

The Upcoming ACEP Clinical Policy on ED Ischemic Stroke Patient Care: What Questions and What Implications for ED Patient Care?

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Disclosures

- Astra Zeneca, King Pharmaceuticals, NovoNordisk, UCB Pharma Advisory Boards
- Eisai Speakers' Bureau
- Chair, ACEP Clinical Policies Committee
- Executive Board, Brain Attack Coalition
- Executive Board, Foundation for Education and Research in Neurologic Emergencies

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Case study: True story: Part I Community Hospital, Minnesota

- A 60 yo man experienced a 10 minute episode of numbness in his right face and left hand.
- When he arrived in the ED, all symptoms resolved
- PMH: HTN on atenolol, DM on metformin.
- PE: BP 140 / 90; HR 60; glucose 130. Alert and appeared well. He had no bruit
- Neurologic exam completely normal
- ECG was normal sinus rhythm.

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Case study: True story: Part I Community Hospital, Minnesota

- Could this be a TIA?
- Is this patient at high risk of having a stroke and should he be admitted to the hospital?
- If this patient is discharged home, should he be placed on an anti-platelet medication?

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Case study: True story: Part II Community Hospital, Minnesota

- Sent home on no new medications
- Scheduled appt to see his internist in 72 hours.
- 24 hours later while watching TV with his wife he developed a right face droop, left arm and leg weakness, difficulty speaking and swallowing (Wallenberg's syndrome).
- EMS was called and the patient arrived in the ED one hour after onset of symptoms.

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Case study: True story: Part II Community Hospital, Minnesota

- The ED was busy and he was not seen for 55 minutes.
- It took 45 minutes for a head CT to be done; results were ready 15 minutes later (2 hours and 55 minutes from symptom onset).
- The patient did not receive t-PA
- 2 years later he had significant disability, unable to live independently.

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Case study: True story: Part II Community Hospital, Minnesota

- Would obtaining carotid dopplers and a cardiac echo have changed the outcome in this case?
- Would starting the patient on aspirin at the time of the first visit have changed outcome?
- Should this patient have received t-PA

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What are the questions to be answered in the new ACEP stroke patient clinical policy?

- When the NINDS criteria are met, is IV t-PA safe and effective for acute ischemic stroke presenting within 3 hours of symptom onset?
- Is there a subset of patients presenting with a TIA that can be effectively and safely managed as outpatients?

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What are the questions to be answered in the new ACEP stroke patient clinical policy?

- Initiative started with AAN in 2005
- Three ACEP members, 3 AAN members
- Evidence based methodology
- Initial MEDLINE search had over 3000 citations
- Approx 200 abstracts reviewed
- Approx 60 articles being graded

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Description of the Process

Strength of evidence (Class of evidence)

- **I:** Randomized, double blind interventional studies for therapeutic effectiveness; prospective cohort for diagnostic testing or prognosis
- **II:** Retrospective cohorts, case control studies, cross-sectional studies
- **III:** Observational reports; consensus reports

Strength of evidence can be downgraded based on methodological flaws



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Description of the process:

Strength of recommendations:

- **A / Standard:** Reflects a high degree of certainty based on Class I studies
- **B / Guideline:** Moderate clinical certainty based on Class II studies
- **C / Option:** Inconclusive certainty based on Class III evidence



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Description of the Process

- Different societies use different classification schemes which may impact applications of the recommendation
- ACEP Class I evidence must have high quality support; AHA allows Class I evidence to include "general agreement that a given procedure or treatment is useful and effective"
 - AHA Class Ic recommendation is based on consensus of experts



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Evidence Based Guidelines: Limitations

- Different groups can read the same evidence and come up with different recommendations
- Outcome measure can be major factor
 - MTBI
 - t-PA in stroke (48 hour vs 3 month outcome)



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Why were these clinical policy questions chosen?

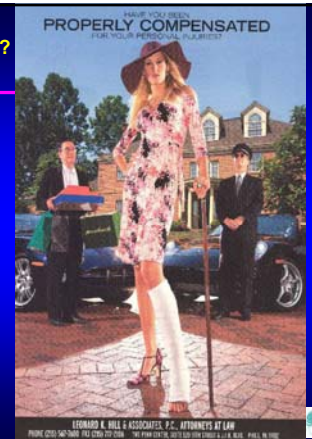
- NINDS trial controversy
- Policy statements from the four North American EM societies
- Impact of the stroke center initiative
- Implications of patient disposition regarding TIA patients



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Is there a standard of care?

- Canadian Association of Emergency Physicians
- American Academy of Emergency Medicine
- Society for Academic Emergency Medicine
- American College of Emergency Physicians



Canadian Association of Emergency Physicians

- June 2001
- Concern over single study and public expectations
- Discusses:
 - Problems with CT interpretation
 - Problems with timely treatment
 - Cleveland experience
- “Further evidence is necessary to support the widespread application . . . Outside of research settings”

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American Academy of Emergency Medicine

- Cites methodological flaws of the NINDS trial
 - Greater benefit was shown in the 0-90 group: Selective enrollment skewed participants to earlier treatment which is not reality of clinical practice
 - Stroke severity in the group treated in the later time group was greater in the placebo group biasing results in favor of t-PA
- “(the evidence supporting) t-PA for acute ischemic stroke is insufficient to warrant its classification as standard of care”.

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SAEM: February 7, 2003

- Currently insufficient data exist to mandate thrombolytic therapy as the standard of care
- SAEM endorses the creation of a national research initiative
- Overcrowding, lack of timely access to expert interpretation of imaging studies and other barriers exist
- Although advocacy of stroke centers is well-intended, it is premature to stratify acute care hospitals. Such hierarchical stratification should await outcomes data demonstrating the overall systems benefit of such centers.

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American College of Emergency Physicians

- IV t-PA may be an efficacious therapy for the management of acute ischemic stroke if properly used incorporating the guidelines established by the NINDS
- There is insufficient evidence at this time to endorse the use of IV t-PA in clinical practice when systems are not in place to ensure that the inclusion/exclusion criteria established by the NINDS guidelines for t-PA use in acute stroke are followed. Therefore, the decision for an ED to use IV t-PA for acute stroke should begin at the institutional level with commitments from hospital administration, the ED, neurology, neurosurgery, radiology, and laboratory services to ensure that the systems necessary for the safe use of fibrinolytic agents are in place.

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EM Position Statements

- Emergency physicians were concerned of being isolated care providers in acute stroke with the inherent liability
- The EM community was skeptical of the NINDS trial's external validity
- The EM community was not convinced that the risk/benefit of t-PA merits its use in all settings

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General EM Community View ACEP Survey on tPA Use

- 1105 practicing EM Physicians responded to survey
- 40% responded not likely to use tPA
 - 65% due to risk of ICH
 - 23% due to lack of efficacy
 - 12% due to both
- Use of tPA associated with:
 - Previous use
 - Female gender

Brown, *Ann Emer Med* 2005;46:56-60

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NINDS Data Re-analysis Committee

- **Kjell Asplund MD**
Umeå University, Umeå, Sweden
- **Lewis R. Goldfrank MD**
New York University, New York, USA
- **Timothy Ingall MD**
Mayo Clinic Scottsdale, Arizona, USA
- **Vicki Hertzberg PhD**
Emory University, Georgia, USA
- **Thomas Louis PhD**
Johns Hopkins Bloomberg School of Public Health, Maryland, USA
- **Michael O'Fallon PhD**
Mayo Clinic Rochester, Minnesota, USA

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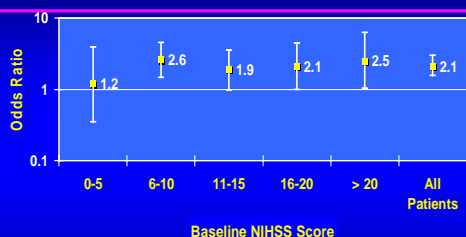
Committee Methods

- Concerns assessed included:
 - Baseline NIHSS imbalance
 - Time from symptom onset to treatment
 - Risk factors for intracerebral hemorrhage
 - Predictors of favorable outcome
- The analysis was adjusted for treating hospital, time to treatment, age, baseline NIHSS, diabetes

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Baseline NIHSS - Specific Odds Ratios



- Test for equal OR's: Chi-square (4 DF) = 1.70; p = 0.79
- Insufficient evidence was found to declare a difference in treatment effects (OR's) across the five strata

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ICH Analysis

Risk Factors for ICH:

- Baseline NIHSS > 20
- Age > 70 years
- Ischemic changes present on initial CT
- Glucose > 300 mg/dl (16.7 mmol/L)

# of Risk Factors	# of patients treated with t-PA (n=310)	# of Symptomatic ICH's (# of placebo patients with ICH)	Percentage (%)
0	114	2 (1)	1.8
1	144	7 (1)	4.9
> 1	52	11	21.2

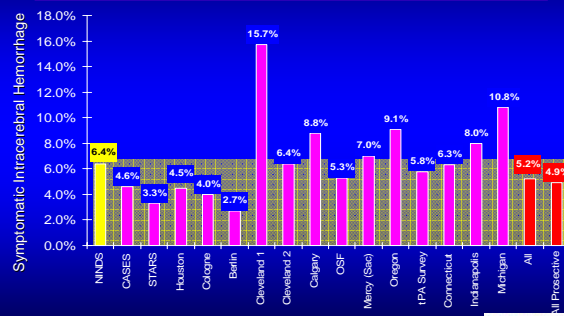
NINDS Re-analysis

- Initial NIHSS <20, no diabetes, age <70, normal CT predict best outcome from t-PA and low risk for ICH
- The committee concluded, despite an increased incidence of symptomatic intracerebral hemorrhage in t-PA treated patients and subgroup imbalances in baseline stroke severity, there was a statistically significant benefit of t-PA treatment measured by an adjusted t-PA to placebo global odds ratio of 2.1 (95% CI: 1.5-2.9) for a favorable clinical outcome at 3 months

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Overall Safety of tPA in General Clinical Practice



(Graham, Stroke 2003; 34:233-250)

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TIA and Stroke

- Johnston, et al. JAMA 2000; 284:2901
 - Follow-up of 1707 ED patients diagnosed with TIA
 - Stroke rate at 90 days was 10.5%
 - Half of these occurred in the first 48 hours after ED presentation
- Gladstone, et al. CMAJ 2004; 170:1099-1104
 - 371 consecutive patients with TIA
 - 8% ischemic stroke in 30 days; ½ within 48 hours
 - 12% in motor deficit group

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Patients at highest risk for stroke after TIA

- Diabetes
- Duration > 60 minutes
- Focal weakness
- Validated in 2908 patients (Oxfordshire & California)

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What implications might this policy have for EM practice and standards of care?

- “Standard of care” is generally defined by what is done in your community
- Clinical policies are changing the definition to some degree by creating national recommendations
- Clinical policies / practice guidelines are being used by the legal community
- This policy will assist decision making but will not in and of itself create a standard

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Deposition of Dr. X in a case of missed meningitis

Q. Do you read the policies of the American College of ER physicians?

A. I don't recall reading that policy. Is it something published by ACEP?

Q. Yes.

A. I don't recall reading it.

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Deposition of Dr. X in a case of missed meningitis

Q. So if toradol relieves a headache, does that cause you to believe the patient does not have meningitis in a patient in whom you are suspecting meningitis a possible cause of their headache

A. It's an indicator that would decrease the likelihood.

Q. If toradol relieved their headache, would you rely on that as a factor in ruling out meningitis?

A. It is part of the package.

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Clinical Policy: Critical issues in the evaluation and management of patients presenting to the ED with acute headache. Ann Emerg Med 2002; 39:108-122

- Does a response to therapy predict the etiology of an acute headache?
 - Level A recommendation: None
 - Level B recommendation: None
 - Level C recommendation: Pain response to therapy should not be used as the sole indicator of the underlying etiology of an acute

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What are other questions that someday need to be addressed in future clinical policies?

- What are anti-platelet strategies for patients who have had a TIA?
- What are ideal blood pressure targets in patients with acute ischemic stroke?
- What are best management strategies for patients with hemorrhagic stroke?
- What are the indications for intra-arterial t-PA or for clot retrieval devices?

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Case Outcome:

- Both of the emergency physicians and the hospital were accused of negligence
 - Failure to recognize TIA
 - Failure to evaluate for TIA
 - Failure to treat for stroke prophylaxis
 - Failure to arrange timely follow up
 - Failure to provide timely evaluation of stroke
 - Failure to administer t-PA
- EPs names were dropped and the hospital settled the case out of court

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Conclusions / Key Points

- It is important to understand the methodology used in creating a Clinical Policy / Practice Guideline
- Clinical policies can be valuable resources in distilling the literature and assisting in clinical decision making
- The upcoming ACEP / AAN Clinical policy will have impact on the management of TIA and on acute ischemic stroke - it should be available by the end of 2007

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Questions?

www.FERNE.org

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