Response to Letters by Whiteley et al, and Goldstein et al

Response:

My prior article on Medicolegal Issues Relating to Thrombolysis (tPA) in Stroke1 has generated many useful and provocative comments.

Currently, there is a major disconnect between advocates who believe the American Heart Association (AHA) position has sufficient data to justify Class I position contrasted by critics who do not believe tPA should represent the standard of care in acute ischemic stroke. Industry participation was acknowledged in the National Institutes of Neurological Disorders and Stroke (NINDS) study, yet the AHA never acknowledged any conflict of interest of its panelists and continues to hold financial “disclosures” secret. Thus, panelists “disclose” to the AHA but the AHA does not disclose to the public. The implication of financial taint as well as refusal to release the NINDS raw data under the Freedom of Information Act to the British Medical Journal has only fueled this controversy. The results of the 1995 NINDS study2 demonstrated a 30% improvement in morbidity and disability scores only at 3-month level in 624 patients with significantly increased incidence of fatal intracerebral hemorrhage and overall symptomatic hemorrhage. Other thrombolytic studies did not confirm benefit yet confirmed an increased rate of hemorrhage and mortality. Despite these negative studies, the AHA changed treatment parameters from IIb to I (mandatory),3 and this move has generated not only major controversy but also has sparked a new increase in malpractice claims against hospitals, emergency medical physicians, neurologists and other participating health colleagues.

There has been growing skepticism regarding industry-sponsored studies, and this has been recently addressed in editorials in Neurology as well as JAMA.5-7 The AHA has not clearly articulated the basis for this change in status and only released 5 lines “based on the results of Parts I (a failure over 24 hours) and Part II of the NINDS study; intravenous administration of tPA is recommended within 3 hours of the onset of stroke symptoms (Class I).” The AHA has subsequently withdrawn the claim that “tPA saves lives.” This is not evidence-based medicine but rather a declarative statement, and it is this specific aspect which is the center of the current controversy.

Recently, I have been informed that all 4 major emergency medicine organizations in North America, ie, the American College of Emergency Physicians (ACEP), the American Academy of Emergency Medicine (AAEM), the Society for Academic Emergency Medicine (SAEM), and the Canadian Association of Emergency Physicians (CAEP) have explicitly refused to endorse tPA as standard of care in their position articles. These organizations represent over 40 000 emergency physicians who are at the forefront of care and this fact cannot be ignored by the AHA/ASA and needs to be addressed. Additionally, methodological concerns about imbalance in stroke severity scores between groups from 90 to 180 minutes persist.

In 2000, Congress passed the “Data Quality Act” (DQA)8,9 regarding false medical claims by companies, organizations, etc. It is intended to ensure that regulations are based on solid science. It is unclear whether a petition will be generated against the AHA for its current Class I position.

After publication, I was contacted by the attorney representing Dr Hochberg. He informed me that this case was appealed to the Supreme Judicial Court of Massachusetts which is the highest Appellate Court. On July 11th the Court issued a decision favorable to both Dr Caragher and Dr Hochberg stating that the trial judge abused her discretion in granting the Plaintiff’s motion for a new trial and imposing sanctions and accordingly vacated the orders of the judge, reinstated the original jury verdict for Defendant and entered a final judgment of dismissal.10

A physician attorney wrote and was of the opinion that if a physician correctly and timely diagnosed a stroke and ruled out intracerebral hemorrhage and then advises/documents the patient of risks, benefits and then makes a treatment recommendation (yes or no to tPA), he believes the physician is protected because the treatment probably falls in the judgment rule “safe harbor”—that is, as long as some percentage of physicians would treat without tPA, then no deviation would occur. However, he was not sure of the answer if the eligible patient requested tPA and the physician refused to treat with tPA.

Other legal opinions do not feel that arbitration or No Fault on a national level will occur because the issues raised are not really policy questions but also substantive legal and even Constitutional questions.

Obtaining informed consent is the ideal process but Courts have recognized and held physicians not liable for “emergency” treatment. Some physicians and stroke centers take the position that following the guidelines and documenting the decision to use or not use tPA is clear and should preclude thrombolytic lawsuits. Many of the large centers do not obtain informed consent because they believe that this represents the standard of care.

Lastly, the comments of Drs Goldstein and Saver regarding the subsequent Stroke Council Guidelines adhering to the
highest standards and attempting to revise every 3 years using evidence-based medicine is correct. Respectfully, however, if the authors would closely read Circulation 2000 Part 7, the 5 lines discussed above are the major problem that the AHA has not clearly articulated or justified its Class I position. Many neurologists have informed me that they are not persuaded by the data.

In conclusion, it would seem prudent that a reappraisal of all the specific issues as well as the positions taken by the 4 emergency medical associations be addressed and perhaps a consensus can be developed so as to resolve this controversy. Additionally, perhaps a moratorium or rescinding of this classification needs to be done until a definitive study is completed. This may also help reduce lawsuits.

Disclosures

None.

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