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tPA for Stroke and Litigation

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Disclosures



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OUTLINE

- Fear of litigation
- Benefit of t-PA
- Literature on t-PA and stroke litigation
- Real closed malpractice cases
- What happens when you give t-PA to stroke mimics?
- Time to t-PA and effectiveness
- What else do I need to be worried about (missed stroke)?
- Take home points

The fear

- If I give t-PA and the patient suffers a symptomatic ICH, I will be sued.

The verdict

- The overwhelming majority of cases are for failure to give t-PA or delay in giving it.



Structured review- 2008

- 7 legal databases, from 1983 forward, were queried for cases of tPA in stroke. 33 were found.
- 64% of decisions were for the defendant, 27% for the plaintiff.
- Only 58% of cases involved emergency physicians.
- 88% were for failure to provide tPA.
- 9% were for injury from tPA.
- Of those cases that the plaintiffs won, 83% were for failure to give tPA.

Table 2. tPA and stroke jury verdicts, settlements, and judgments.

Case	Verdict, Settlement, Adjudication	Year	Liability, \$
1	Verdict-defendant	1999	
2	Verdict-plaintiff	2000	315,000
3	Verdict-defendant	2001	
4	Verdict-defendant	2001	
5	Verdict-defendant	2001	
6	Settlement	2002	100,000
7	Verdict-defendant	2002	
8	Verdict-defendant	2003	
9	Verdict-defendant	2003	
10	Verdict-defendant	2003	
11	Verdict-defendant	2003	
12	Verdict-defendant	2003	
13	Verdict-defendant	2003	
14	Verdict-plaintiff	2003	5,000,000
15	Verdict-plaintiff	2004	3,100,000
16	Verdict-plaintiff	2004	969,777
17	Verdict-plaintiff	2004	5,200,000
18	Verdict-plaintiff	2005	1,500,000
19	Verdict-defendant	2005	
20	Verdict-defendant	2005	
21	Verdict-defendant	2005	
22	Verdict-defendant	2005	
23	Verdict-defendant	2005	
24	Verdict-plaintiff	2005	1,256,552
25	Verdict-defendant	2005	
26	Verdict-defendant	2005	
27	Verdict-defendant	2005	
28	Verdict-plaintiff	2006	30,000,000
29	Verdict-defendant	2006	
30	Verdict-plaintiff	2006	2,110,708
31	Verdict-defendant	2006	
32	Arbitration	2007	421,570
33	Settlement	2007	17,550,000

Updated review 2013

- Reviewed 789 stroke malpractice cases; 40 tPA cases
 - ▶ Failure to diagnose: 25% (defendant won 60%)
 - ▶ Failure to give tPA: 70% (defendant won 67%)
 - ▶ Complication from tPA: 5% (defendant won 50%)
- Who was sued:
 - ▶ Emergency physician: 62%
 - ▶ Neurologist: 20%
 - ▶ Other: 17%
 - ▶ Hospital: 90% (75% community, 25% academic)

Updated review 2019

- 246 medical malpractice cases related to the acute management of ischemic stroke
- 71 cases alleged a failure to treat with t-PA and 7 cases alleged a failure to treat, or to timely treat, with thrombectomy.
- 151 cases (56%) which ended with no payout, 74 cases (27%) were settled out of court.
- Only 47 cases (17%) went to court and resulted in a verdict for the plaintiff.
- Average payout in settlements was \$1 802 693, and the average payout in plaintiff verdicts was \$9 705 099.

Updated Review 2021

- Westlaw database review 1993-2020, total 36 cases
- In all cases, the plaintiffs sued for issues stemming from either *failure to give tPA* or a *delay in giving tPA*.
- defendant won in 22 cases; plaintiff in 10
- It is more common for patients to sue physicians for *not* administering tPA in a timely fashion or at any point.
- Thus, tPA should not be withheld or delayed in patients who meet criteria, and physicians should not fear litigation in these situations

Benefit of t-PA for stroke

- 30% greater likelihood of no or minor disability at 3 months if given within 3 hours and ~28% for those receiving within 4.5hr [NINDS 1995 trial]
- Every 15-minute reduction in time to tPA is associated with a 3-4% greater odds of walking independently at discharge, and being discharged to home rather than an institution, and 4% lower odds of in-hospital death or hemorrhagic transformation of their infarct [Saver et al]. *That's more than 30,000 patients every year for whom prompt IV alteplase can make a life-altering difference.*

Case 1: Motor vehicle collision

- 60-year old male presents after motor vehicle collision at 11:20.
 - ▶ As per the car passenger, he was driving and talking, then stopped talking and veered off the road.
 - ▶ EMS arrived at 11:40, found him nonverbal with right sided weakness and uncooperative.
 - ▶ Arrived to the ED at 12pm.
- Neurologic Exam
 - ▶ Right facial droop
 - ▶ Aphasia
 - ▶ Motor strength 1+/5 RUE, 3+/5 RLE.
 - ▶ Hyperreflexic, hypertonic.
- Workup: Head CT and C-spine CT were negative.
- The passenger is not available and cannot be reached.
- A/P: “Given increased tone, likely old stroke rather than new. Admit to medicine for altered mental status.”

Question: Is admission to Medicine the correct next step from the ED?

1. Yes. His neurologic deficits are likely due to an old stroke; it is not clear why he is altered.
2. Yes. Even if he had a stroke, the onset time cannot be established, so no specific treatments are available in the ED.
3. No – the available data suggests an acute event (such as stroke) occurred within the last hour, and he should be treated as such.

Case 2- What to do if LAR not available?

- A 53 year old man presented with an acute expressive aphasia and right face, arm, and leg weakness. EMS was given time of LKW by his wife at the scene. By the time the patient arrived to the ED, 3.5 hours had passed since symptom onset.
- Upon the patient's arrival to the hospital, the emergency physician at bedside documented NIHSS 15. NCCT negative for ICH. The patient's records revealed no contraindications to IV t-PA.
- Now, at 4 hours from symptom onset, should t-PA be given?
- The ED doctor did not give t-PA because the patient was aphasic, and no one was available for formal informed consent.
- By the time the patient's wife was located, more than 4.5 hours had elapsed since the onset of stroke symptoms. The patient never regained the ability to function independently.
- Allegation: Failure to administer t-PA in a timely manner.

Discussion: Is the standard of care to try to immediately reach family?

- ▶ The ED is busy, and it can often be impossible.
- ▶ Is it enough to make a brief reasonable attempt? Should you call EMS dispatch, the police, using the patient's cell phone, traffic light cameras, whatever it takes to clock the last seen well time?

For case 1: Family arrived hours later and confirmed that all symptoms were new. Final diagnosis was that this was a new ischemic stroke, but now (many hours later) is outside of time window.



Verdict

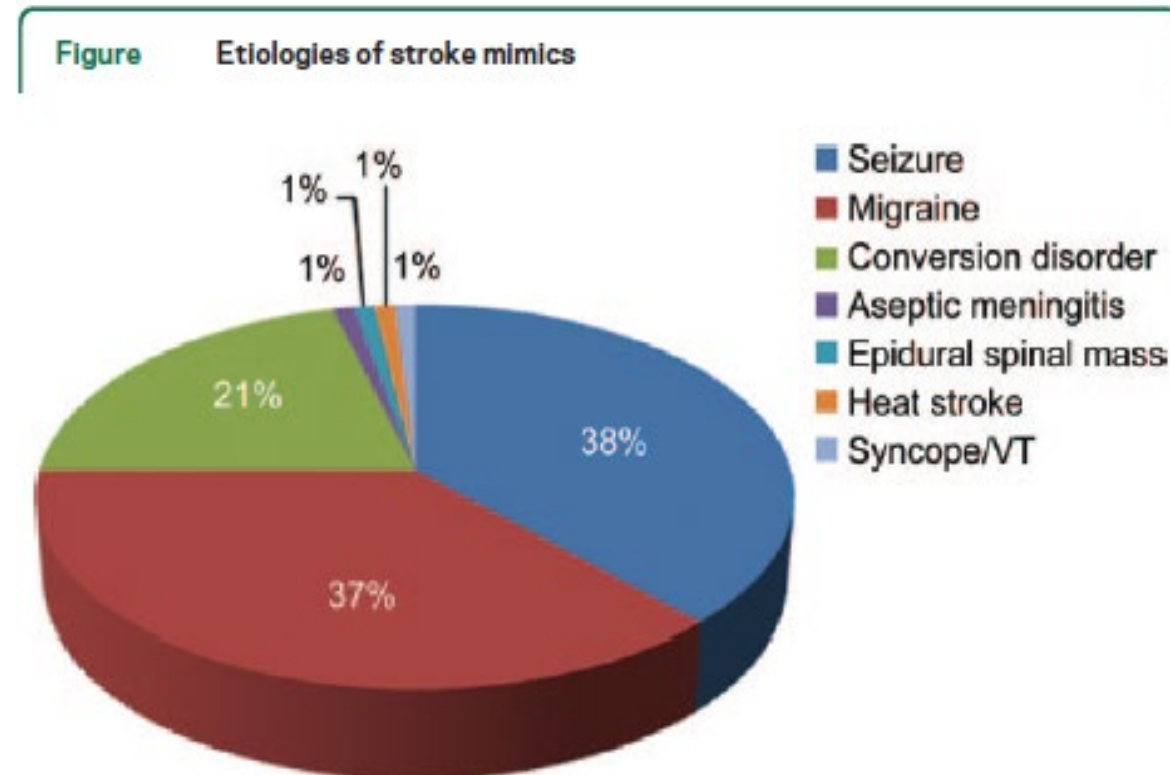
- Because of the proven benefit of tPA and the need to expedite treatment, when a patient cannot provide consent (eg, aphasia, confusion) and a legally authorized representative is not immediately available to provide proxy consent, it is justified to proceed with IV thrombolysis in an otherwise eligible adult patient with a disabling acute ischemic stroke.” [2018 ASA guidelines]
- An intervention labeled as standard of care by the field’s guideline-promulgating organization and that significantly reduces either mortality or morbidity risk meets the reasonable person standard.
- If a patient who lacks decision-making capacity arrives at the ED with an acute ischemic stroke that meets criteria for tPA administration and no surrogate decision maker is readily available, the doctrine of emergency or implied consent allows the clinician to administer tPA to that patient.

Litigation landscape

- Normally, one must prove that “to a reasonable degree of medical probability” that the action (eg- lack of treatment/ tPA) has at least a 51% likelihood of causation. This is almost impossible to prove bc we cannot look into the future.
- Bring in the loss of chance doctrine, and this is where the plaintiff could win
- (n/a in California, Florida, Michigan, and Texas)

What happens when you give tPA to someone who is NOT having a stroke (stroke mimic)?

- Randomized trials of thrombolytics for STEMI: risk of sICH is about 0.5%.
- Review of 100 patients who received tPA for stroke and negative MRI: **0% had sICH.**



What if it's a mild stroke (NIHSS <5)?

→ ***Need to decide if disabling or non-disabling***

- For the first time ever, the 2019 update to the 2018 ASA guidelines state that it may be harmful and thus contraindicated to give t-PA for mild non-disabling strokes
- This recommendation is so new that there are no documented cases of litigation for giving tPA for this to date.
- Remember “disabling” is in the eye of the patient.
- Careful documentation of t-PA decision is paramount!

What's a disabling stroke?

Complete hemianopia:
≥2 on NIHSS

Severe aphasia:
≥2 on NIHSS

Visual extinction:
≥1 on NIHSS

Any weakness limiting sustained effort against gravity:
≥2 on NIHSS question 5 or 6

Any other deficit considered potentially disabling by the patient, family, or the treating clinician

Any deficit that would prevent the patient from performing basic activities of daily living (ie, bathing, walking, toileting, and eating or returning to work)

Missed strokes

OK, so now I know

- I should not withhold or delay t-PA for eligible stroke patients
- I can reasonably apply implied consent when LAR (Legally Authorized Representative) not available
- Stroke mimics have low risk of sICH after t-PA
- Mild non-disabling strokes should not receive t-PA

What else do I need to worry about?

Case 3 - Headache, Blurry Vision

- HPI: 38-year old female with acute onset 3 hours ago of left eye pain, left sided headache, and left blurry vision. She has a history of migraines but never with vision changes. Associated with vomiting.
- Physical: Vitals benign
 - Eyes: PERRL, EOMI. Visual acuity right 20/20, left 20/50
 - ENT: normal
 - Neuro: Normal motor, normal sensory, no focal deficit.



Question: Does She Need Further Neurologic Workup?

1. No. She has a history of migraine headaches, and has a normal neurologic exam.
2. Maybe. If you treat her migraine and she gets better, you can safely discharge her with no further workup. You should use response to pain treatment to help with diagnosis.
3. Yes. This is a new type of migraine (visual symptoms), and she has a new deficit (decreased visual acuity).
4. Yes. Everyone presenting to the ED with headache should undergo neuroimaging.

Question: What Should We Test For?

1. Check an ESR to evaluate for temporal arteritis.
2. Check an MRV to evaluate for cerebral venous sinus thrombosis.
3. Check a head CT to evaluate for brain tumor.
4. Check a neck CTA to evaluate for carotid artery dissection.



Case 3: Headache, blurry vision contd...

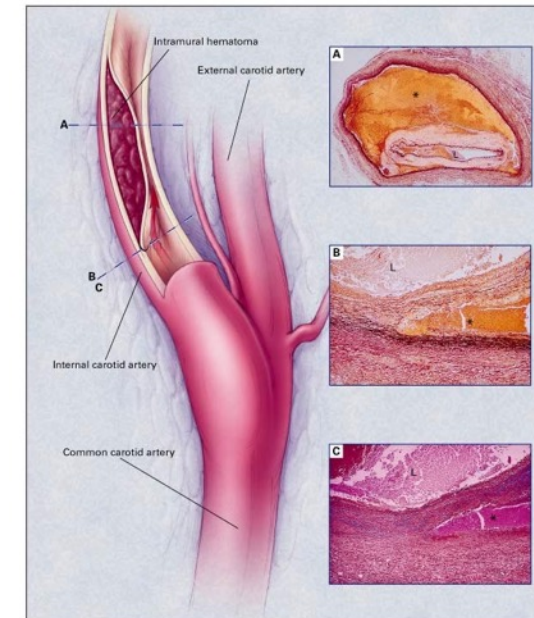
- Assessment and plan: She was given diphenhydramine, compazine. Headache improved, still some headache. Discharged with diagnosis of migraine.
- She was seen by a first-year surgery resident who wrote the note. The full attending documentation is below:

Teaching-Supervisory Addendum-Brief

I participated in the following activities of this patient's care: I personally interviewed and examined this patient. I discussed the findings, diagnostic studies, interventions and treatment plan with the provider. I reviewed the clinical notes and test results and agree with the information in the resident or PA note. The following note was

Case 3 – Headache and blurry vision

- 9 hours after discharge, the patient was found down.
- She had right hemiparesis on exam.
- She was diagnosed with left ICA (internal carotid artery) dissection and left MCA stroke.
- Allegations:
 - ▶ Missed dissection
 - ▶ Can migraine cause unilateral vision loss?
 - ▶ Attending never saw the patient



Question: Could This Stroke Have Been Prevented?

1. Yes. A diagnosis in the ED would have led to antithrombotic therapy which would have prevented the stroke.
2. No, but she would have been admitted and the stroke diagnosed/treated more quickly.
3. No, the time frame was too short – no preventive intervention would reasonably have happened in that time frame.

Case 4:

- 57 year old man presented with dizziness that started 2 hours prior to ED arrival. He endorsed a couple cocktails last night before going to bed. He does not have any focal weakness or slurred speech. He denies fever, chills, chest pain, shortness of breath, abdominal pain or any other ailments.
- The emergency physician examined the patient in the stretcher and felt that this was peripheral vertigo, but given his age, decided to get a non contrast head CT “just in case.” No stroke alert was called.
- Neurologic exam states only “Moves all extremities”. There was no documentation of eye movements or gait. Head CT was negative. Labs were unremarkable. The patient received meclizine and felt “better”. The patient was discharged home.
- Several hours later, the patient’s wife found him at home unresponsive.
- When he returns to the hospital, a large vertebrobasilar infarct was diagnosed.
- ALLEGATION: Failure to diagnose stroke.

Posterior circulation strokes- why they are easy to miss

- Frequently presents as “dizziness”
 - stroke often not considered in differential
- Classic symptoms: “the 3Ds”- dysphagia, dysarthria, diplopia
 - All symptoms that can be easily missed if not specifically assessed
- Typical physical exam signs: gait disturbance, cerebellar signs
 - easily missed because patient is supine in stretcher, or when neurologic exam consists only of NIHSS. **MAKE SURE TO CHECK GAIT!** Consider HINTS exam.
- Common imaging: non contrast CT
 - **POOR CHOICE** for dizziness - Often misses posterior ischemia

What goes into a stroke litigation case?

- Can have multiple parties in the suit, not all may be sued
- Opinions of experts- can be for or against defense
- Who assessed patient, time to decision whether a stroke, timeliness of radiology reports, how long spent reviewing images
- Was the standard of care met?
- Does the patient and/or family make a sympathetic witness
- Calculations of economic specialist

Thank You