
IEME/FERNE
Case Conference:
*Legal Issues in the ED
Management of Acute
Ischemic Stroke Patients*

Edward P. Sloan, MD, MPH



ED Ischemic Stroke
Patient Management:
*Specific Recommendations to
Minimize Liability to the
Emergency Care Provider*

Edward P. Sloan, MD, MPH



IEME
**“Current Concepts in
Emergency Care”**

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Edward P. Sloan, MD, MPH



Edward P. Sloan, MD, MPH
Professor

Department of Emergency Medicine
University of Illinois College of Medicine
Chicago, IL

Edward P. Sloan, MD, MPH



Attending Physician
Emergency Medicine

University of Illinois Hospital
Our Lady of the Resurrection Hospital

Chicago, IL

Edward P. Sloan, MD, MPH



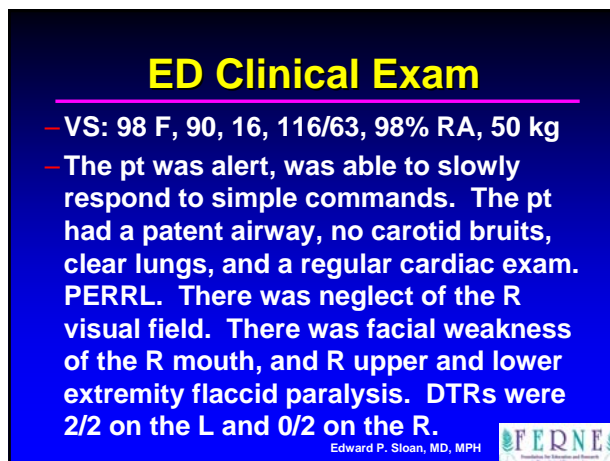
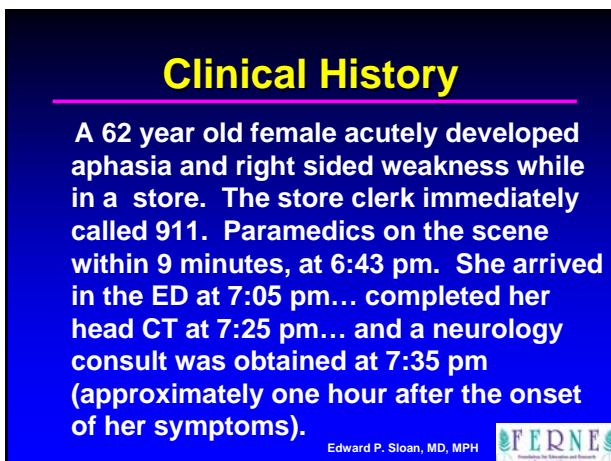
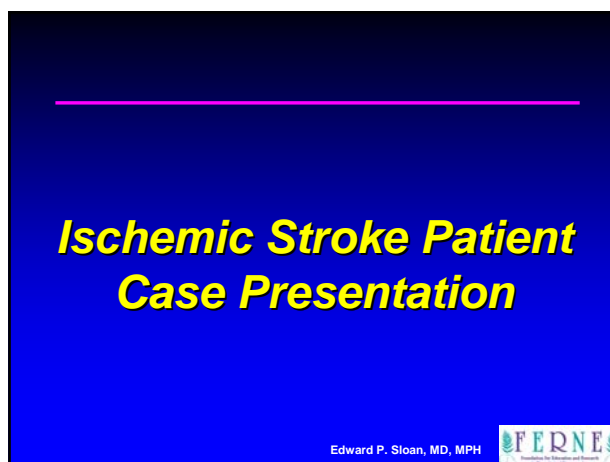
Disclosures

- ACEP Clinical Policies Committee
- ACEP Scientific Review Committee
- Executive Board, Foundation for Education and Research in Neurologic Emergencies

- No individual financial disclosures

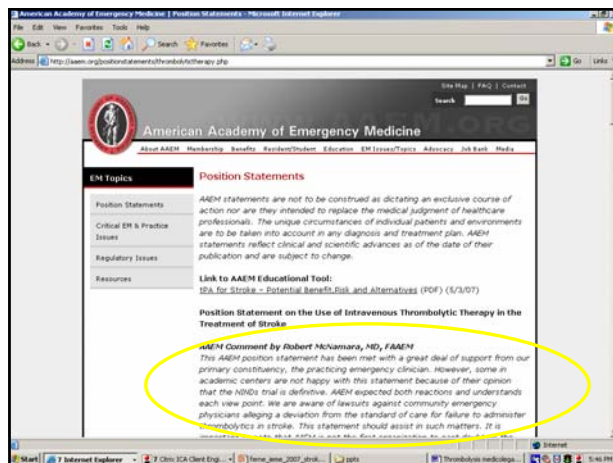
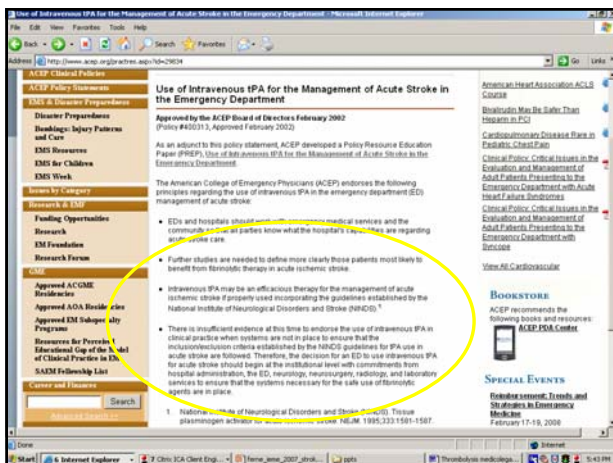
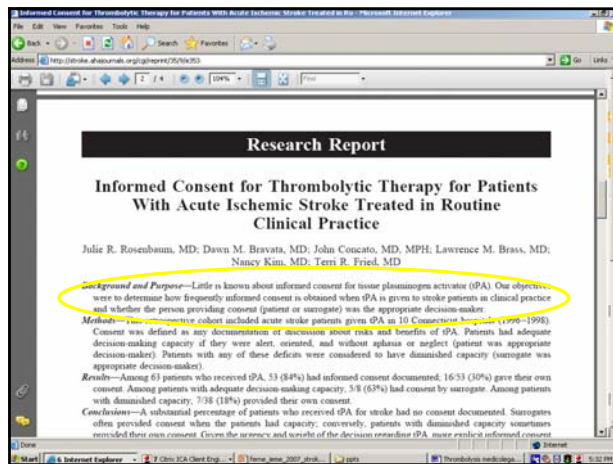
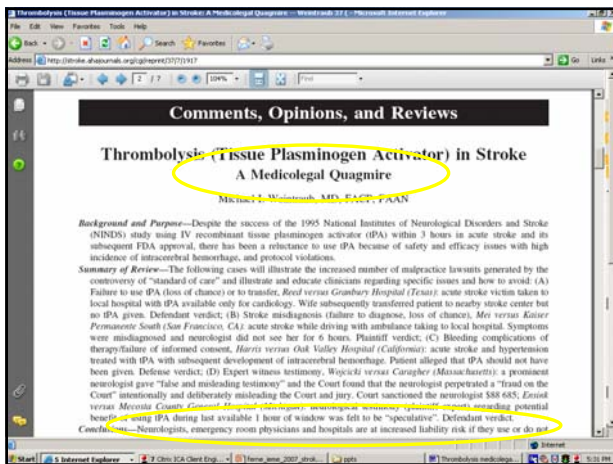
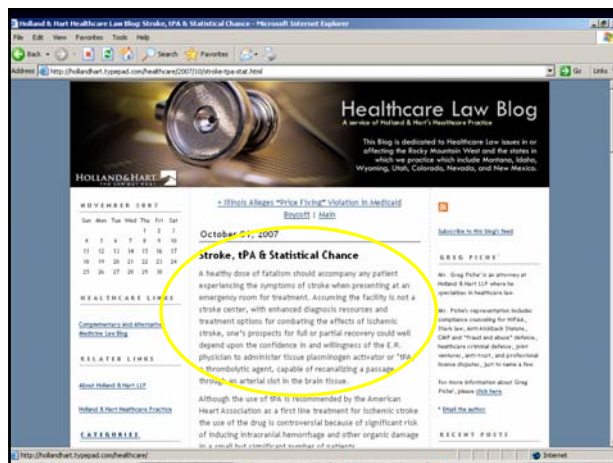
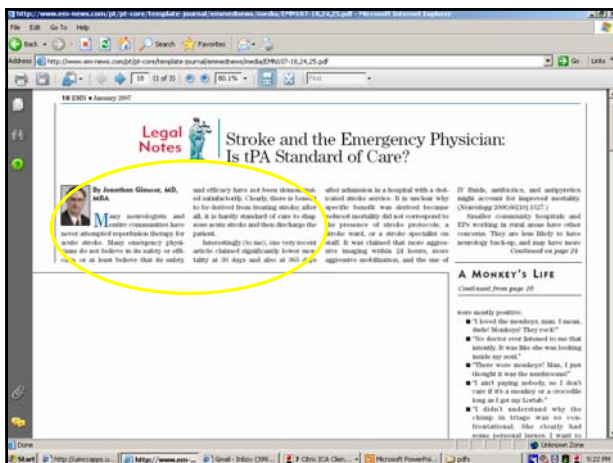
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FERNE / IEME 2007 Acute Ischemic Stroke Patient Care: Specific Recommendation for Risk Mitigation

Edward P. Sloan, MD, MPH, FACEP



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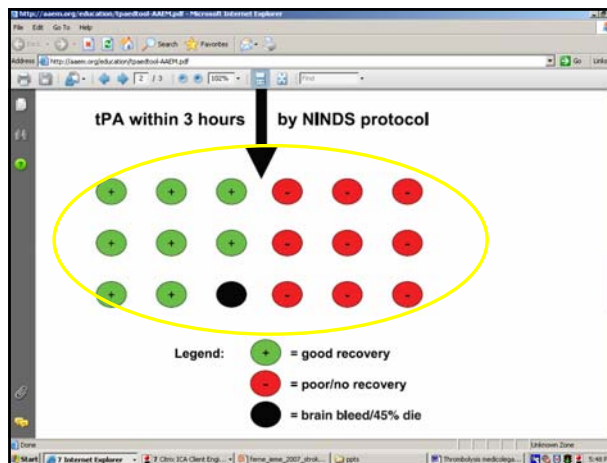
tPA for Stroke – Potential Benefit, Risk and Alternatives

Definitions
tPA stands for tissue Plasminogen Activator, a strong "clot dissolving" medicine.

Stroke occurs when an area of the brain is deprived of oxygen and nutrients because of a blocked blood vessel. Many sudden blockages are due to a blood clot, and can result in loss of function in the affected area of the brain. Common signs and symptoms of stroke include abrupt onset of one-sided weakness/numbness, and difficulty with vision, speaking, thinking or coordination. The National Institute of Health Stroke Scale (NIHSS) is a standardized way to measure the severity of a stroke on a 0-42 point scale (normal to worst).

Stroke mimic is a term used for medical problems that can present in a manner similar to stroke and not the result of a blocked blood vessel. Causes include aftereffects of seizures and migraine headaches, among others. Stroke mimics may be initially misinterpreted as a stroke.^{1,2}

Potential Benefit
The National Institute of Neurological Disorders and Stroke (NINDS) study suggested that 8 out of 18 stroke patients who receive tPA according to a strict protocol will recover by three months after the event without significant disability. This is compared to 6 out of 18 stroke patients (one-third) who recover substantially regardless of treatment.¹ See illustration on next page.



Potential Risk
As with most treatments, there are risks associated with tPA administration. Studies vary in predicting the likelihood of complications, which include bleeding into the brain, other types of serious bleeding (e.g., gastrointestinal), and death. Here is a recap of those research findings:

- The NINDS study suggested that bleeding into the brain occurred in about 1 out of 18 patients receiving tPA (specifically, 5.8%). When this occurred, there was a 45 percent fatality rate.
- Several studies suggested treatment with "clot-dissolving" medications increases the number of patients who die following a stroke.^{3,4,7,8,9}
- Subsequent studies demonstrated that using tPA more liberally than is recommended in the NINDS protocol resulted in a higher rate of intracranial hemorrhage.^{10,11,12,13}

Complications are more likely when tPA is used in patients over 70 years old, those with more severe stroke (NIHSS over 15), or those with glucose over 300 mg/dl.

Balancing Benefits and Risks and Alternatives
It is important for physicians and patients (or family members) to weigh the possibility of benefit (improved function at 3 months) against the possibility of harm (severe bleeding or death). Stroke symptoms alone are insufficient to definitely diagnose stroke and, in patients with a stroke mimic, tPA use results only in potential adverse effects without any possibility of benefit.

Alternative treatments with proven benefit for patients with stroke include aspirin and care in a specialized unit where staff members pay careful attention to a variety of basic aspects of care.^{14,15} Several other experimental treatments, including invasive de-clotting procedures, may prove to be beneficial.

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tPA for Stroke – Potential Benefit, Risk and Alternatives

Optimizing Care of the Stroke Patient

The SAEM Board of Directors developed and approved this position statement in January 2003.

Improving treatment of the stroke patient must be a priority for emergency physicians and the healthcare system. Important research needs exist in both basic and clinical science. Further, health services research is needed to identify the optimal delivery mechanisms, accounting for both benefits and burdens, when considering new therapies for stroke treatment.

Since delays in assessing medical care is one of the largest barriers to improving stroke care, research and policy directed at the education and behavior change of all citizens regarding stroke symptoms and the need for immediate medical attention is the first priority. Other aspects in need of attention include system and therapeutic strategies for care. Importantly, emergency department, radiology, and laboratory resources cannot be assumed. Overcrowding, lack of timely access to expert interpretation, ongoing studies, and other factors must also be considered. Areas of high priority is to optimize preventive strategies. Effort to minimize the risk of sustaining stroke should be similarly appreciated and investigated.

Ongoing controversies surround the use of thrombolytic therapy for acute stroke. Although evidence demonstrates the therapeutic benefit for important minority of patients, substantial increased risk of intracranial hemorrhage exists. The narrow therapeutic window and strict protocol demands make this intervention far different from other therapeutic interventions. There is little available information surrounding subgroup of patients most likely to benefit and also most likely to be harmed. Many important questions remain.

It is not yet clear whether the treatment risk is outweighed by the likely therapeutic benefit. Minimizing the complication rate must remain an important priority. The Society for Academic Emergency Medicine endorses the creation of a national research initiative, including a registry to gather outcomes data for stroke victims, whether or not thrombolytic therapy is administered. Data should include details of the care process, including timeliness and quality of the clinical interventions and adequacy of important support systems. At this time, decisions regarding thrombolytic therapy must be individualized, based on specific clinical and operational circumstances. Currently insufficient data exist to make thrombolytic therapy as the standard of care for acute ischemic stroke for all patients across all medical treatment settings.

Although advanced stroke centers is well-intended, it is premature to stratify acute care hospitals. Such hierarchical allocation should await outcomes data demonstrating clear system benefits of such centers.

The Society for Academic Emergency Medicine enthusiastically endorses efforts to optimize stroke care and prevention through ongoing scientific investigation, assessment of outcomes data, and improved education of health care providers and the lay public.

Medical Legal Risk Mitigation: An Assessment

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Risk Mitigation in EM

- High quality care always stands out as such (as does low quality care)
- If you act in a way that is systematic, straightforward, and always advances the best interests of the patient, risk is minimized for both the patient and practitioner

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Risk Mitigation in EM

- If the patient always is provided the best chance for a good outcome based on your actions, risk is minimized regardless of the actual outcome
- This approach is possible with tPA use in ED acute ischemic stroke patient care by EM physicians

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Public Perceptions

- Every person has an opinion about the potential use of tPA in acute ischemic stroke
- These people are most often not physicians or rocket scientists
- These opinions matter, establishing the standard of care
- Was proper procedure followed?

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Challenger Disaster



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Challenger Disaster

- A teacher watching the takeoff commented:
 - 'I never once had seen icicles on the space shuttle prior to take-off. It had never been freezing the night before a launch prior to the Challenger disaster'
- Not a rocket scientist, but an opinion none the less...perhaps valid, also!

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Arizona Controlled Burn



Arizona Controlled Burn



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Arizona Controlled Burn

- When asked about the fact that the controlled burn went out of control and homes were burned, the government official stated:
 - ‘These things happen...I am most interested in knowing whether or not proper procedure was followed in order to minimize the chances of this happening.’

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Translation

- Stuff happens.
- Were things done the right way, or did something happen because somebody didn't do his or her job?
- In other words, was it fated to happen or was a mistake made?
- This is always the critical question when a bad outcome occurs.

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Conclusions

- What is “appropriate” is determined by all of us who are part of this process: patients, families, officials, and physicians
- Most of the legal issues are straightforward systems issues that are seen and understood by those who do not practice EM

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Recommendations

- We, as the Emergency Medicine specialists, must take charge, lead the process, and promote excellent stroke patient care
- We must act in a way that enhances clinical practice, patient care, and patient outcomes for ED ischemic stroke patients

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The Medical Record

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MR is Like a Kevlar Vest

- It is your greatest source of protection
- It protects you such that it must always be used wisely, as is the case with police officers
- You often don't know when it protects you



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MR is Like a Seeing Device

- You see things that can only be seen as you write up the chart
- You only know fully what you know and what you must do once the record is completed
- It promotes excellence in patient care



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Specific Recommendations Regarding Documentation in the Medical Record

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Emergency Medicine Recommendations

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Stroke Pt Diagnosis

- 'The pt has symptoms that are fixed and are consistent with an acute ischemic stroke'

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Stroke Neurological Exam

- Document a systematic neuro exam, one that could be used to develop an approximate NIHSS
- 'The approximate NIHSS was 12-18, in the range that suggests that IV tPA may be of benefit as was the case in the NINDS clinical trial'

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Stroke Onset Time

- 'The ischemic stroke onset time has been confirmed in the following way, suggesting the three hour window for IV tPA has not expired'

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Stroke CT Interpretation

- 'The CT has been reviewed and has been cleared by the radiologist who is aware of the potential use of IV tPA'

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Blood Pressure Rx

- 'The blood pressure was stabilized without extraordinary intervention and was consistently less than 185/110, allowing for safe IV tPA use'

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IV tPA Informed Consent

- 'The following were discussed with the patient and family:
 - With tPA, there is a 30% greater chance of a good outcome at 3 months
 - With tPA use, there is 10x greater risk of a symptomatic ICH (severe bleeding stroke)
 - Mortality rates at 3 months are the same regardless of tPA use, because stroke is a bad disease
 - About two patients will improve for every one that develops a symptomatic ICH'

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IV tPA Informed Consent

- If you document in the medical record, state the specifics
- 'The following individuals were part of and consented to the decision to use IV tPA'
- If not, use a specific consent form with the data printed on it

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IV tPA Risk/Benefit

- 'The potential risks and benefits of the use of IV tPA were discussed with the patient and/or family and these discussions lead to the decision to treat (not to treat) with IV tPA'

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IV tPA Contraindications

- 'The stroke pt was not a candidate for IV tPA because the time of stroke onset was not conclusively determined'
- 'IV tPA was not indicated because of the presence of AFIB and an approximate NIHSS above 20'
- There were no specific ...

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NINDS Protocol Followed

- 'I am aware of the specifics of the NINDS protocol regarding IV tPA use and followed the protocol in order to maximize the likelihood of a good outcome for this patient'

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tPA Not Clinically Indicated

- 'IV tPA was NCI in this ischemic stroke patient for the following reasons:
 - Risk/Benefit profile does not suggest improved outcome with IV tPA use
 - Stroke onset time unclear
 - Pt/Family decline use
 - Systems in place do not favor its use'

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ED Systems Recommendations

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Obtain the CT Quickly

- 'The ED staff and CT techs were informed that the CT for this patient had to be expedited because of the potential use of IV tPA'

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Obtain a CT Read Quickly

- 'The CT techs and radiologists were informed that the CT reading for this patient had to be expedited because of the potential use of IV tPA'

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Obtain a Directed CT Read

- 'The CT techs and radiologists were informed that the CT reading for this patient was for the specific purpose of determining if the potential use of IV tPA was appropriate'

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Obtain Consults Early

- 'The neurologist was notified of the potential use of IV tPA prior to obtaining the head CT so that he could be present in the ED at the time of the decision to administer tPA, if indicated'

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Document Neurologist Agreement with Plan

- 'The neurologist was fully aware of the circumstances surrounding the use of IV tPA and fully concurred with the decision by the patient, family, and myself'

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Pt, Family Interactions

- 'Risks and benefits were fully explored with the patient and relatives, leading to the decision to use tPA'

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IV tPA Dosing, Time

- 'Based on the clearly established time of stroke onset and the estimated (how) pt weight, at 8:21 pm, approx 1'45" after CVA sx onset:
 - Initial bolus: 5 mg slow IVP over 2 min
 - Infusion: 40 mg infusion over 1 hour'

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Avoid Blood Thinners

- Order the following:
- 'Besides ASA, no additional blood thinners such as coumadin, heparin, or plavix should be administered to this patient because of the use of IV tPA'

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Conclusions

- The IV tPA skill set is identified, limited, and manageable
- It is possible to provide quality emergency care with IV tPA and meet a reasonable care standard
- Identify good patient candidates
- Make it happen quickly
- Document the ED management

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Conclusions

- A high standard is achievable
- The record makes this happen
- Good documentation minimizes risk
- Good documentation enhances likelihood of a good outcome
- Documenting the ED management is a critical step in the Rx plan

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Recommendations

- Do it right!
- Be an expert and demonstrate it by documenting well in the record
- Use IV tPA to treat ischemic stroke patients when indicated ,
- Know the numbers and nuances
- Improve patient care and EM practice
- Do so without excessive risk

Edward P. Sloan, MD, MPH



Questions?

www.FERNE.org

edsloan@uic.edu

312 413 7490

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Edward P. Sloan, MD, MPH

