease while delivering 24/7 emergent care for acute ischemic stroke as close to the patient as is reasonable????

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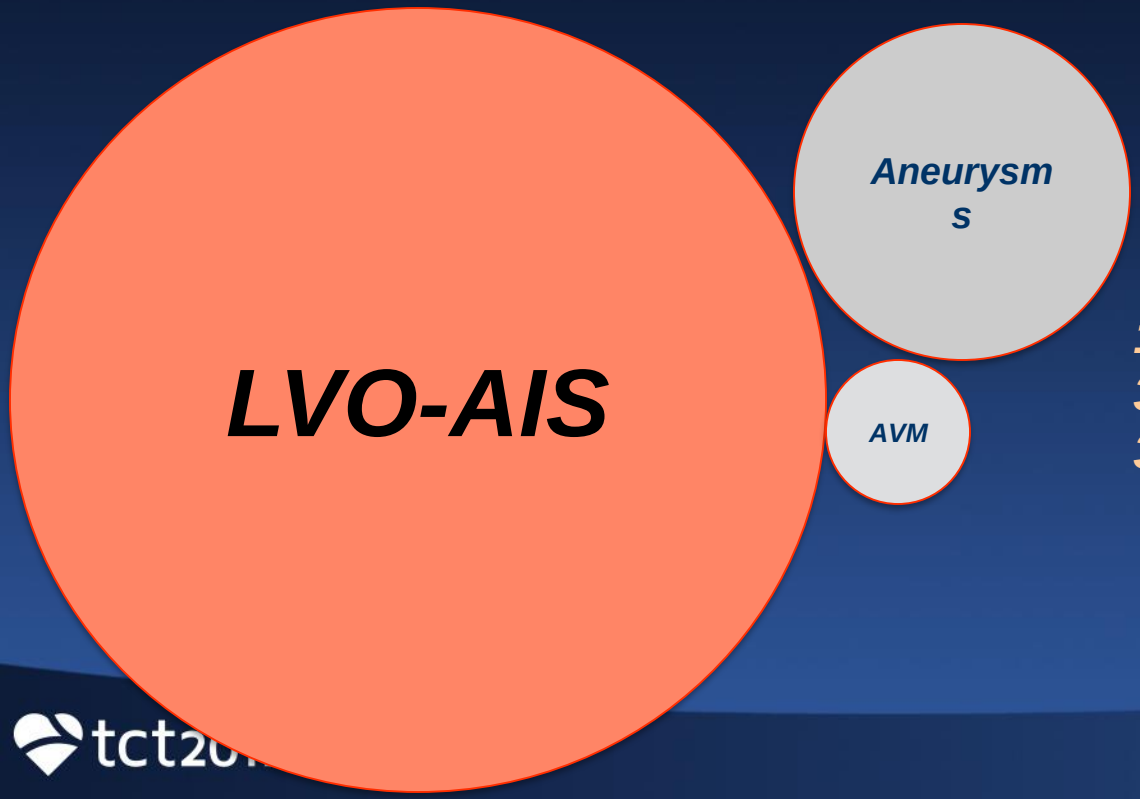

We will double in 5 years

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Future

- **Multidisciplinary Teams to allow coordinated care for acute ischemic stroke as close to patient mirroring STEMI care without abolishing expertise for hemorrhagic stroke**
  - **Neurosurgeon**
  - **Neurologist**
  - **Neuroradiologist**
  - **Cardiologist/vascular surgeon/interventional radiologist?**


Thank you!
Questions?