CLINICAL POLICY: Use of Intravenous tPA for the Management of Acute Ischemic Stroke in the Emergency Department

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Policy statements and Clinical Policies are the official policies of the ACEP

- Developed by a joint panel of the ACEP (American College of Emergency Physicians) and AAN (American Academy of Neurology)

- Evidence-based recommendations for clinicians
CRITICAL QUESTIONS:

1. Is intravenous tissue plasminogen activator (tPA) safe and effective for acute ischemic stroke patients if given within 3 hours of symptom onset?

2. Is intravenous tPA safe and effective for acute ischemic stroke patients if treated between 3 to 4.5 hours after symptom onset?
The ACEP and AAN joint panel was formed to produce a clinical evidence-based guideline on the use of tPA for acute ischemic stroke. Recommendations were based on extensive review of literature (1,140, of which 330 were selected for review and grading).
Articles received a final grade (Class I, II, III) based on design and quality of study.

Clinical findings and strength of recommendations were then made according to the following:

– Level A recommendations
– Level B recommendations
– Level C recommendations
The GOAL of the panel was to provide evidence-based recommendations when the medical literature provides enough quality information to answer a critical question.
In 1996, the FDA approved intravenous (IV) tPA as a treatment for acute ischemic stroke.

Reaction to the availability of tPA has ranged from skepticism to unbridled enthusiasm.
National Institute of Neurologic Disorders and Stroke (NINDS)

- NINDS tPA Stroke Study Group - 1995
- Randomized controlled trial showing that human recombinant tPA improved outcomes after ischemic stroke
- Two parts to the Study
- This publication led to FDA approval.
ADDITIONAL TRIALS

- European-Australasian Acute Stroke Study (ECASS) Part I and Part II

- Alteplase Thrombolysis for Acute Noninterventional Therapy in Ischemic Stroke (ATLANTIS)

- Echoplanar Imaging Thrombolytic Evaluation Trial (EPITHET)
NINDS in addition to analysis of data from all other studies showed that outcomes WERE significantly improved for patients treated within the three hour window.
QUESTION 2—YES, BUT...

- Meta-analysis of all of the studies suggested that tPA’s benefit DIMINISHED over time but remained significant up to 4.5 hours after onset of symptoms.

- Safety and efficacy were shown.

• TIME IS BRAIN !!!
WHAT WERE THE CONCERNS FOR CLINICIANS?

- Does the data from controlled clinical trials equate to mainstream clinical practice?

- Safe Implementation of treatments in Stroke-International Stroke Thrombolysis Registry (SITS-ISTR) 2002-2010, >2000 patients were studied to evaluate the 3 to 4.5 hour outcomes.

- Safety and efficacy were demonstrated.
Hospitals must have systems in place for treating stroke patients.
- Rapid and accurate diagnosis
- Rapid access to lab, brain imaging and accurate image interpretation
- Protocols for drug administration, monitoring
- Active blood pressure management
- Treatment of hemorrhagic complications
If infrastructure is not available, establish protocols for transferring patients to a facility that can treat patients with acute ischemic stroke.

Ongoing quality assurance program
• BRAIN ATTACK COALITION and the CANADIAN STROKE CONSORTIUM recommend not only neurologists but other physicians with expertise and experience in stroke care, including ER physicians.
In addition, this policy statement also addresses the management of patients through telestroke programs.
Accumulated data show that this model produces results similar to those obtained by onsite consultation.

A randomized controlled trial showed that more accurate decisions were made when video consultation, rather than telephone consultation, is used.
CAUTIONS

- SEVERE CLINICAL DEFICITS
- CT HYPODENSITY IN A LARGE PORTION OF THE MCA TERRITORY
- ADVANCED AGE
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Annals of Emergency Medicine, Volume 61, NO. 2: February 2013