Delivering Acute Stroke Therapy in the Pre-Hospital Environment in Houston, Texas, U.S.A.

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Disclosures

- Funding/donations/support:
  Genentech
  Covidien
  Zoll
  In Touch
  Frazer Ltd
  Various Donors
IV TPA 0.9 mg/kg over 1 hr (90 mg max.); 10% bolus over 1 minute

NINDS STUDY 1995 –POOLED DATA 622 PTS- TTT VS FAV OC
Problem: ED Door to Needle Times are Too Slow
Of > 50,000 pts treated with t-PA in the U.S., < 1% are treated within first 60 min after onset.

Fonarow et al—GWTG, JAMA 2014
Median CT to tPA Times by Year
(NIH-recommended time for CT to tPA is 35 mins)

Median Door to tPA Times by Year
(NIH-recommended time for Door to tPA is 60 mins)

Median Door to CT Times by Year
(NIH-recommended time for Door to CT is 25 mins)

ED Processes are too slow!!

Neurologist integration of data and decision

Registration, initial eval by ED nurses and docs

Data from UT Stroke Center.
Problem: ED Door to Needle Times are Too Slow

Solution:

• Take the ED door to the patient
• Keep the process stroke focused and simple
Of 302 patients treated within 90 minutes of onset with tPA vs placebo in the NINDS study, only 2 were randomized within 60 minutes of onset, and 41 were randomized between 60-80 minutes. The rest were randomized between 81-90 minutes.
Nation's first mobile stroke unit to bring ER to Houston patients
Mobile Stroke Unit

- Standard 12 foot ambulance
- Diagnostic Equipment
  - Portable CT scanner (CereTom)
  - Point-of-care laboratory
  - Teleradiology/Teleneurology connection
- All management is S. O. C.
Steps in Establishing the MSU
March 2013-Feb 2014

- Full time Medical Director and Project Manager take ownership
- Funding
- Purchase and buildout
- Collaborative agreements with stakeholders (UT, MHH, other CSCs, EMS)
- Policies, Guidelines and Procedures; System for accountability
- State and City inspection and licensing
- Radiation safety inspection and certification
- Insurance on vehicle and personnel
- Staffing
- Supplies and equipment
- Secure location, power, office
- EMS education
- EMS communication pathway
- HIPPA compliant grid for CT transmission
- Study protocol developed; CRFs and MOP. Grant funding sought
- IRB approval
Steps in Establishing the MSU

Funding

From March 2013– May 2014

- Successfully raised $1.8 million from community businesses and leaders

Gray Matters
Houston Mobile Stroke Unit
Steps in Establishing the MSU

Purchase and Buildout
Steps in Establishing the MSU

Collaborative agreements with stakeholders

- Support from Local EMS
- University of Texas Medical School
- All Comprehensive Stroke Centers (MHH, TMH, BSLCHI, HH)
- Houston Mobile Stroke Unit Consortium
1. Symptom onset within 6 hours AND
2. Time to arrival at CSC is less than 30 minutes AND
3. Patient has one of the following:
   a. Not alert – requires persistent, strong or painful stimulation to make movements or talk
   b. No or very minimal movement of one arm or hand
   c. Intubated

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- Call receiving Stroke Center and request CODE STROKE
- Continue algorithm during rapid transport
- DO NOT DELAY TRANSPORT TO PERFORM INTERVENTIONS
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Steps in Establishing the MSU

Communication and Technology Systems

- Dispatch Pathway Development with 3 different cities
- Houston Fire Dept. Radios and Pagers
- Dispatch numbers and phones
- Mobile Data Terminal – to track location and times
- HIPPA compliant DICOM Sharing grid for sharing CT images
Who is inside?

- Licensed Vascular Neurologist with an ACLS Certification
- Critical Care/ER trained Registered Nurse with ACLS certification
- Licensed Paramedic with ACLS certification
- Licensed CT radiology technician with BLS certification
- Telemedicine Doc!!

Steps in Establishing the MSU
BEST-MSU Study

Benefits of Stroke Treatment Delivered Using a Mobile Stroke Unit Compared to Standard Management by Emergency Medical Services

AIMS

1. Determine the logistics and clinical outcomes of MSU vs SM in the U.S.—speed, #, first hour.

2. Can MD be replaced by Telemedicine?

3. What is the Cost-Effectiveness?
Cost Projection

Cost of CT Scanner $375,000
Ambulance Retrofit $60,000
TM equipment $30,000
Cost of added paramedic and TM coverage X 5 yrs $1,000,000
Total fixed and continuing costs for 1 MSU X 5 yrs $1,465,000

Less than the cost to sustain an endovascular program!

Lifetime cost per stroke: $200,000

Therefore, cost neutral if:

1 MSU results in 7 more patients completely recovering over 5 yrs
1. All 911 calls for acute neurological deficits suspicious for stroke Last Seen Normal after 00:01 that day

2. Mobile Stroke Unit (MSU) not available:
   a) MSU or study nurse unable to reach site before EMS is ready to depart after assessing the patient
   b) MSU equipment failure
   ii) Not meeting study exclusion criteria

3a. MSU (mobile stroke unit) dispatched

4a. Clinical diagnosis of AIS confirmed ≤ 4hrs 15min Included in Study *

4b. Non-Stroke or symptoms ≥ treatment window

4c. Clinical diagnosis of AIS confirmed ≤ 4hrs 15min Included in Study *

4d. Non-Stroke or symptoms ≥ treatment window

5a. ICH

5b. ICH

5c. TPA not recommended: >4.5hrs; CT/lab exclusion

6a. TPA recommended

6b. TPA not given (refused, or other)

6c. TPA recommended

6d. TPA not given (refused, or other)

6e. TPA not given

7a. TPA treated

7b. TPA treated

7c. Only TPA exclusion criteria was time (would’ve been eligible at time of blinded assessment 4c)

8. PRIMARY OUTCOME

   Specific Aim 1: Median time from symptom onset to TPA (MSU vs. SM) and other process and clinical outcomes.
   Specific Aim 2: Agreement between a vascular neurologist (VN) remotely assessing a suspected stroke patient via TM in the MSU and in-person assessment by a VN in the MSU.
   Note: includes all patients which begin in box 4a and 4c.
   Specific Aim 3: Cost Effectiveness of MSU vs. SM (Cost Utility Analysis) measured in cost per quality adjusted life years (QALY) gained. Note: Includes all patients which begin in box 4a and 4c.

* Assessed by MSU-VN or nurse.
Dispatch by:
• Dispatch center: only if stroke pathway.

OR
• On-scene EMT (identify possible stroke → rendezvous)

OR
• We monitor EMS radio and add ourselves on
About 2-4 runs/day
1 rt-PA treatment per 7 calls

rt-PA Exclusions:
  • Time (too long or uncertain),
  • Too mild
  • Too sick
  • Mimics
    • Hypoglycemia
    • Seizure
    • Migraine
    • Psychiatric
BEST-MSU enrollments- First Two Years

- **136** Treated with rt-PA (2.7/wk, 135/yr)
- **67** More Transported (but not treated)
  - ICH
  - Sz
  - Too mild
  - Uncertain onset time
  - Other (tumor, cerv. spond.)
- Avg. on-scene time- **21 min**

- **Symptom onset to t-PA treatment**
  - **42%** 0-60 min  (vs 0% control)
  - **37%** 61-80 min  (vs 20% control)
  - **21%** 81-270 min  (vs 80% control)
Conclusions

• Pre-hospital triage and treatment will be the next quantum leap forward in speeding treatment and improving outcomes

• Before this strategy is widely implemented in the U.S., we need more data on feasibility, outcomes and costs

• These are the Aims of the BEST-MSU study
Conclusions

1. Endovascular therapy for acute stroke is here to stay
2. The first new effective treatment for stroke since tPA
3. Mobile Stroke Units may help speed and triage patients for IAT
Final Thought...

A Stroke is like a GSW to the brain...

except that we can reverse a Stroke!