Empirical Characteristics of Litigation Involving Tissue Plasminogen Activator and Ischemic Stroke

Bryan A. Liang, MD, PhD, JD
Justin A. Zivin, MD, PhD

From the Institute of Health Law Studies, California Western School of Law, San Diego, CA (Liang); San Diego Center for Patient Safety (Liang), Department of Anesthesiology (Liang), Department of Neurosciences (Zivin), University of California San Diego, School of Medicine, La Jolla, CA (Liang); Graduate School of Public Health, College of Health and Human Services, San Diego State University, San Diego, CA (Liang).

Study objective: The use of tissue plasminogen activator (tPA) in potential stroke victims by emergency physicians is controversial. One factor that may represent a barrier to use is medicolegal concerns resulting from adverse outcomes. The jury verdicts, settlements, and other adjudications associated with tPA and stroke care are assessed to determine the characteristics of these cases, including whether cases arose from adverse consequences associated with tPA or failure to provide tPA.

Methods: Using 7 primary jury verdict, settlement, and other adjudication legal databases, lawsuits involving tPA and stroke were collected for analysis of the clinical circumstances of the litigation, the causes of action against providers, the basis for liability, and the presence of emergency physicians and neurologist consultation in the litigation.

Results: Thirty-three cases were found involving tPA ischemic stroke therapy. In 29 (88%) of these cases, patient injury was claimed to have resulted from failure to treat with tPA. Emergency physicians were the most common physician defendants. Defendants prevailed in 21 (64%) cases, and among the 12 with results favorable to the plaintiff, 10 (83%) involved failure to treat and 2 (17%) claimed injury from treatment with tPA.

Conclusion: The available evidence concerning litigation involving stroke therapy with tPA indicates liability is predominantly associated with failure to provide tPA, rather than adverse events associated with its use. [Ann Emerg Med. 2008;xx:xxx.]

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INTRODUCTION

The use of tissue plasminogen activator (tPA) in patients with acute ischemic stroke in the emergency department is controversial. Although widely considered proven effective therapy by stroke neurologists and many specialty societies,[1] many emergency physicians and emergency medicine specialty societies are not so sanguine about its use.[2-6]

One barrier to tPA administration may be concerns about medicolegal risks associated with its use or its nonuse because of potential adverse events.[3-5,7] There appears to be much interest in this issue of potential litigation associated with tPA in the ED.[3-5,8] Further, Scott, in preliminary assessments of data associated with determining barriers to tPA use in the ED, found medicolegal concerns as a reported barrier in all 12 randomly selected hospitals in the study (P. Scott, written communication, November 2007). Hence, we wished to empirically identify the litigation characteristics of treatment and failure to treat with tPA in patients with acute ischemic stroke.

MATERIALS AND METHODS

Through the Westlaw Attorney Database, a portal for US legal materials, we queried the 7 primary national jury verdicts, settlements, and judgment materials therein, each of which comprise their own database. These were the Combined ALM VerdictSearch Jury Verdicts & Settlements, Combined JAS Jury Verdict and Settlements, Combined Jury Verdicts Review & Analysis, Jury Verdict & Settlement Summaries, Jury Verdicts—National, National Jury Verdicts Review & Analysis, and Verdicts, Settlements & Tactics—Personal Injury. These databases are composed of jury verdicts, settlements, and judgment materials as reported by the attorneys involved in the case and represent more than 290,000 case listings. Each

Editor's Capsule Summary

What is already known on this topic

Treatment of stroke patients with tissue plasminogen activator (tPA), as well as failure to treat, is perceived to carry substantial medicolegal risk.

What question this study addressed

The characteristics of the claims, defendants, and outcomes of all 33 closed lawsuits involving tPA in stroke in 6 verdict databases are described.

What this study adds to our knowledge

Most cases were for failure to use tPA and most were settled in favor of the physician defendant. Of 12 cases settled in favor of the plaintiff, 10 claimed injury from failure to treat with tPA and 2 claimed injury resulting from treatment with tPA.

How this might change clinical practice

Perceptions of medicolegal consequences of tPA use in stroke may be overstated.

database case entry provides information on the date of adjudication, the parties, the attorneys, expert witnesses, judge, type of accident/injury, award amount, county, state, and miscellaneous text. A summary of these databases, including their coverage by date and geography, as well as estimated number of case entries in each, is provided in Table 1. For Jury Verdict & Settlement Summaries, Jury Verdicts—National, National Jury Verdicts Review & Analysis, and Verdicts, Settlements & Tactics—Personal Injury databases, there were no available estimates on the number of cases within the entire database. However, a search of the term "plaintiff" resulted in greater than 10,000 case results (the maximum number of cases that may be retrieved per search), and because many of these databases are national and have been in existence for decades, the number of cases in each is likely significantly greater.

The query terms used were "tissue plasminogen activator, tPA," and "tPA," as in previous work.[8] Searching these databases with these query terms resulted in 162 cases. We limited analysis to only those cases that had a clinical manifestation of stroke by the plaintiff/patient as indicated in the description of the type of injury. That process resulted in the 33 cases that are reported here.

RESULTS

The 33 cases that involved tPA and stroke are summarized in Table 2. Of the cases, the majority (N=21; 63.6%) were decided in favor of the defendant providers. Of the remaining, 9 (27.3%) resulted in plaintiff verdicts, 2 (6.1%) resulted in settlements, and 1 (3.0%) was an arbitration favorable to the plaintiff. For nondefendant verdicts, ie, those plaintiff verdicts or settlements resulting in payment to the plaintiff, liability or settlement payment ranged from $100,000 to $30,000,000. Among the 33 cases, 19 (57.6%) involved emergency physicians as defendants, and 6 (18.2%) involved neurologists as defendants. All 6 cases involving neurologists as defendants also involved emergency physicians as defendants. Over time, cases are becoming more numerous, although the trend is not continuous: 1 case in 1999, 1 case in 2000, 3 cases in 2001, 2 cases in 2002, 7 cases in 2003, 3 cases in 2004, 10 cases in 2005, 4 cases in 2006, and 2 cases in the first 6 months of 2007.

In most (N=22; 66.7%) of the cases, patients presented to EDs, and the emergency physicians' evaluation and treatment were at issue in the litigation. Of these cases, 10 (45.5%) did not involve a neurology consultation.

In general, plaintiffs claimed failure or delay in stroke diagnosis as one cause of action (N=22; 66.7%). Plaintiffs claimed a failure of the treating physician to provide tPA in a majority of cases (N=29; 87.9%), with only 3 cases (9.1%) in which patients sued the providers and claimed that the use of tPA caused their injury. Plaintiffs claimed both failure/delay in diagnosis and failure to provide tPA in most (N=21; 63.6%) of the cases.

Finally, of the 12 verdicts favorable to the plaintiff, 2 cases (16.7%) involved claims that the tPA caused injury (case 3, the $315,000 verdict; and case 28, the $30,000,000 verdict), with the remainder (N=10; 83.3%) claiming that a failure to receive tPA caused patient injuries.

DISCUSSION

It appears that on this review of trial cases, the medicolegal risks associated with tPA are more often associated with acts of omission—failure to provide tPA—rather than adverse events resulting from its use. On the basis of this review, it appears that the typical characteristics of a stroke/tPA lawsuit is a patient suing an emergency physician who has failed to make or delayed a stroke diagnosis, with the patient not receiving tPA. These findings may provide insights as to the actual litigation risks associated with tPA administration in potential acute stroke circumstances.

Previous work has empirically assessed some of the legal results associated with stroke care and tPA. Bambauer et al[8] reviewed formally published, appellate final court decisions involving stroke and tPA. They evaluated 7 cases and found that all 7 involved patients claiming injury against physicians for failure to provide tPA. Six of the 7 cases were won by the defendant providers, with 1 won by plaintiffs. No additional information was provided, such as causes of action, liability amounts, or involvement of emergency physicians. Although useful, the appellate court decisions do not reflect the primary adjudicatory source of liability decisions, which are trial court cases. These appellate cases instead focus on unique matters of law rather than simply liability.

Another legal review was performed associated with thrombolysis and stoke. An article by Weintraub[9] included a description of anecdotal cases of tPA treatment, discussing both failure to treat and inappropriate therapy. The conclusion of the

Table 1. Jury verdict database coverage.

Name of Database	Year Coverage Begins	Number of Case Entries	Comments
Combined ALM VerdictSearch Jury Verdicts and Settlements	1996	>100,000	Combines cases from CA, FL, IL, NJ, PA, NY, TX, and miscellaneous reported cases from other parts of the country Source: http://www.verdictsearch.com
Combined JAS Jury Verdicts and Settlements	1988	>52,000	Combines cases from CT, DC, GA, MD, MA, MI, OH, RI, VA Source: http://www.verdicts.com
Combined Jury Verdicts Review & Analysis	1983	>100,000	Combines cases from FL, New England states, NJ, NY, PA, and miscellaneous reported cases from other parts of the country Source: http://www.jvra.com
Jury Verdict Settlement Summaries	1987	>10,000*	Combines cases from CT, FL, GA, MD, MA, MI, OH, RI, northern VA, DC, and miscellaneous reported cases from other parts of the country Source: http://www.westlaw.com
Jury Verdicts-National	1987	>10,000*	Combines cases from AK, CA, CT, DC, ID, FL, GA, MD, MA, MI, OH, OR, RI, VA, WA, Atlanta metropolitan area, and miscellaneous reported cases from other parts of the country Source: http://www.westlaw.com
National Jury Verdicts Review and Analysis	1984	>10,000*	Combines cases from entire United States Source: http://www.westlaw.com
Verdicts, Settlements & Tactics	1988	>10,000*	Combines verdicts and settlements reported in legal newsletters, law reviews, continuing education courses, bar journals, and practice-oriented journals. Source: http://www.westlaw.com

*Derived from search of database with term "plaintiff."

author was that detailed documentation, informed consent, or timely transfer should reduce threat of legal action, and physicians and hospitals were at increased liability risk "if they use or do not use tPA."

This work extends these previous findings and provides additional information on the medicolegal risks of tPA use in the ED for patients presenting with stroke. If emergency physicians are reticent to use tPA because they believe that serious adverse effects are common with it,[1,6] which then may lead to litigation, the findings in this work may dispel some of these concerns. Indeed, if these findings are generalizable, it would appear that not giving tPA for purportedly eligible patients in the ED may be the primary source of litigation associated with this therapy. This is perhaps not surprising, given the known low rates of tPA use in eligible stroke patients across the country. Also, most stroke patients at present either do not arrive in the ED within 3 hours of stroke onset or have another contraindication to standard intravenous tPA, so there are more ineligible than eligible patients. Because eligible patients are often untreated, and because there are presently fewer eligible patients, the pool of patients that can potentially claim injury from failure to treat is larger than the pool that can claim injury from treatment.

As do other studies of jury verdicts, here we find that providers generally win these stroke/tPA cases. Yet, it appears that cases are growing more numerous. During the 5 years after tPA was approved by the Food and Drug Administration (1996 to 2001), there were only 5 cases, whereas from years 6 to 10 (2002 to 2007), 28 cases were reported. If, controlling for increased tPA use, these numbers indicate that patients and their attorneys are becoming more aware of tPA and its use in stroke care, increasing litigation may mean they are trying to hold ED and other physicians liable for stroke events that are associated with lack of tPA use.[3-5,7] Hence, clinical practice must coincide with legal practices to ensure that the appropriate care is provided to the patient and to avoid liability.

Although this work is, as far as we know, the first attempt to systematically review trial court cases, judgments, and settlements involving tPA use in patients with stroke, it is not definitive because of several limitations. First, jury verdict reporters collect information voluntarily submitted by attorneys. Hence, there is an issue with self-selection in the materials available and the limited ability to ascertain the completeness of the information provided within a case and the extent to which those reported represent the total population of cases involving stroke and tPA. Furthermore, there are no other external sources of data from which to determine the number of cases involving stroke and tPA that may not have been reported in one of these databases.

Mitigating these issues, both plaintiffs and defendants have an incentive to report their wins to these databases because it provides notice to the legal community that they, in fact, are experienced in trying these types of cases and can prevail in them. The incentive to provide these reports is strong because demonstrating legal prowess in a particular type of case, with specific experts, in front of a particular judge in a particular court, is valuable in marketing a practice and pursuing additional business. These reports result in referrals of new clients and offers to participate as cocounsel.

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

Further, these databases represent the only source for trial jury court verdicts and are widely used and accepted in practice and in legal research. They are useful because they provide a source of information on the persons, places, and things that can influence a particular kind of case. Many of them have been operating for decades, amassing large data sets and reputations for accuracy and legitimacy.

Finally, although the legal system assumes that judges and juries decide cases on the basis of the facts, law, and a realistic assessment of the strength of the case, there is always the possibility that this may or may not be true for the stroke and tPA cases reported in this article. Juries and judges may be making liability decisions on the basis of law, clinical facts, or other nonlegal factors such as sympathetic nature of the plaintiff, sex, education, or some or none of the above.[10] In other words, cases involving patients with stroke and treatment with tPA may represent circumstances that are unique or peculiar to judges and juries assessing the appropriateness of care provided in the ED because of the injury, patient population, or other factors. Further research would be required to assess whether stroke and tPA cases are in fact evaluated differently from other malpractice cases.

Overall, we find that on an empirical review of available jury verdicts, settlements, and judgments, the typical stroke/tPA lawsuit involves an ED presentation by a patient to an emergency physician, with the patient claiming a failure/delay in diagnosing stroke and failure to provide tPA, rather than lawsuits based on harm associated with tPA use. In these cases, liability is most often associated with failure to provide tPA.

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Address for reprints: Bryan A. Liang, MD, PhD, JD, Executive Director, Institute of Health Law Studies, California Western School of Law, Co-Director, San Diego Center for Patient Safety, UCSD School of Medicine, 350 Cedar Street, San Diego, CA 92101; 619-515-1568, fax 619-515-1599; E-mail baliang@alum.mit.edu.

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