A medicolegal quagmire

Michael I. Weintraub, MD, FACP, FAAN

Background and Purpose—Despite the success of the 1995 National Institutes of Neurological Disorders and Stroke (NINDS) study using IV recombinant tissue plasminogen activator (tPA) within 3 hours in acute stroke and its subsequent FDA approval, there has been a reluctance to use tPA because of safety and efficacy issues with high incidence of intracerebral hemorrhage, and protocol violations.

Summary of Review—The following cases will illustrate the increased number of malpractice lawsuits generated by the controversy of “standard of care” and illustrate and educate clinicians regarding specific issues and how to avoid: (A) Failure to use tPA (loss of chance) or to transfer, Reed versus Granbury Hospital (Texas): acute stroke victim taken to local hospital with tPA available only for cardiology. Wife subsequently transferred patient to nearby stroke center but no tPA given. Defendant verdict; (B) Stroke misdiagnosis (failure to diagnose, loss of chance), Mei versus Kaiser Permanente South (San Francisco, CA): acute stroke while driving with ambulance taking to local hospital. Symptoms were misdiagnosed and neurologist did not see her for 6 hours. Plaintiff verdict; (C) Bleeding complications of therapy/failure of informed consent, Harris versus Oak Valley Hospital (California): acute stroke and hypertension treated with tPA with subsequent development of intracerebral hemorrhage. Patient alleged that tPA should not have been given. Defense verdict; (D) Expert witness testimony, Wojcicki versus Caragher (Massachusetts): a prominent neurologist gave “false and misleading testimony” and the Court found that the neurologist perpetrated a “fraud on the Court” intentionally and deliberately misleading the Court and jury. Court sanctioned the neurologist $88 685; Ensink versus Mecosta County General Hospital (Michigan): neurological testimony (plaintiff expert) regarding potential benefit of using tPA during last available 1 hour of window was felt to be “speculative”. Defendant verdict.

Conclusions—Neurologists, emergency room physicians and hospitals are at increased liability risk if they use or do not use tPA. Detailed documentation, informed consent or timely transfer should reduce threat of legal action. (Stroke. 2006;37:000-000.)

Key Words: lawsuits ■ malpractice ■ stroke ■ thrombolytic drugs ■ tissue plasminogen activator

Acute ischemic stroke is a leading cause of death and disability in the United States. One-third of patients who experience stroke die within 1 year. It has been estimated that ~600 000 new cases occur yearly. In 1995, 624 patients were randomized in the National Institute of Neurological Diseases in Stroke (NINDS) study demonstrating that intravenous recombinant tissue plasminogen activator (rtPA, alteplase) produced clinical and statistical benefit over placebo for patients treated within 3 hours of evaluation. The benefits also appear to be long-lasting at 3 months and 1 year as well as cost-effective and thus a great deal of enthusiasm was generated. Specifically, it was stated that if the guidelines for eligible persons were followed within a 3-hour time period then there was at least 30% more likely to have minimal or no disability at 3 months and a 3-month mortality of 17%. There was a 6.4% risk of intracerebral hemorrhage. On the basis of these results, alteplase (rtPA) was approved in the United States for use within 3 hours of onset of symptoms. However, closer scrutiny of this study raised methodologic concerns that there was an imbalance in stroke severity scores between groups from 90 to 180 minutes. Specifically, the placebo-treated group had more severe strokes than the tPA-treatment groups, and thus the results favored the mild stroke groups. Others felt that chance could explain the benefits. A prior European multicentered trial (ECASS I) of 620 patients used a maximum interval from onset to treatment of 1.1 mg/kg with 6-hour window. This was a higher dose than used in the NINDS trial and resulted in a negative study with no difference between treatment and placebo groups. A high degree of protocol violations were also noted. Mortality was increased 33% as well as increased intracerebral cerebral hemorrhage in the treatment group of 40%. A follow-up study ECASS II of 800 patients was subsequently designed with a lower dose of alteplase (0.9 mg/kg) which was identical to NINDS criteria given IV within 6 hours of onset. Stricter criteria were followed as well as CT eligibility and blood...
pressure control parameters. The results indicated that mortality was not increased and supported the use of dose of 0.9 mg/kg within 3 hours of stroke onset. However, there was a 2- to 5-fold increase in symptomatic intracerebral hemorrhage.

The Alteplase Thrombolysis for Acute Noninterventional Therapy in Ischemic Stroke (ATLANTIS) study, a phase 3, placebo-controlled trial of 547 patients, used a protocol similar to NINDS trial using tPA in a 3- to 5-hour window. Treatment with tPA basically was ineffective. However, a Cochrane review using meta-analysis of various types of thrombolysis, including tPA, urokinase, streptokinase, etc, concluded that this therapy was effective. Some critics would argue that the conclusions of the Cochrane review are not always considered valid. Reanalysis of the original NINDS trial confirmed benefit.

A disturbing community study from the Cleveland area’s experience revealed that <2% of admitted patients with acute ischemic stroke received intravenous tPA. There was a 50% incidence of protocol deviation from national treatment guidelines. In-hospital mortality was higher among treated patients (16%) compared with placebo (5%) and there was a 16% rate of intracerebral hemorrhage with a 55% mortality in this group. These findings significantly differed from the NINDS trial.

In August 2000, the American Heart Association upgraded its recommendation of tPA for stroke from optional (Class III) to definitely recommended (Class I) despite safety and efficacy concerns from the treatment. Several national groups made position articles contrary to the above. For example, the Canadian Association of Emergency Physicians (CAEP) concluded “further evidence is necessary to support the wide-spread application of stroke thrombolysis outside of research settings”. The American Academy of Emergency Medicine reached a similar conclusion: “objective evidence regarding the efficacy, safety, and applicability of tPA for acute ischemic stroke is insufficient to warrant its classification as standard of care”. Critics of the AHA’s approval based only on 1 NINDS study led to further investigation demonstrating that in the minutes of AHA Board of Directors meeting of October 18, 1991, Genentech contributed $2.5 million to build the Dallas headquarters of AHA, and subsequent contributions to AHA have totaled $11 million. A panel of 9 was responsible for the guidelines and 1 investigator noted that 6 out of 8 panelists who supported alteplase for stroke as a Class I recommendation had ties to the manufacturer. The specific decision, however, to approve could have been reflective of scientific analysis of the data rather than the alleged taint of financial conflict. Two panelists who supported the upgraded classification had no ties to the manufacturer and 1 physician dissented from the recommendations.

**Current Catalyst**

Despite the debate regarding efficacy and safety of tPA in acute ischemic stroke, there has been significant pressure exerted on physicians and hospitals to expand its use. In 2000, the Brain Attack Coalition (BAC) proposed numerous specific criteria for developing academic primary stroke centers so that a standardized treatment would prevail which would facilitate early treatment. None of the 11 BAC recommendations was associated with the reduction of hospital mortality or an increased frequency of discharge to home.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) began certifying primary stroke centers in 2005 using guidelines based on the American Stroke Association and BAC. The Department of Health of several states (New York, California, North Carolina) have been active in trying to create community stroke centers. New York State has compelled emergency medical services to divert appropriate stroke patients past a closer hospital to a state designated stroke center within 2 hours.

Medicare has now created a new DRG 559 code for “acute ischemic stroke with use of thrombolytic agent” which pays about $6,000 more than the previous DRG 014.

**Current Standard of Care**

It is clear that currently there is no universal standard of care. Less than 2% of community hospitals use tPA. There is anticipation that this number will increase attributable to the direction of Board of Health, JCAHO and Medicare. It is also clear that there are strong advocates as well as critics as well as cautious, concerned clinicians and the practicing physician and patient are in the middle of a quagmire. What is the correct decision? This is currently not known from the literature, yet this has not stopped the generation of civil (medical malpractice) lawsuits for both the use and nonuse of tPA. There has been a shift in court thinking to accept “community care” rather than standard of care (nationwide). Thus, if neighboring hospitals are designated stroke centers, individuals will be held to an elevated criterion.

**Definitions**

“Malpractice” is defined as any medical treatment that fails to conform to the standard of care within the profession and that results in injury to the patient. Plaintiffs have the burden of proving their case by a preponderance of the credible evidence (51%). They must show that there was a departure from standard and accepted medical practice and that this departure caused or was a substantial contributing factor causing the alleged injuries. Current tort law requires a physician-expert statement of deviation and negligence in order to initiate a lawsuit. In many states, any licensed physician can testify as an expert. Expert witness testimony is often indispensable in medical malpractice outcomes with opinions offered on behalf of both plaintiffs and defendants. Guidelines exist as to the qualifications in many specialty organizations.

In the United States, physicians and hospitals are involved in lawsuits whether they use or do not use tPA. Although all medical malpractice claims measure a physician’s actions against the standard, how does one address this issue in controversial and evolving standards of care? “Malocurrence” is defined as a negative outcome based on the natural history of the condition. There is often a fine line between negligent medicine and poor quality of care or inherent risks of disease. Persuaded by partisan expert witnesses, the jury often cannot tell the difference between medical malpractice and malocurrence, standard of care and evolving standard of care. These issues are of paramount importance because there is a
major thrust by national organizations to expand the number of stroke centers in the United States. It is clear that physicians in hospitals are faced with increased malpractice risk in dealing with stroke and thrombolysis.

Elements of a Malpractice Claim

Currently, there is a marked increase in the number of lawsuits regarding stroke and tPA. Physicians are currently being sued if they treat or do not treat with tPA. This topic is somewhat complex but usually revolves around several issues relating to documentation, informed consent, etc. Inherent in this is the fact that there are protocol deviations noted with absence of National Institutes of Health Stroke Scale (NIHSS) in 84%,39 and a recent retrospective analysis study revealed that one major protocol deviation in 67% and 97% had combined major and minor protocol deviations.40 When protocol deviations arise, there is increased mortality and morbidity.

The Locality Rule, which calls for physicians to be judged according to the standards of practice in their communities, has been in decline because of the explosion of information on the Internet, etc. The current burgeoning of local stroke centers in the community has now produced a change from “nationwide standard of care” to “standard of community care”.

“Competence (testamentary capacity)” is the threshold element of informed consent because only a competent person can give valid consent to treatment or treatment refusal. Physicians are obligated and must make an assessment of the individuals capacity or lack of capacity before accepting a patient’s consent or refusal as being informed.41 Under emergency situations where the patients lack testamentary capacity, the physician should turn to a family member for consent if time and circumstances permit. It is noteworthy that a recent study42 found a substantial percentage of patients who received tPA for stroke had no consent documented. Surrogates often provided consent (63%) despite patients having capacity. Additionally, patients with diminished capacity sometimes provided their own consent. In 16%, there was no documented informed consent.

“Informed consent” refers to the legal principle that patients have the right to make an informed judgment as to their care after receiving the pertinent facts regarding a proposed treatment option rather than the appropriateness of the treatment. Informed consent should include statements regarding the condition being treated with its associated morbidity and mortality and if a specific treatment is being offered, describe state of current knowledge, ie, accepted standard of care or controversial therapy as well as risks associated, and specifically describe hemorrhage into the brain, spinal cord and death.43 Because of the critical 3-hour time window, physicians must offer a timely transfer and this must be documented to both the patient and/or family (surrogate). Failure to do so results in liability for any complication from the treatment so long as a reasonable patient informed of the foregoing would have refused the treatment.

Documentation

This issue is critical to the success or failure of a lawsuit. Despite all allegations, legible documentation remains the key factor that leads to success or failure of a claim in a significant number of cases. Because the time of the trial is often years later, an accurate memory for the events can be reflected only by the records. Physicians need to adopt good habits of documentation to be aware of their obligations. A number of malpractice cases have been reported to a large malpractice insurer and were found to be “difficult to defend, not because of the medical care, but because the physicians did not document their thought processes in the medical records”. An Alert bulletin was sent out urging physicians to document the reasons for their decisions, particularly when there are multiple acceptable therapies to treat a patient’s condition. Specifically, legible records should reflect the time of onset, the time of workup completion, the diagnosis and differential diagnosis as well as the proposed treatments. Specifically, the use of tPA or lack of tPA should be described in the chart. Thus, good clinical care is not sufficient if the medical record does not adequately document that care. The records should reflect the diagnosis and proposed treatment and the bases for them, etc. In the absence of documentation, the litigation may come down to the word of the injured patient or his family versus the memory and reputation of the physician defendant. Poor medical records can suggest negligence to the jury.44

Methodology

A legal search of Jury Verdict Reporter (JVR) and West Law regarding thrombolysis (tPA) and malpractice produced various case reports related to the heart, peripheral arterial and venous disease and stroke. The following cases were selected to illustrate and represent the types of malpractice lawsuits generated that should be of concern to neurologists, emergency room physicians and hospitals. It does not represent a selection bias and I hereby affirm that I personally do not know or have any relationship with any of the individual parties or their attorneys.

As will be noted, these vignettes are inconsistent in detail from venue to venue and were submitted not by physicians but by the involved successful attorney to JVR which may also have edited the vignette. Hospital records, deposition or trial testimony transcripts were not personally reviewed for more detailed clinical information. However, the Courts in each of these cited cases accepted the alleged damages as representing “stroke”.

A. Failure to Use tPA. Absence of a Specific Hospital Protocol

Reed vs Grandbury Hospital45

Plaintiff experienced stroke-like symptoms and was taken to a local hospital 10 minutes away. His wife (nurse) wanted tPA to be used but Emergency Room physician (defendant) did not choose this option and wife transferred him to local Fort Worth Hospital for specific tPA treatment. He arrived outside the 3-hour window and did not receive treatment. The original defendant hospital did have tPA available and had a written protocol for administering only to cardiac patients. The Trial Court ruled summary judgment for the defendants with no evidence on applicable standard of care. Despite plaintiff’s expert, the Court stated that there was no showing that a common or universal standard of care for administering tPA to stroke patients applied to both physicians and hospitals or even to all physicians. The case was appealed and the Court of Appeals affirmed the Trial Court’s decision.
B. Failure to Offer tPA or Promptly Transfer to Another Hospital

Mei vs Kaiser Permanente South San Francisco Medical Center\textsuperscript{45}

In 2001, 45-year-old woman (plaintiff) experienced a stroke while driving. An ambulance took her to local hospital (defendant). The Emergency Room doctor diagnosed her with “depression and stress” for her symptoms of aphasia, inability to walk and facial weakness. A neurologist did not see her for a total of 6 hours. An arbitrator found negligence.

Lane vs TH Allied Services IC\textsuperscript{46}

In 1996, plaintiff experienced a stroke after an endoscopy procedure at Boone City Hospital (defendants). An emergency CAT scan was ordered and performed revealing findings compatible with ischemic stroke. The attending physician recommended transfer to the Intensive Care Unit (ICU) and emergency treatment with tPA. However, the orders for transfer and administration of treatment of tPA were not carried out. A Neurology consultation was called to determine whether anything else could be done after 3 hours. She then started tPA 6 and a half hours after the onset of symptoms. There was no benefit and the patient had residual dysphasia and hemiparesis. There was a plaintiff’s settlement of $500,000.

Paige vs HCA Health, RC Gesser, MD, SA Norris, MD\textsuperscript{47}

Plaintiff experienced an ischemic stroke in February 1998 and was brought to Blake Medical Center (defendant) where he was evaluated by Emergency Room physician (defendant). The on-call neurologist (defendant) examined the patient and spoke with patient and physician son regarding treatment options and they decided on heparin. A second neurological opinion was sought and it was later determined that plaintiff was a candidate for tPA treatment. Defendant neurologist stated that this was untrue because symptoms were improving. Because of residual damages, the patient and his wife filed a lawsuit against defendant medical center and all involved physicians for failure to recommend tPA. A settlement of $50,000 was reached with defendant hospital. The claims against defendant Emergency Room physician were dismissed before trial. A defense verdict was returned for defendant neurologist.

C. Stroke Misdiagnosis as Vertigo and Loss of Chance

Fernandez vs University of Pennsylvania\textsuperscript{48}

Fifty-seven year-old male (plaintiff) with prior history of stroke complained of sudden headache, blurred vision, dizziness and weakness. He went to the local hospital (defendant) Emergency Room where Emergency Room physician (defendant) diagnosed vertigo and sent him home. He was on clopidogrel (Plavix) for prior stroke prophylaxis. He returned several times to the Emergency Room and ultimately was admitted with stroke symptoms of slurred speech, incontinence, right facial numbness and inability to walk. A lawsuit ensued for failure to diagnose stroke and loss of opportunity to give tPA, because it was alleged that this intervention could have significantly improved outcome. Verdict: $5 million to plaintiff.

D. Complications of Therapy/Failure of Informed Consent

Brooks vs SSM HealthCare and Fernando De Castro, MD\textsuperscript{49}

The plaintiff brought actions against doctor and hospital for negligently administering tPA rendering the patient quadriplegic secondary to cervical epidural hematoma. She required 2 surgeries and was left with permanent incontinence of bowel/bladder, flaccid quadriplegia and wobbly head. A jury awards plaintiff $315,000 but defendant requested a new trial and Court of Appeals reviewed the Trial Court decision. While defendant cardiologist was using the drug for a cardiac condition, he did not specifically mention bleeding and also used higher amounts of tPA. Defendant cardiologist contested the plaintiff’s neurology expert’s qualifications in his rendering of the opinion because he did not have a knowledge of tPA as it applied to the heart rather than the brain. The Court of Appeals reversed the Trial Court’s granting of a new trial and reinstated the jury verdict.

E. Hemorrhagic Stroke After tPA/Informed Consent

Harris vs Oak Valley Hospital, MS, Al-Hussan, MD\textsuperscript{50}

Plaintiff was a 65 year-old female who presented to the Emergency Room (defendant) with stroke-like symptoms and hypertension. A CAT scan revealed an ischemic stroke and tPA was started. She subsequently developed an intracerebral hemorrhage producing permanent damages of dysphasia and walking difficulties and started a malpractice suit alleging that the tPA should not have been given and that her blood pressure was not adequately controlled and that her symptoms were rapidly resolving before the inappropriate administration of tPA. The defense argued that the patient and family received appropriate informed consent and that her blood pressure was in the appropriate range and under good control. A defense verdict was reached.

Expert Witness Testimony

The following 2 cases illustrate the influence of expert witness testimony in failure to offer tPA or transfer to local stroke center.

Ensink vs Mecosta County General Hospital\textsuperscript{51}

The patient was brought to local hospital with sudden paralysis. Stroke work-up was concluded 2 hours after onset but tPA was not given and residual damages occurred generating a lawsuit for allegations of loss of chance, failure to transfer and failure to treat. Dr S. Levine, a stroke neurologist expert for plaintiff, admitted that he could not say how much the patient’s condition would have been expected to improve in this last available hour of window but that “it was more likely than not that there would be "some improvement". He also acknowledged that there was a "20% spontaneous improvement without tPA". The Trial Court approved summary judgment for the defense but the patient appealed. The Court of Appeals felt that plaintiff neurological expert’s testimony was “speculative” and that the patient could not show that opportunity to achieve better results exceeded 50% had tPA been given by ER within 3 hours. The decision was affirmed.
Comments

Neurologists and emergency room physicians stand at the forefront of stroke management and are at increased liability risk if they use or do not use tPA. Regardless of one’s personal view regarding the efficacy and safety of tPA, it is essential to discuss and document with patient and family (surrogate) all treatment options. By maintaining legible, detailed and timely documentation as to time of onset, examination findings and informed consent why patients should or should not receive tPA should substantially reduce the threat of legal action. If patient or family wish to receive tPA and physician disagrees with this approach, then a second opinion with another stroke physician is necessary or alternatively offering a timely transfer to a nearby stroke facility may also avoid litigation. However, this issue will not disappear as long as there is controversy regarding standard of care. The current guidelines are outdated and do not even include the benefit of MRI and diffusion-weighted imaging as well as the increased mortality associated with older age and large infarcts, etc. Therapeutic decisions for treatment of acute stroke need to be current and precise, yet the current FDA guidelines which physicians are using are too imprecise and controversial. Currently, tPA is not used universally and thus it is not a standard of care across the United States but rather is becoming a local community health care standard. However, the public’s demand for acute treatment and high expectations only fuels this controversy. We need to re-establish trust and confidence in our professional societies which can only occur with a definitive new trial and updated protocol. Because the medical designation of Class I status is controversial, perhaps any potential litigation should be directed into a mandatory arbitration or a No-Fault format until a formal consensus can be established.

Disclosures

None.

References

Thrombolysis (Tissue Plasminogen Activator) in Stroke. A Medicolegal Quagmire
Michael I. Weintraub

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