ESC Heart & Brain Workshop

Innovation: The Future of Stroke Treatment North American and Personal Perspective

Supported by Bayer, Bristol-Myers Squibb and Pfizer Alliance, Boehringer Ingelheim, Daiichi Sankyo Europe GmbH and Medtronic in the form of educational grants. The scientific programme has not been influenced in any way by its sponsors.



Stroke: Next Horizon in Medicine The Game Has Changed

Major Opportunity; Major Challenges

INNOVATION is Key

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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

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit1

Company

- Toshiba, Medtronic, Microvention
- None
- Claret, Boston Scientific, Medina, Ostial, Apama, Ocular, Silk Road, TSP
- None
- None
- None
- None



16 Million Strokes per Year World wide Patient Outcomes • 1/3 recover • 1/3 die • 1/3 destroyed



Until 2015 All we had was tPA

- FDA-approved stroke treatments(up to 2016)
 - 1) IV tPA
 - Time constraints
 - 22 exclusion criteria
 - Ok for small distal vessels, not LVO
 - ~60% dead or disabled at 60 days

Smith et al: Stroke 36:1432-38, June 2005



Can Stroke be Reversed? Y E S !!





Nothing in Medicine Matches the Staggering Change... From Severe Stroke One Minute to Normal the Next





ESC

Council

Stroke



What's the Catch?



Time IS Brain



We are approaching coronary reperfusion rates, BUT... The clinical results (MRS) are not so good

Trends in complete reperfusion rates in coronary and cerebral reperfusion trials





Saver JL, Stroke 2013;44:270-277



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 from 2015: If we can reopen a blocked brain artery ... Within 2 hours:

-Recovery rate is 90% !!

After 6 hours:

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





Extending the Time Window

DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention

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,
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J.L. Saver, and T.G. Jovin, for the DAWN Trial Investigators*



CT perfusion-based patient selection Is the Brain Viable??



Patient 1: has "penumbra" and likely to benefit from intervention



Patient 2: has volume loss (*arrow*) and no "penumbra"



Co-primary endpoints



NNT for 90-day functional independence = 2.8



*Similar to p<0.0001



Amazing Parallels

Brain is much more sensitive to ischemia



Acute Ischemic Stroke Care Delivery

Best Model = Myocardial Infarction (stemi)

- "Time is Brain" >>> "Time is muscle"
- Rapid Revascularization is the goal
- How can we achieve Revascularization in < 2 hours??
 - Treatment location close to onset !!!
 - STEMI model- mandated door to revascularization times



Stroke Demographics

Patients close to a Comprehensive Stroke Center are in luck OTHERS ARE NOT

- >50% population in towns with < 30,000
- Most "Stroke Centers" are NOT Comprehensive
 - Transfer times are long
- Comprehensive Stroke Centers (CHS)
 -rare in cities with < 150,000



Why NOT Train Many More Neurointerventionalists ?

Not enough work in small towns Where they need to be "Short transfer times" are a myth



16 Million Acute Ischemic strokes worldwide 30-40% amenable to clot removal ??? 24/7/365 Comprehensive Stroke Centers

TIME IS BRAIN...2 Hours!!!

Many more physicians needed... Where will they come from??

New stroke Interventionists In existing hospitals



ICCA in Warsaw Poland April 20-21

Horst Sievert

How we do Stroke training



It's All About Technology



Access

Getting to the clot Safely removing it





Innovation: Devices Evolution of stroke devices





And Practice...





Mentice Endovascular Simulation -



Any Interested MD with catheter skills can learn to do this

And create a Multidisciplinary Stroke Team

Population Health Demands a Solution *If we don't do it... someone else will*



Another possibility... What Do Cardiologists Do All Day?

Fix narrowed and blocked arteries

... on **Awake Patients** ... on a **Moving Target**!!



Infrastructure for the provision of emergent endovascular care exists



Cardiac centers in most cities Cardiac centers have the necessary tools

Acute stroke intervention techniques -clot removal, angioplasty etc -Similar for other interventionists

Training is absolutely necessary but...

-Better technology will shorten learning -Training programs can be developed



For rural areas and smaller cities: a New Paradigm

Retrieve the clot immediately and then ship to a major neuro center If necessary

i.e. Get the artery open... First !!





The Public Health Urgency Created by the Success of Mechanical Thrombectomy Studies in Stroke

Authors

L. Nelson Hopkins MD¹⁻⁴ and David R. Holmes Jr MD⁵



INNOVATION IN STROKE CARE



Collisions ... Collaboration ... Innovation



Impact of Cardiovascular Disease and Stroke

- 1 in 3 adults (81.1 million in US) live with 1 or more types of cardiovascular disease.
- Leading causes of death and disability in the world
- Hundreds of billions of \$\$ economic loss every year.



Neuro, Cardiac, Peripheral

Same Diseases Same Arteries -Vascular highway Similar Tools

Why are we not together?



Innovation *Building a Better Future for Stroke*

Systems of Care

Technology

A North American Perspective



Stroke is a Complex Public Health Issue



Time Really IS Brain!! Huge Public Health Challenges

Challenges

- Patient & Physician awareness
- Inertia
- Cataclysmic specialty shift
- Reimbursement
- Man Power
- Systems of care
- Technology
- SPEED to treatment goals:
 - <u>Onset revascularization < 2 hours</u>
 - Home to ER door ~ 1 hour
 - ER Door CT scan-- needle ~ 30 minutes
 - Needle to Revascularization ~ 30 min





☎ ☎ Gates☎ ☎ Vascular Institute

Clinical and Translational Research Center

Iniversity at Buffalo, The State University of New York

Jacobs Institute

875 Ellicott Street

JACOBS INSTITUTE





Innovation in Systems of Care

New Infrastructure





Why a Vascular Center in Buffalo?

U.S. Stroke Belt Why Buffalo?



Source: US Census Bureau Postcensal Population Estimates (IDC9 430-438.9))













Number One Crippler and Killer Heart Head Legs

Vascular Disease Specialists Work in Silos





Goal #2: Change the Treatment Paradigm





Future Vascular Care Delivery?

Goal #3: Build an Innovation Center



COLLISIONS. COLLABORATION. INNOVATION.

Independent Center for Innovation in Medicine



How the building was conceived ... **Multidisciplinary Collaboration** Yazdani Studios & Jacobs Family



FAILURE ANALYSIS ADVISORY COUNCIL (FAAC) JACKSON HOLE, WYOMING Cardiology, Radiology, Vascular Surgery, NS, Vascular Med

FINDING Synergies for Better Patient Care



Clinical & Architectural Vision...

Vascular Center of the Future (25 Yrs)



Yazdani "Sandwich" Design Fits Vision Meat = Jacobs Institute



Gates Vascular Institute

NAL OF STREET, STREET,

Gates Vascular Institute \$300M 1 Acre Floorplate

Vasc OR's

Emergency

Cath Labs

Jacobs Institute i2R

Hotel Hotel Hotel Hotel

NY AL

-enter

VALUE AND DE



Fourth Floor- 15 Cath Labs on One 1-Acre Floor Plate









Jacobs Institute i2R



Innovation in Med Tech







The Usual Innovation Pathway First Steps: Idea Evaluation & Raise \$\$\$ *Friends, Family, Angels, VC*



i2R Shortcut



Innovation Pathway Next Steps...Get to Proof of Concept







First "Valley of Death" IDEA TO PROOF OF CONCEPT

- 1-2 years
- 1-2 Million
- High energy
- Grit
- <u>90+% Failure Rate</u>



Jacobs Institute i2R Concept

i2R "Idea to Reality" Center = Idea to Proof of Concept Improving the Process ... Avoiding the 1st Valley of Death

Innovation Funded by Philanthropy in an <u>Independent</u> Not for Profit Environment In the heart of a major clinical and research complex Focus = Vascular Disease



- i2R = Nascent idea to commercially ready product
- No up front cost for the Inventor...
 - JI equity or royalties if successful in the marketplace (5-10 years)
 - Failure... NO COST to the inventor
 - Success... JI gets minor equity stake (5-8%)
 - Assistance with placement in an Accelerator







Make a Prototype





Testing ... 3D patient specific vascular models









Getting to Proof of Concept

Toshiba Stroke and Vascular Research Vivarium Animal Models



ESC Council Stroke



- Want to be part of it
- Companies donate equipment
- Trainees become ambassadors



OPPORTUNITY

Never a Better Opportunity for Buffalo

You'll always

miss 100%

of the shots

you don't take.



an actual drawing, handed to a flight attendant on a Quantas flight by an 8 yr old girl

0000000 -7dear Captain My name is Micola im " a years old, this is my first flight but im not scared. I like to watch the clouds go by. My mum says the crew is nice. I think your plane is good. thanks for a nice flight dan't fyck up the landing LUV Micola XXXX



Innovation The Future of Medicine...and Neurosurgery

