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Litigation Regarding tPA and Stroke

To the Editor:

I suggest there is another factor involved in the overrepresentation of "failure to treat" cases involving tPA and stroke, reported by Liang and Zivin in the August 2008 issue of *Annals*.¹ That factor is "informed consent."

I would expect that those patients who actually did receive thrombolytic therapy for their stroke were the recipients of truly informed consent which laid out the risks and benefits of treatment prior to administration of the drug. They would therefore have less grounds for a lawsuit. On the contrary, those patients whose physician either chose not to treat or were presented the option of tPA in a negative light are less likely to have been the beneficiaries of truly informed consent, if they received such counsel at all.

I would be interested in the authors' view of the role of informed consent in the cases they reviewed.

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any potential conflict of interest. The author has stated that no such relationships exist. See the Manuscript Submission Agreement in this issue for examples of specific conflicts covered by this statement.

1. Liang BA, Zivin JA. Empirical characteristics of litigation involving tissue plasminogen activator and ischemic stroke. *Ann Emerg Med.* 2008;52:160-164.

In reply:

We thank Dr. Pilcher for his letter regarding our article. The issue of informed consent may indeed play a role in the fraction of cases that we found represented a failure to treat. Unfortunately, the granularity of the case information that we can access in the legal databases cannot provide us with a definitive determination on the role of whether the treating physician provided appropriate disclosure of tPA risks and benefits in the informed consent discussion. However, if he or she did not, such an act of omission will certainly contribute to an attorney filing a tort claim for failing to treat because of the significant benefits associated with tPA's correct use and the legally protective effect of appropriate discussion of its risks and benefits. In fact, Dr. Pilcher is quite prescient in his observation, for in a recently published article,¹ we discuss the potential for lack of informed consent liability in these very circumstances.

We once again thank Dr. Pilcher for his comments. They illustrate the need to ensure accurate and appropriate information be provided to eligible patients regarding tPA to avoid liability.

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1. Liang BA, Lew R, Zivin J. A review of tissue plasminogen activator, ischemic stroke, and potential legal issues. *Arch Neurology* 2008;65:1429-1433.

Etomidate as an Induction Agent for Endotracheal Intubation in Patients With Sepsis

To the Editor:

I was excited to read the feature "Clinical Controversies: Etomidate as an induction agent for endotracheal intubation in patients with sepsis" as this relates to one's everyday practice if working at a busy emergency department (ED).^{1,2} I want to make a few points in response to the commentary: "Etomidate: not worth the risk in septic patients."² The assertion in the body of the paper, and then again in the concluding paragraph, that response to adrenocorticotropic hormone and performance of adrenal glands affects outcome including survival in sepsis (based on a small cohort study with only 9 nonsurvivors, and 2 editorials/review articles) seems to be in conflict with the result of the CORTICUS study, the largest randomized trial of patients with sepsis and septic shock which showed that there was no significant difference in mortality between patients who did or did not have a response to corticotrophin.³

The use of etomidate is decried based on selective use of data from the study by Lipiner-Friedman et al.⁴ The results of

univariate analysis are mentioned but not those of multivariate analysis which showed no significant difference in the risk of death for patients receiving etomidate.⁴ Further weakening the author's assertion is the use of data mining and analysis from the den Brinker et al meningococcal study which is so far removed from the objectives of the original study (to evaluate adrenocortical function in meningococcal disease) that the authors of the original paper did not perform this data analysis.⁵

Further down, the commentary refers to the study by Ray and McKeown and states that "their review demonstrated no improvement in mortality in septic patients receiving etomidate plus hydrocortisone compared with those receiving etomidate alone," implying that patients receiving etomidate had higher mortality than those receiving other induction agents.⁶ This is in direct contradistinction to the study's main finding that use of etomidate did not affect mortality or any other clinical outcome feature among patients with septic shock.⁶

There may be reasons to be careful about the use of etomidate as an induction agent for endotracheal intubation in patients with sepsis, but the commentary unfortunately fails to bring good information to that effect to light.

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1. Walls RM, Murphy MF. Continue to use etomidate for intubation of patients with septic shock. *Ann Emerg Med.* 2008;52:13-14.
2. Sacchetti A. Etomidate: not worth the risk in septic patients. *Ann Emerg Med.* 2008;52:14-16.
3. Sprung CL, Annane D, Didier K, et al. Hydrocortisone for septic shock. *N Engl J Med.* 2008;358:111-124.
4. Lipiner-Friedman D, Sprung CL, Laterre PF, et al. Adrenal function in sepsis: the retrospective Corticus cohort study. *Crit Care Med.* 2007;35:1012-1018.
5. den Brinker M, Joosten KF, Liem O, et al. Adrenal insufficiency in meningococcal sepsis: bioavailable cortisol levels and impact of interleukin-6 levels and intubation with etomidate on adrenal function and mortality. *J Clin Endocrinol Metab.* 2005;90:5110-5117.
6. Ray DC, McKeown DW. Effect of induction agent on vasopressor and steroid use, and outcomes in patients with septic shock. *Crit Care.* 2007;11:R56.