PROVIDENCE Brain and Spine Institute

MEDICO-LEGAL CONSIDERATIONS OF INTRAVENOUS TPA

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EVIDENCE

- Prior to 1995, there was no FDA-approved thrombolytic treatment available for AIS.
- tPA-treated stroke patients were 32 percent more likely to show minimum or no disability at 3 months (odds ratio 1.7, CI 1.2–2.6, NNT 8, NNH 16, and ARR 12%), compared to patients who did not get tPA.
- Class IA evidence by AHA/AAN within 3 hours
- Class IB evidence by AHA within 4.5 hours

- *NINDS Trial NEJM 1995.*

STANDARD OF CARE

- tPA should be considered in all patients who are eligible within three/ or 4.5 hours of ischemic stroke symptom onset.

- AHA/ASA guidelines 2012

MALPRACTICE

- Malpractice is defined as "the failure to meet a standard of care or standard of conduct that is recognized by a profession reaches the level of malpractice when a client or patient is injured or damaged because of error."

In absence of standard of care

- The burden of the proof or preponderance of evidence is on the plaintiff, in any medical malpractice litigation.
- In other words, if a jury believes there is at least **51 percent likelihood that a defendant was negligent or liable**, the plaintiff has met its burden of proof and will prevail. This is particularly helpful when juries cannot decide between the testimonies of two expert witnesses presenting opposite opinions or views.

Outcomes

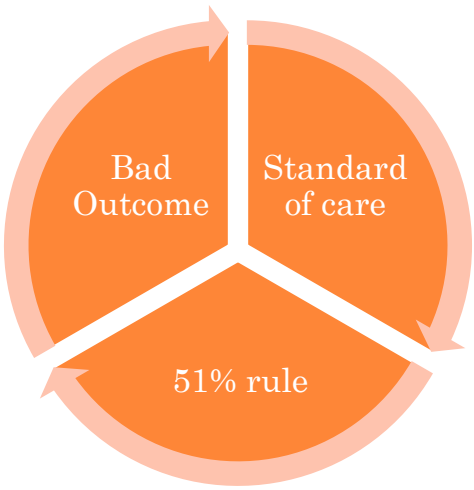
- *A study reviewing malpractice cases in New York State showed that severity of the patient's disability, not the occurrence of an adverse event due to medical negligence, was predictive of payment to the plaintiff*
- *From patient`s perspective, "high expectations and poor outcomes"*

- Studdard NEJM 2006

TPA AND LITIGATION

- In the case of tPA and stroke, medical litigation works as a double-edged sword. Frequently reasons cited for litigation in the court of law include lost opportunity to give tPA or adverse events related to tPA.

COURTROOM



Review

- We reviewed 46 cases of tPA related litigation
- Information was available for 40 cases
- For 38 cases, litigation was pursued because tPA was not given.
- For 2 cases, litigation was pursued for side effects of tPA

- Bhatt et. al. Stroke Research and Treatment Volume 2013 (2013), Article ID 562564,

Did not receive tPA N =38

- Ischemic stroke as a diagnosis 28
- Unable to diagnose or delay in diagnosis 10
- Two out of three verdicts were defendant favored
- One out of three verdicts were plaintiff favored.

Characteristics

- Neurologists named: 8/40 cases
- ED physicians named: 25/40 cases
- Hospital/ICU/Neurosurgeons: 7/40 cases
- Hospital involved 36/40 cases
- In-hospital strokes 5/40 cases
- In 1 out of 4 cases, more than one physician is involved.

Factors Favoring the Defendant

- Factors favoring the defendant included proper documentation of contraindications and discussion regarding risks and benefits (50%),
- Expert witness testimony (25%),
- Duration of symptoms beyond 3 hr at the time of presentation (15.6%),
- Informed consent (6.3%), no specific time of onset of symptoms (6.3%), tPA protocol in hospital (9.4%), and tPA not available in hospital (3.1%).

Factors favoring plaintiffs - Claims

- Among all malpractice claims, factors favoring the plaintiff were
- Failure to treat with tPA (67.5%),
- Failure to diagnose (20%),
- Failure to transfer to an institution where thrombolytics can be given (20%),
- No informed consent or proper documentation regarding contraindication (7.5%),
- Delay in evaluating the patient by a doctor (12.5%) obtaining tests (10%), failure to perform proper medical exam (5%),
- Complications as a result of tPA treatment (5%).

Expert witness testimony

- Expert witness testimony on the plaintiff side frequently argued that according to NINDS trial, there is a >51 percent chance that the patient will improve if the patient received tPA.
- However, expert testimony from the defendant side frequently argued that there is only a 32 percent greater chance that the patient would improve.
- Taking the legal definition of malpractice, the plaintiff needs to prove that the "patient is more likely to improve than not," and in other words the emphasis is on the chance of improvement and not the actual percentage

Case 1

- 44 year old woman comes with stroke like symptoms. On exam facial weakness, flaccid weakness on right side. Previous episodes of similar symptoms with "normal MRI scans". Previous diagnosis of conversion disorder.
- CT scan unremarkable
- tPA not administered due to "stress, conversion disorder"
- MRI brain subsequently showed: Brain stem stroke
- Plaintiff verdict: 2.5 million

Case 2

- 54 year old comes with altered mental status, respiratory failure, intubated in ED. Two days later stabilized but not moving right side
- CT scan shows left MCA stroke
- Plaintiff: Failure to recommend tPA
- Defense argument: Patient too unstable for evaluation, unclear time of onset.
- Defense verdict

Case 3

- 61 year old male presents to blurring of the eyes, "rapidly improved". Discharge from ED. CT scan was unremarkable. Eye doctor diagnosed patient with hemianopia.
- Claim: Failure to diagnose
- Defense: Symptoms rapidly improved
- Plaintiff verdict

Case 4

- 63 year old male presents with headache for 5 hours and vomiting/imbalance for 1 hour.
- CT negative
- MRI massive cerebellar stroke
- Plaintiff: Failure to treat with tPA
- Defense: Symptoms started with onset of headache
- Verdict: Defense

Case 5

- 1 yr old child-mental retardation-west syndrome-home health care-IV-feeding tube-clot in thigh leads to stroke-not treated with tPA-cognitive deficiency.
- Plaintiff verdict: 30 million

Case 6

- 36 y/o male with seizure/syncope, with change in mental status 5 hours. tPA not administered because "seizure" and out of window. Patient intubated sent to the ICU. Not waking up Day 3. MRI shows widespread pontine/cerebellar ischemia. CTA shows basilar artery thrombosis.
- Claim: Faliure to treat with endovascular therapy
- Plaintiff verdict.

Case 7

- 64 year old female presents with sudden onset aphasia/confusion and right sided weakness at 3:00 pm. ED physician talked to family member 1 revealed last known well 10:00 am. No stroke alert activated.
- Nurse spoke to Family member 2 documented onset time 1:00 pm.
- Claim: Faliure to give tPA
- Plaintiff verdict

Summary

- Physicians and hospitals are at an increased risk of litigation in patients with AIS when in IV-tPA is being considered for treatment.
- While majority of the cases litigated were cases where tPA was not administered, only about 1 in 20 cases was litigated when complications occurred.
- Proper documentation of why tPA given or not given.
- tPA protocols in hospitals/Telemedicine support

SUMMARY

- Consider tPA in patients with "rapidly improving"/mild symptoms. Age is not a contraindication for tPA
- Not all contraindications can be uniformly applied, eg. seizure.
- Consider endovascular therapy as an option for massive strokes who present within appropriate time windows.
- Document why you "consider or don't consider tPA". Consistency in documentation amongst providers
- "Patient is not having a stroke" is never a reason for not giving tPA

REFERENCES

- J. R. Marler, "Tissue plasminogen activator for acute ischemic stroke," The New England Journal of Medicine, vol. 333, no. 24, pp. 1581–1587, 1995. View at Publisher · View at Google Scholar · View at Scopus
- C. Fieschi, W. Hacke, M. Kaste, D. Toni, and E. Lesaffre, "Thrombolytic therapy for acute ischaemic stroke. ECASS Study Group," Lancet, vol. 350, no. 9089, pp. 1476–1477, 1997. View at Scopus
- W. M. Clark, S. Wissman, G. W. Albers, J. H. Jhamandas, K. P. Madden, and S. Hamilton, "Recombinant tissue-type plasminogen activator (Alteplase) for ischemic stroke 3 to 5 hours after symptom onset the ATLANTIS study: a randomized controlled trial," Journal of the American Medical Association, vol. 282, no. 21, pp. 2019–2026, 1999. View at Publisher · View at Google Scholar · View at Scopus
- W. Hacke, M. Kaste, E. Bluhmki et al., "Thrombolysis with alteplase 3 to 4.5 hours after acute ischemic stroke," The New England Journal of Medicine, vol. 359, no. 13, pp. 1317–1329, 2008. View at Publisher · View at Google Scholar · View at Scopus
- H. P. Adams Jr., T. G. Brott, A. J. Furlan et al., "Guidelines for thrombolytic therapy for acute stroke: a supplement to the guidelines for the management of patients with acute ischemic stroke. A statement for healthcare professionals from a special writing group of the Stroke Council, American Heart Association," Circulation, vol. 94, no. 5, pp. 1167–1174, 1996. View at Scopus
- "Position statement of the american academy of emergency medicine on the use of intravenous thrombolytic therapy in the treatment of stroke," http://www.aaem.org/em-resources/position-statements/2002/thrombolytic-therapy.
- T. A. Brennan, C. M. Sox, and H. R. Burstin, "Relation between negligent adverse events and the outcomes of medical-malpractice litigation," The New England Journal of Medicine, vol. 335, no. 26, pp. 1963–1967, 1996. View at Scopus
- D. M. Studdert, M. M. Mello, A. A. Gawande et al., "Claims, errors, and compensation payments in medical malpractice litigation," The New England Journal of Medicine, vol. 354, no. 19, pp. 2024–2033, 200