Ischemic Stroke Patient Case Presentation

Clinical History
A 62 year old female acutely developed aphasia and right sided weakness while in a store. The store clerk immediately called 911. Paramedics on the scene within 9 minutes, at 6:43 pm. She arrived in the ED at 7:05 pm... completed her head CT at 7:25 pm... and a neurology consult was obtained at 7:35 pm (approximately one hour after the onset of her symptoms).

ED Clinical Exam
- VS: 98 F, 90, 16, 116/63, 98% RA, 50 kg
- The pt was alert, was able to slowly respond to simple commands. The pt had a patent airway, no carotid bruits, clear lungs, and a regular cardiac exam. PERRL. There was neglect of the R visual field. There was facial weakness of the R mouth, and R upper and lower extremity flaccid paralysis. DTRs were 2/2 on the L and 0/2 on the R.

Medical Legal Overview
- There exist today, over 10 years since the NINDS publication, concern and controversy regarding the use of IV tPA in ED acute ischemic stroke patients
- This is due, in part, to the statements made by practitioners, lawyers, and EM organizations
FERNE / IEME 2007 Acute Ischemic Stroke Patient Care: Specific Recommendation for Risk Mitigation
Edward P. Sloan, MD, MPH, FACEP

**tPA for Stroke – Potential Benefit, Risk and Alternatives**

**Definitions**
- Acute ischemic stroke: A transient ischemic attack, a “stroke” without neurological deficit.

**tPA within 3 hours by NINDS protocol**

**Legend:**
- Green = good recovery
- Orange = poor recovery
- Red = brain bleed, 14% die

---

**Potential Benefits**

The National Institute of Neurological Disorders and Stroke (NINDS) study suggested that tPA within 3 hours of stroke onset led to better outcomes than no treatment, with a significant difference in mortality. The study compared two groups of patients: one received tPA and the other did not.

**Potential Risk**

- Rebleeding
- Hemorrhagic transformation
- Allergic reactions
- Hypotension
- Bleeding complications

**Balancing Benefits and Risks and Alternatives**

To weigh the benefits of treating with tPA, it is important to consider the potential risks, such as the risk of rebleeding and hemorrhagic transformation.

---

**Medical Legal Risk Mitigation: An Assessment**

Edward P. Sloan, MD, MPH
**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

**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

**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?

**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!

**Arizona Controlled Burn**
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.’

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.

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

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
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

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

Specific Recommendations Regarding Documentation in the Medical Record

Emergency Medicine Recommendations

Stroke Pt Diagnosis
- ‘The pt has symptoms that are fixed and are consistent with an acute ischemic stroke’

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’
**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’

**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’

**Blood Pressure Rx**

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

**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’

**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’

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
### 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 …

### 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.

### 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

### ED Systems Recommendations

### 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.

### 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.
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’

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’

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’

Pt, Family Interactions

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

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’

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’
ED Ischemic Stroke Patient Outcome

Clinical Case: CT Result

Clinical Case: ED Rx
- CT: no low density areas or bleed
- No contraindications to tPA, BP OK
- NIH stroke scale: approx 18-20
- Neurologist said OK to treat
- tPA administered, no complications

tPA Administration
- tPA dosing:
  - 8:21 pm, approx 1’45” after CVA sx onset
  - Initial bolus: 5 mg slow IVP over 2 minutes
  - Follow-up infusion: 40 mg infusion over 1 hour

Repeat Patient Exam
- Repeat neuro exam at 90 minutes:
  - Repeat Exam: Increased speech & use of R arm, decreased mouth droop & visual neglect
  - Repeat NIH stroke scale: approximately 12-14

Hospital Course & Disposition
- Hospital Course: No hemorrhage, improved neurologic function
- Disposition: Rehabilitation hospital
- 3 Month Exam: Near complete use of RUE, speech & vision improved, slight residual gait deficit
- Able to live at home with assistance
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

Edward P. Sloan, MD, MPH

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

Edward P. Sloan, MD, MPH

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