

Does Standard of Care for Acute Ischemic Stroke in the ED Include tPA? A Legal Perspective

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ABSTRACT

Acute ischemic stroke accounts for 85% of approximately 750,000 new stroke cases each year. Only 2-3% of these patients receive tissue plasminogen activator (tPA).¹ Reasons for not administering tPA include lack of neurologic support, onset too far removed from time of treatment, medical conditions increasing risk of complications, refusal by the patient after informed consent, or refusal by the physician to offer this treatment. Statistics for benefit vs. risk following tPA infusion are controversial. If looking at data from a meta analysis of the major studies, relative improvement occurs in approximately 37% of patients, while around 5% are at risk for an adverse outcome.² For many physicians, the risk outweighs the potential benefit. Emergency physicians are sharply divided on the issue of whether or not tPA is an appropriate treatment modality. In a survey of 2,600 active members of the American College of Emergency Physicians (ACEP), 40% said that they would not use tPA, even in the ideal patient under ideal conditions.³ Both the ACEP's and the Academy of Academic Emergency Medicine's official policies reflects that split and do not take a position on whether or not tPA should be used, and thus do not set a standard for care.⁴ From a legal perspective, these declarations do not mean that there is no standard. This paper first examines the literature regarding tPA safety and efficacy. Next, it covers legal concepts that drive malpractice cases involving tPA: loss of chance, standard of care, how that standard is shaped by expert testimony, and informed consent. This is followed by a section on what

the emergency physician can do to mitigate legal liability. The paper concludes with a discussion on medical decision-making and how this may affect the use of tPA as a treatment modality.

LITERATURE REVIEW OF tPA FOR ACUTE ISCHEMIC STROKE

The most frequently cited study by emergency physicians is the National Institute of Neurological Disorders and Stroke (NINDS) Trial, which was published in 1995 in the *New England Journal of Emergency Medicine*. In this trial, treatment had to be given within 3 hours of onset of stroke, patients had to meet strict treatment protocols (see Figure 1), and 0.9 mg/kg of tPA was used in the treated group. In the treated group of the randomized, placebo-controlled patients with acute ischemic stroke, the symptomatic intracerebral hemorrhage (ICH) rate was 6.4%, but provided a 32% (12% absolute) better likelihood of minimal or no disability at 3 months. The odds ratio of improvement was 2.⁵

A study published in *JAMA* in 1999 looked at tPA benefit between 3 and 5 hours of onset of stroke symptoms and found no difference between tPA and placebo in symptom improvement, but found a 7% rate of symptomatic hemorrhage rate vs. 1.1% with placebo. This study solidified the 3 hour rule for IV tPA treatment of acute ischemic stroke.⁶

Other studies have been flawed because of treatment protocol deviations, treatment beyond 3 hours of symptom onset, small numbers of patients, and including other treatment modalities such as heparin and osmodiruretics. Some studies have had no controls. These other studies have been confusing to the casual observer, because they have had such widely deviating results from the NINDS trial. For example, rates of ICH

ranged from 3.3-16% in the tPA treated groups, and improvement of symptoms at 90 days ranged from 31-57%.

Because of this conflicting data, a meta-analysis was done by Dr. Graham of the University of New Mexico in 2003 in an attempt to assess the safety of tPA in stroke patients. He analyzed 13 studies (10 of which were prospective), and looked at a total of 2,529 patients. This data included the large Canadian Activase for Stroke Effectiveness Study (CASES). Reports that were limited to special populations such as the elderly, or that had less than 25 patients were excluded from review. Dr. Graham found that the overall intracerebral hemorrhage rate was 5.1%, slightly lower than the 6.4% found in NINDS. The mean total death rate was 12.9%, and the proportion of patients achieving a very favorable outcome (as measured by a modified Rankin score of 0 or 1) was 36.7%, which was comparable to NINDS. Of note, the analysis found protocol deviations in 19% of the studies that were included, and that there was a strong trend between protocol violations and symptomatic ICHs ($r=0.57$; $p=0.052$).⁷

*See Evidentiary Table under ACEP Practice Resources at

<http://www.acep.org/practres.aspx?id=29936> for a summary of the major tPA studies to date.

THE LEGAL PITTFALLS OF tPA FOR THE EMERGENCY PHYSICIAN

A common scenario

A 63 year-old female is brought to the emergency department (ED) by her husband. She is complaining of diplopia, nausea, and right-sided weakness. The onset of symptoms occurred suddenly, 45 minutes prior to arrival at the ED, and they have not abated. There was no seizure activity associated with the symptoms. The patient has a

history of hypertension and hyperlipidemia. Her medications include hydrochlorothiazide and atorvastatin. A non-contrast CT scan of the head shows an ischemic stroke in a branch of the basilar artery and a neurologic exam is consistent with this lesion. This is the patient's first known stroke, and she does not have a history of head trauma, intracranial or gastrointestinal hemorrhages, recent surgeries, arterial punctures, or other contra indicators. The patient is alert and cooperative, with a respiratory rate of 16, pulse of 85, blood pressure of 140/85, and temperature of 37°C. Her electrocardiogram is normal. Lab values show a blood glucose of 205 mg/dL and a platelet count of 178,000 per mm³. At this particular hospital there is no pre-established stroke team, and the on-call neurologist is only available by telephone due to time constraints. The neurologist concurs with the diagnosis of ischemic stroke and states that this patient is an appropriate candidate for infusion of tPA, and strongly suggests that it be administered by the emergency physician. There are sufficient resources to adequately monitor this patient following infusion. The policy of the hospital is to offer this treatment to acute ischemic stroke patients who meet criteria, and tPA is available. Does the standard of care require consideration of tPA? What is the legal liability for the emergency physician in this situation?

*See Figure 1.

Assume that this patient meets the strict criteria for infusion of tPA. If there is a stroke team at the facility, of which the emergency physician is not a part, then care of the patient is given to the team, taking the decision out of the hands of the emergency physician. In other situations, the emergency physician may be expected to infuse the tPA on recommendation of a neurologist, or after receiving results of a non-contrast head

CT that has been read by a radiologist. Either way, the emergency physician must look to the stroke policy in place at the parent institution. If it is the policy to administer tPA where a patient meets the criteria, there are resources to monitor the patient, and there is neurologic support, then the emergency physician will not have much latitude in a medical malpractice case if the treatment is not offered. The reason is that in a legal setting, if the patient is not given all reasonable options for treatment, there could be a successful lawsuit under the legal doctrine of “loss of chance.”

THE BASIS FOR A MALPRACTICE SUIT: LOSS OF CHANCE

The traditional tort law of negligence requires that plaintiffs prove that it was more probable than not that the alleged negligence caused the injury in question. Under that rule, a plaintiff must prove that there is a greater than 50% chance that an injury would not have occurred, but for the action(s) or omission(s) of the defendant(s). For example, if a patient’s estate sues the doctor for failure to diagnose breast cancer when she first presented with possible signs and symptoms, the plaintiff must prove that but for the negligence of the doctor, there was a greater than 50% chance that the patient would have survived longer (or at all). So the staging of the cancer is important. If the chance is even 49% at the point at which the negligence was alleged to have occurred, there can be no recovery, and the plaintiff’s case fails.

Historically, it is difficult to pinpoint where or when the loss of chance doctrine arose. Some argue that it was first applied to a contracts case in 1911 in England, yet there are earlier cases associated with medical malpractice cases in the United States.⁶⁰ Regardless, this legal doctrine dramatically changed centuries of tort law and has had a huge impact on medical malpractice litigation. Whereas before, a medical expert was

required to testify that “within a reasonable degree of medical certainty” there was a greater than 50% chance that the injury would not have occurred but for negligence, many jurisdictions now recognize an injury for negligence based upon a possible loss of a chance for a more favorable outcome. In other words, it is this loss of a chance that is being compensated rather than the outcome itself, which cannot be known.

To complicate things further, while most states recognize this theory, some do not. Further, how the theory is applied varies greatly in states that allow it. So under this doctrine, a medical expert must merely testify that there was a chance, however slim in some states, for a better outcome. It would be difficult to think of a scenario in which that would not be true, so the flood gates for medical malpractice suits have been opened. This theory is highly speculative, and the speculation ultimately rests with the jury, not with the medical expert.

*See Figure 2.

Has the jury supplanted the medical expert? Where there are dueling experts, it is a jury that decides which opinion is correct. Therefore, it is the jury that is making a judgment about the probability of a medical outcome and which is the correct medical opinion. In a sense, they become the medical experts in such a scenario, regardless of whether or not they have the education and knowledge necessary to competently make such difficult decisions. It is their judgment upon which the final outcome rests.

Take, for example, a patient who enters the ED with some significant neurologic deficits resulting from an ischemic stroke. If all of the guidelines for infusion of tPA are met and, depending upon which statistics the jury finds most persuasive, they could find that there is a roughly 70% chance that those sequelae will not resolve, and a 7% chance

that a more significant injury will result if tPA is given. Yet if tPA is not offered, there is a possibility that the patient will prevail in a law suit for “loss of chance” for a better outcome, because the jury’s assumption is that there is up to a 30% chance that the patient would have benefited. Therefore, failure to offer tPA may be compensable, depending upon the laws of a given state and depending upon how a jury interprets the current statistics, which can be confusing, even for physicians.

STANDARD OF CARE: WHO DECIDES?

The medical expert

Medical malpractice cases are often called “the battle of the experts.” Each side finds an expert to support their side. In the case of tPA, the opinions will center on whether or not administration of tPA is the standard of care. When an expert gives testimony on standard of care, it is supposed to be supported by the literature. In the case of testimony on the standards of care relating to failure of an EM physician to offer tPA to qualifying patients, we see a clear split on the issue and no convincing consensus. So it would seem that there could be no liability for the EM physician, because one cannot prove that there was a failure to meet standard of care. This may be an incorrect assumption, depending upon the applicable rule for expert testimony.

One major challenge in the legal defense is that restrictions on the specialty of the testifying expert relative to the physician on trial are rare. In fact, although all states have different rules on experts, less than a third of the states require that the expert be of the same specialty as that of the defendant. That presents an interesting problem for emergency physicians, because while there is no consensus within the emergency medicine literature, there is fairly broad support in the neurology literature, and it is often

a neurologist who testifies as the Plaintiff's expert at trial. Therefore, in the case of failure to offer tPA by an emergency physician, a neurologist could easily be found who would testify that the medical literature clearly supports the use of tPA for all qualifying patients, and that failure to do so is a deviation from the standard of care. It is the jury that ultimately decides which standard of care to apply.

This is problematic for emergency physicians, because in most jurisdictions, it is the physician who has the most expertise in a certain type of injury who will testify about what should or should not have been done in the case. Does that mean that emergency physicians will be held to the standards of other specialists? In this type of system it may, even though it is neither reasonable nor is it the true standard.

The Jury

For a plaintiff to prevail, an "expert" must testify and persuade a jury that there was negligence, and that such negligence caused the injury, even if merely a loss of chance for a better outcome. The expert opinion may support a standard of care that is a different standard from that of an emergency physician expert. A jury may not appreciate this, and is not necessarily equipped with the knowledge and background required for understanding the science and medical issues of the case. Still, it is tasked with the difficult job of determining which opinion is "correct." Such decisions may not necessarily be focused on standard of care, but may instead be based upon external factors such as: (1) which argument is easiest to follow; (2) the charisma of the witnesses, defendant, or attorneys; or (3) sympathy for the plaintiff, regardless of medical opinion, compelling the jury to "help the victim."

To illustrate, in one failure to administer tPA case, a physician testified that the window for administration of tPA was three hours; another physician testified that the window was eight hours. At the time of the case, the national standard was clearly a three hour period, as supported by the medical literature and protocols of the American Heart Association. The jury decided that it was the eight hour window that should be applied.⁴⁹ While this case is an outlier and has as much to do a failure on the part of the attorney to muster the weight of evidence that would easily refute this claim, it does illustrate how our current system may substitutes true expert testimony with the judgment and opinion of a less qualified jury. The results are unpredictable, at best, because the true standard of care, for any specialty, is not necessarily what decides the case.

Jury Decisions Set Precedent for Future Cases

Courts make decisions based upon two things: (1) laws and regulations, created by elected law-makers; and (2) by interpreting these laws and prior cases, thus creating legal precedent. Legal precedent is a concern for physicians, because where the door is opened, others will follow with similar suits. So even though a case may lack merit, as in the above example, it could have a broader effect in terms of spawning more lawsuits involving "loss of chance" in cases that extend beyond the three-hour window for administering tPA. Regardless of whether or not these additional suits prevail, they are expensive in terms of both time and money necessary to respond and defend the action, and they create an enormous amount of unnecessary stress for the defendant physician(s).

*See Figure 3.

GUIDANCE FOR EMERGENCY PHYSICIANS

Expanded Use of tPA

First, regardless of one's position on the use of tPA, forces are mounting for its expanded use: (1) In 2002, the American Heart Association upgraded its recommendation of tPA for stroke from optional (Class IIB) to definitely recommended (Class I); (2) in 2005, JCAHO began certifying primary stroke centers using American Stroke Association and Brain Attack Coalition guidelines, which call for expanded use of tPA and early intervention; and, (3) Medicare has created a new DRG559 code for "acute ischemic stroke with use of thrombolytic agent" which pays almost \$6,000 more than the previous DRG014 code.¹¹⁵ As use expands, so too may liability for not offering this potential treatment, particularly if there is no requirement that the expert be an emergency physician. On the other hand, as use expands, so too will the absolute adverse outcomes associated with its use, which may lead to a decline in support of its use.

Laws on Expert Testimony May Impact "Standard of Care"

Second, state law varies with respect to expert testimony. Specialists may have different standards of care than do emergency physicians. Defense counsel should argue that the appropriate standard of care must be applied to the physician in question. This is done during arguments and cross-examination of the expert witnesses. Alternatively, legal counsel could argue the specialist's opinion is not appropriate and file to dismiss for failure to state a claim. Organizations such as the ACEP maintain a list of experts who are both qualified and who have signed an oath to provide accurate, truthful, and ethical testimony. This includes testifying about standards of care that are consistent with those outlined by the organization. If a physician refuses to sign such an oath, that would be admissible when querying the "expert" on his or her credentials to testify in a case involving an emergency physician.

Follow Protocols – Avoidance of Medical Error

Third, strictly follow protocols. One community study showed that there was a 50% incidence of protocol deviation from national treatment guidelines for tPA.¹¹⁶ Deviations are associated with much higher mortality and morbidity rates. If tPA is used in the ED, the patient or the patient's family should not be allowed to persuade the clinicians to offer thrombolytic therapy outside of the established protocol, including extending the time limits set forth in the protocol guidelines. The criteria are conservative, but they are the result of evidence-based medicine, and the risks of ICH are too great to make any exceptions. Further, if these strict guidelines are not followed, there is no legal defense. This would be considered a medical error amounting to negligence. The lesson from this latter case is that if the decision to infuse is made, the clinicians should make certain that it happens within the three-hour window.

Documentation and Informed Consent are Critical

Fourth, appreciate that documentation of treatment decisions is the most important thing a physician can do to avoid legal liability. With respect to tPA, the chart notes should document the following: (1) details of the informed consent discussion; (2) a list of people present; (3) notes on the patient's decision making capacity¹¹⁷; (4) the patient's decision; and (5) any and all inclusion or exclusion criteria that are not already noted in the chart. Documentation of the inclusion and exclusion criteria are important even if tPA is not offered, as would be the case where the protocols are not met, in order to be sure that the record is complete in the event of a loss of chance lawsuit. Remember, if it is not in the record, an assumption will be made that it did not happen.

The treating physician is the one making treatment decisions and is responsible for the care and outcome of the patient. The physician has an obligation to express concerns he or she may have about the different treatment options. Regardless of where the physician stands, the risks and benefits of tPA should be discussed if the patient meets the criteria, and the details of that discussion should be documented. Although it would seem that obtaining and documenting informed consent would be a high priority given the significant risks of tPA, at least one study shows that this is frequently not done.¹¹⁸

Where the treating physician is opposed to tPA infusion, yet the patient meets all criteria and the patient, or surrogate, still wishes to have it, there are two options: (1) completely document the informed consent discussion and offer tPA; or (2) transfer the care to another doctor who is willing to do the infusion, such as a neurologist or another emergency physician, keeping in mind that this must be done quickly to allow this option for the patient. However, if it is the policy of the treatment facility to offer tPA to patients who are eligible to receive it, the treating physician may be subject to a loss of chance lawsuit if he or she refuses. On the other hand, many physicians do not oppose the use of tPA and actively use in their practice. Still, informed consent and documentation of all criteria for infusion are equally important in those cases, because if there is a bad outcome following administration of tPA, the record must be complete for adequate defense in a subsequent negligence lawsuit.

MEDICAL DECISION-MAKING AND tPA: ANCHORING BIAS AND THE RISKY CHOICE FRAMING EFFECT

In contrast to neurologists, the decision to offer tPA as a treatment modality has proven to be a difficult one for EPs. While it is true that there are significant risks of

symptomatic ICH, there is also an excellent chance for a better or complete recovery when tPA is used. Further, the meta-analysis referred to in the literature review above shows that a substantial percentage of the adverse outcomes occurred when the protocols for the use of this drug were violated. And the vast majority of those violations occurred at the hands of the EPs in comparison to neurologists (19% versus 1%).

So perhaps one explanation for why EPs are reluctant to treat with tPA, in contrast to neurologists, is anchoring bias. The early studies of tPA varied widely in assessing risk of symptomatic ICH, but one number put the risk as high as 16%. The true risk is more likely to be around 5% (and likely even lower than that if one were to remove approximately 20% of the cases that occurred in conjunction with protocol violations). When considering serious adverse outcomes, that is a big difference in risk, and would surely sway the decision to use the drug, one way or the other. The concept of anchoring bias is that one's judgments will assimilate toward the "anchor" or belief, and that one will then selectively activate memories to support this belief.¹¹⁹ So having the number of 16% out there in the literature, and having case reports of a fair number of symptomatic ICH supporting that (even if there were significant violations of protocol during those cases), may further fuel the idea that this drug should not even be offered to patients for some EPs.

Another potential reason for difference in risk aversion between EPs and neurologists may be due to a framing effect, a concept developed by Kahneman and Tversky, who have demonstrated that "losses loom larger than gains" when making decisions regarding risk.¹²⁰ That idea has been deemed "risk aversion." The idea behind

the framing effect is that alternative framing of information in positive or negative terms affects judgments and decisions.¹²¹

This concept was further demonstrated in their famous 1981 “Asian disease problem” study, where participants who were given positively framed information of a task (certainty of saving 1/3 of lives versus a 1/3 chance of saving all lives and a 2/3 chance of saving no lives) selected the option with the certain outcome. In contrast, participants given the negatively framed version (a sure loss of 2/3 chance of losing all lives) selected the less risky option. The manipulation of the same information, or “framing,” determines whether outcomes are viewed as gains or losses.¹²²

So perhaps neurologists simply view outcomes in a different way than do EPs. If one were to say, “37% of patients with acute ischemic stroke have a chance for improved outcome, or even complete resolution of deficits, with tPA versus no treatment,” an aggressive approach to treatment will commence. On the other hand, if one were to say, “It is certain that 1:20 patients I treat will get much worse because I will give them a symptomatic ICH on top of the acute ischemic stroke they already have, while 37 will appreciate a benefit,” treatment may be less aggressive. The numbers are the same; the perception is different.

The difference in the choice of how to frame the data may stem from the fact that this is an opportunity for a specialty such as neurology to change an outcome, where such opportunities are rare, given the types of patients and diseases that they treat. On the other hand, EPs are trained to approach patient problems with the notion that we must first rule out the worst possible diagnoses and treat those. Perhaps this more conservative

approach and focus on preventing and treating bad outcomes is what drives the differences in treatment approach of candidates for tPA in acute ischemic stroke.

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Figure 1⁸

* Adapted from original table by Oscar Benavente and Robert G. Hart.

Criteria for Thrombolysis of Patients with Acute Ischemic Stroke Using Tissue Plasminogen Activator (tPA).

Inclusion Criteria:

- Age greater than 18 years
- Clinical diagnosis of ischemic stroke, with onset of symptoms within three hours of initiation of treatment
- Non-contrast CT scan with no evidence of hemorrhage

Exclusion Criteria:

History

- Stroke or head trauma in previous three months
- History of ICH that may increase risk of recurrent hemorrhage
- Major surgery or other serious trauma in previous 14 days
- Gastrointestinal or genitourinary bleeding in previous 21 days
- Arterial puncture in previous seven days
- Pregnant or lactating patient

Clinical Findings

- Rapidly improving stroke symptoms
- Seizure at onset of stroke
- Symptoms suggestive of subarachnoid hemorrhage, even if CT scan is normal
- Persistent systolic pressure greater than 185 mm Hg or diastolic pressure greater than 110 mm Hg, or patient is requiring aggressive therapy to control blood pressure
- Clinical presentation consistent with acute myocardial infarction or post-myocardial infarction pericarditis requires cardiologic evaluation before treatment

Imaging Results

- CT scan with evidence of hemorrhage
- CT scan with evidence of hypodensity and/or effacement of cerebral sulci in more than one third of middle cerebral artery territory

Laboratory Findings

- Glucose level less than 50 mg per dL (2.8 mmol per L) or greater than 400 mg per dL (22.2 mmol per L)
- Platelet count less than 100,000 per mm³ (100 x 10⁹ per L)
- Patient is taking warfarin and has abnormal International Normalized Ratio
- Patient has received heparin within 48 hours, and partial thromboplastin time is elevated

Figure 2: Loss of Chance Doctrine by State

	<p><u>Loss of Chance Doctrine is recognized to varying extents in the following states:</u> AL¹⁰ AK¹¹ AZ¹² CO¹⁵ CT¹⁶ GA²⁰ HI²¹ IN²³ IA²⁴ KS²⁵ LA²⁶ MA⁵¹ MI²⁸ MO¹³ MT³⁰ NV³¹ NH³² NJ³³ NM³⁴ NY³⁵ OH³⁷ OK³⁸ PA⁴⁰ VA⁵² WA⁴⁷ WI⁴⁹ WV⁴⁸ WY⁵³</p>
	<p><u>Loss of Chance Doctrine NOT recognized in the following states:</u> AR⁵⁰ DE¹⁷ DC¹⁸ FL¹⁹ ID⁵⁴ KY⁵⁵ MD²⁷ MN²⁹ MS⁵⁶ NC³⁶ OR³⁹ RI⁴¹ SC⁴² SD⁴³ TN⁴⁴ TX⁴⁵ UT⁵⁷ VT⁴⁶</p>
	<p><u>Courts are mixed, undecided, or unclear on this issue in the following states:</u> CA¹⁴ IL²² ME⁵⁸ NE⁵⁹ ND</p>

Figure 2: What is the medical expert rule in your state?⁶¹

	<p><u>Specific statutory or case law requirements for experts in the following states:</u> AL⁶² CO⁶⁸ DE⁷⁰ GA⁷³ ID⁷⁵ IL⁷⁶ IN⁷⁷ IA⁷⁸ KS⁷⁹ MD⁸⁴ MA⁸⁵ MI⁸⁶ MN⁸⁷ MS⁸⁸ MO⁸⁹ NE⁹¹ NV⁹² NH⁹³ NJ⁹⁴ NY⁹⁶ NC⁹⁷ ND⁹⁸ OH⁹⁹ RI¹⁰³ TN¹⁰⁶ TX¹⁰⁷ VA¹¹⁰</p>
	<p><u>Specific rules for arbitration or review panel in the following states:</u> AK⁶³⁻⁶⁴ LA⁸¹⁻⁸²</p>
	<p><u>Expert required to determine standard of care unless negligence is grossly apparent and/or not with a layman's knowledge in the following states:</u> AZ⁶⁵ AR⁷⁴ CA⁶⁷ CT⁶⁹ DC⁷¹ FL⁷² HI⁶⁶ KY⁸⁰ ME⁸³ MT⁹⁰ NM⁹⁵ OK¹⁰⁰ OR¹⁰¹ PA¹⁰² SC¹⁰⁴ SD¹⁰⁵ UT¹⁰⁸ VT¹⁰⁹ WA¹¹¹ WV¹¹² WI¹¹³ WY¹¹⁴</p>

* See references on where to find details of the expert witness laws in your state.