


**EM TREATMENT OF ACUTE STROKE**

**Progress, Problems, Politics**


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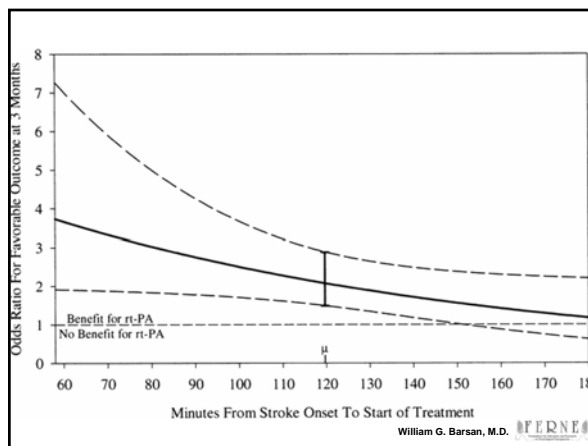
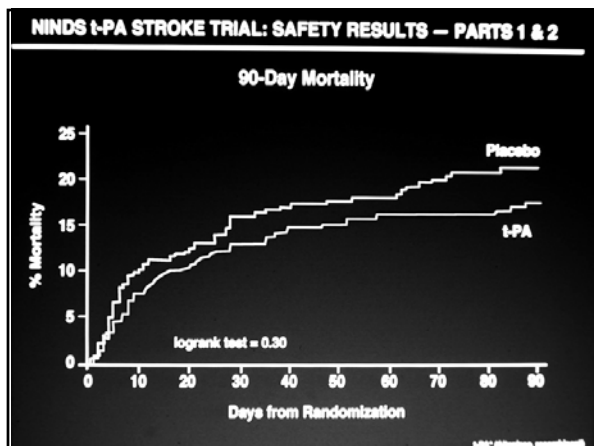
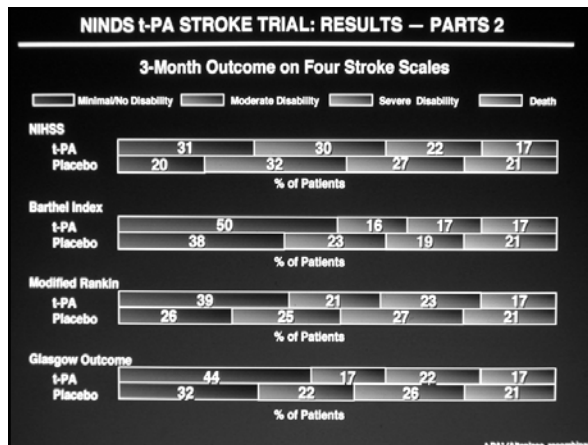
Dec 1995 - NINDS t-PA trial publication  
Dec 1996 - NINDS Symposium on Acute Stroke  
Dec 2002 - 2nd NINDS Symposium  
2003 - Only 2% of acute strokes Rx'd following t-PA

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**WHAT'S THE EVIDENCE?**


- NINDS trial
- Other trials

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**IS THERE BENEFIT AFTER  
 3 HOURS?**  
**A Pooled Analysis of the ATLANTIS,  
 ECASS,  
 and NINDS rtPA Stroke Trials**


**The ATLANTIS, ECASS, and  
 NINDS  
 Study Group Investigators**

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**Methods**

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- Original individual patient data were pooled from 6 randomized controlled trials
- Method differs from meta-analysis where individual patient data are not generally available and limited adjustment for co-variables is possible

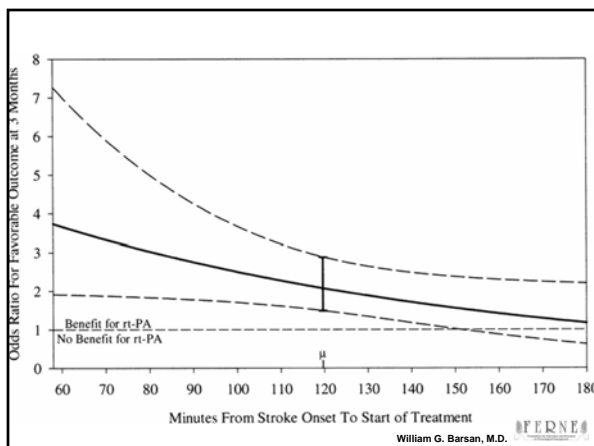
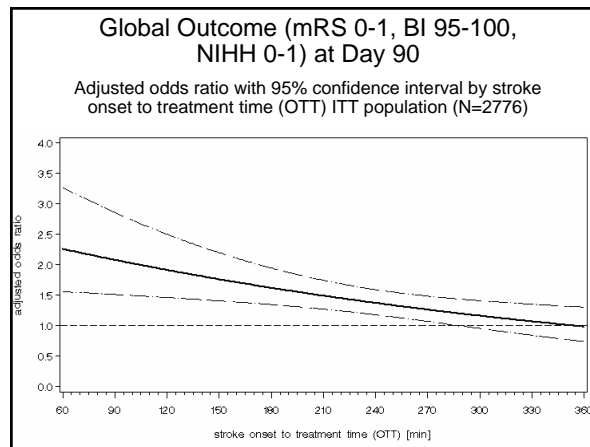
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**Results**

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- 2776 patients
- Over 300 hospitals
- 18 countries
- Median age 68 years
- Median baseline NIHSS 12

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**Results**

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**Odds Ratios for Favorable Outcome**


<u>Time Interval</u>	<u>Odds Ratio</u>	<u>95% Conf. Interval</u>
0-90	2.8	1.8 - 4.5
91-180	1.5	1.1 - 2.1
181-270	1.4	1.1 - 1.9
271-360	1.2	0.9 - 1.5

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### WHAT'S THE PROBLEM?

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- Knowledge gaps
- Teamwork issues
- Potential for harm
- Patient selection

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### KNOWLEDGE GAPS

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- Many EM programs have no formal neuro rotation
- Lack of familiarity with measurement tools
- No formal training in CT interpretations
- Question of EP's ability to dx stroke

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### EP ABILITY TO Dx STROKE

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- Variable reports
- Kothari 1996 - 100% sensitivity, 98.6% specificity
- Allder 1999 - 6/70 patients misdiagnosed (UK)
- Libman 1996 - 19% stroke "mimics"

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### TEAMWORK ISSUES

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- EMS
- Neurology support
- Radiology support
- Institutional support

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### NEUROLOGY

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- <50% neurologists treating with t-PA
- Significant number are skeptical
- Lack of reimbursement
- Lack of neurologists

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### RADIOLOGY


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- Who can interpret CT's?
- Availability of radiology interps
- What about early hypodensity?
- ECASS data
- Schriger study

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### INSTITUTIONAL SUPPORT

- Lose money on stroke DRG
- No reimbursement for t-PA
- No verification process for stroke centers
- ED's are overcrowded

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### POTENTIAL FOR HARM

- NINDS - 1/17 chance of ICH
- 10x incidence as placebo
- No difference in mortality
- *Primum non nocere*

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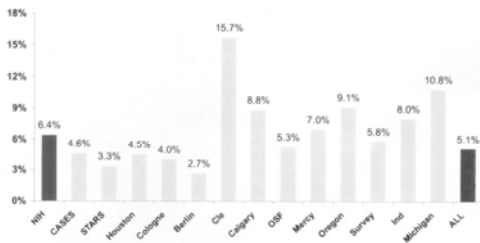




Figure 1. Symptomatic intracerebral hemorrhage rates, ordered by decreasing sample size (retrospective studies shown last).

Glenn D. Graham 2002

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### PATIENT SELECTION

- Few patients eligible for Rx
- MD's have limited experiential knowledge
- Limited numbers lead to feelings of futility
- What about mild strokes? (Canadian data)

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### POLITICS

- EP's are "in the hot seat"
- Patients expectations vs. reality
- Lack of support from others
- Concerns about litigation

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### POLITICS


- ACEP
- AAEM
- CAEP

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**ACEP**

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- “IV t-PA may be an efficacious therapy.”
- “There is **insufficient evidence** to endorse the use of t-PA....when systems are not in place to ensure that....NINDS guidelines....are followed.”
- “Decision to use t-PA....should begin at the institutional level.”

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**AAEM and ACEP, in Tacit Agreement, Question tPA for Stroke**

*The specialty groups say insufficient evidence exists to use tPA when EDs cannot ensure that the NINDS criteria are followed*

By Ruth SoRelle, MPH

**F**or once, in the frequently adversarial and split world of emergency medicine, the two houses of the medical specialty—the American College of Emergency Physicians and the American Academy of Emergency Physicians — almost agree.

And what they agree on is that they do not know the extent to which the clot-buster called tissue plasminogen activator should be used in the immediate treatment of stroke.




that said tPA “may be an efficacious therapy for the management of acute ischemic stroke if properly used incorporating the guidelines established by the National Institute of Neurological Disorders and Stroke (NINDS).” However, they noted the systems to follow the guidelines frequently do not exist in many hospitals or regional systems.

“There is insufficient evidence at this time to endorse the use of intravenous tPA in clinical practice when systems are not in place to ensure that the inclusion/exclusion criteria

**AAEM**

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- Commentary “We are aware of lawsuits against EP’s.”
- “This statement should assist in such matters.”
- “The Board’s primary constituency, the EP at the bedside has not been convinced by those promoting this therapy.”
- “There needs to be recognition that the circumstances....resources....cannot be easily duplicated by the average center.”

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**AAEM**

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- Efficacy concerns
  - 0-90 patients skewed results
  - Differences in stroke severity between t-PA and placebo
- Safety concerns
- Applicability concerns
  - mimics
  - CT interp

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**AAEM**

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- “Objective evidence....insufficient to warrant classification as standard of care.”
- “Physicians advised to use their discretion.”


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**CAEP RECOMMENDATIONS**

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1. “Only radiologists or neurologists....should provide interpretations of CT scans.”

Based on data from ECASS, Schriger

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### **CAEP RECOMMENDATIONS**

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2. "Stroke thrombolysis....limited to centers with appropriate....resources. Emergency physicians....should not be primary decision makers. Neurologists should be directly involved."

Concerns about EP ability to make diagnosis

### **CAEP RECOMMENDATIONS**

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3. "Administration of thrombolytic agents....should be carried out only in the setting of an approved research protocol or formal clinical practice protocol."

Concern about protocol violations

Cleveland data

### **WHERE DO WE GO FROM HERE?**

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- Validation of data from NINDS
  - in process
  - need for further study?
- Recognition that early treatment is beneficial
- Implementation of recommendations from 2002 NINDS Symposium
- Further efforts to improve safety
- Establish the time limits of efficacy
- Investigate the role of interventional treatments

**Questions?**