Lack of Association Between Pretreatment Neurology Consultation and Subsequent Protocol Deviation in Tissue Plasminogen Activator-Treated Patients With Stroke

William J. Meurer, MD, MS; Angela F. Caveney, PhD; Alex Lo, MD, PhD; Lingling Zhang, MS; Shirley M. Frederiksen, BSN, MS; Annette M. Sandretto, MSN; Robert Silbergleit, MD; Phillip A. Scott, MD

Background and Purpose—We evaluated the hypothesis that consultation with neurology would be associated with fewer protocol deviations in tissue plasminogen activator-treated patients with stroke.

Methods—A retrospective analysis of consecutive tissue plasminogen activator-treated patients with acute patients was performed. Using \( \chi^2 \) tests, the proportion of patients with a protocol deviation was calculated and compared between those with evidence of a neurology consultation and those without. Logistic regression was then used to determine the OR for protocol deviation at the same time as controlling for clinical presentation covariates.

Results—Two hundred seventy-three subjects were included. Protocol deviation rates did not significantly differ between those with (44%) and those without (41%) a consultation. The adjusted OR for deviation comparing any consultation versus no consultation was 1.25 (95% CI: 0.58 to 2.68). There was no statistically significant difference between symptomatic intracranial hemorrhage and in-hospital mortality rates between the groups. The proportion of patients with pretreatment deviations not related to timing was low in both the consultation (9.7%) and nonconsultation groups (8.1%).

Conclusions—Neurological consultation was not found to be associated with decreased protocol deviations in this cohort, although the high proportion of deviations with and without consultation suggests that quality improvement is needed. Most observed pretreatment deviations were attributable to timing. As acute stroke care becomes more efficient and additional methods in reducing door-to-treatment times are sought, models in which emergency physicians direct the initial phase of treatment may merit further consideration. (Stroke. 2010;41:2098-2101.)

Key Words: emergency care ★ referral and consultation ★ stroke ★ thrombolytic therapy
protocol deviation, including pre- and posttreatment. Protocol deviations were defined as per the alteplase package insert; therefore, timing violations were treatment >180 minutes from the witnessed onset or time known to be last at baseline.

Standards for chart reviews in emergency medicine were incorporated into the planning of this study. Cases were identified using several concurrent methods, including International Classification of Diseases, 9th Revision codes, pharmacy logs, and participation in a statewide stroke registry. Cases were included if there was definitive evidence the patient received tPA for stroke. Trained investigators used a standard abstraction form. These investigators were unaware of this study question. A sample of 10% of charts went through double review. The interrater agreement for presence or absence of consultation with neurology (κ = 0.78) or with an acute stroke research team (κ = 0.83) was high.

Using χ² tests, the proportion of patients with a protocol deviation was calculated and compared between those with evidence of a consultation with neurology or an acute stroke research team and those without. Median arrival to treatment time interval was computed for both groups. The proportion with symptomatic intracranial hemorrhage, in-hospital mortality, and the proportion with timing deviations was compared using the Fisher exact test.

Multivariable binary logistic regression was then used to determine the ORs for protocol deviation between the consultation and nonconsultation groups. Treating hospital, history of stroke, history of atrial fibrillation, stroke severity, and patient demographic factors (age, gender, and race) were considered as potential covariates. Because this was an exploratory analysis in which potentially important clinical factors were not known, covariates with a P < 0.05 on bivariate analysis were all included in the final model.

In our sensitivity analyses, we compared the deviation rates at the same time as considering only pretreatment deviations and excluding timing deviations. Treatment from 3 to 4.5 hours is now recommended in certain cases and no included cases were treated outside this window. We also compared deviation rates using modified European Cooperative Acute Stroke Study (ECASS) III criteria from our data set. Because our protocol only considered prior anticoagulant use a deviation if the prothrombin time was out of range, we did not consider any use of an anticoagulant as an exclusion as had been done in ECASS III.

Statistical analyses were performed with SPSS Version 14.0. The study was approved by the Institutional Review Boards at all participating hospitals.

**Results**

There were 273 patients included in the study. Thirty-seven had no documented neurology or thrombolytic expert consultation before tPA administration. The clinical characteristics of the 2 groups are depicted in Table 2. There were 119 patients with protocol deviations (52 in emergency department, 48 inpatient, 19 both). Patients receiving any consultation had a protocol deviation rate of 44.4%, whereas those without a consultation had a rate of 40.9% (P = 0.614 by χ²). The door-to-drug time was similar with and without consultation, 94 and 98 minutes, respectively. Between those with and without consultation, there was no statistically significant difference in symptomatic hemorrhage rates (P = 0.3) or in-hospital mortality (P = 0.5).

The types of protocol deviations observed in each group are presented in Table 3. Some patients experienced multiple deviations (commonly 1 pretreatment and 1 posttreatment) and therefore more deviations are in this table than the overall number of patients who experienced ≥1 deviations. There were more timing deviations in the nonconsultation group, although this did not achieve statistical significance (P = 0.1).

Treating hospital, history of stroke, and history of atrial fibrillation were significant predictors and were included in the final model. In the adjusted model, the associations between obtaining a neurology consultation and protocol deviation also did not achieve statistical significance after controlling for covariates. The adjusted OR for deviation and 95% CIs for consultation with either a neurologist or acute stroke research team was 1.25 (95% CI, 0.58 to 2.68).

**Sensitivity Analyses**

There were 26 patients with pretreatment deviations other than timing, 3 (8.1%) in the nonconsultation group and 23 in the consultation group (9.7%). This difference was not statistically significant (P = 0.1). Five of the documented deviations in the consultation group were the lack of evidence of testing of glucose before treatment.

When applying the ECASS III criteria, no patients treated from 3 to 4.5 hours had a National Institutes of Health Stroke Scale >25 or the combination of diabetes and prior stroke. Older patients were observed in this group: 4 in the noncon-
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might have produced more efficiency. The efficacy of tPA for suspected that treating patients without awaiting consultation and nonconsultation groups, although we had strate a difference between the door-to-treatment times in the was higher in the nonconsultation group. We did not demon-

eral deviations may be especially amenable to reduction through process improvement. Few treated patients were ineligible for other reasons; it is highly likely that glucose was checked before treatment in the 5 patients in whom this was consid-
ered a deviation but the medical record did not reflect this. Within this investigation, the number of timing deviations was higher in the nonconsultation group. We did not demon-

Conclusions

Neurological consultation was not found to be associated with decreased protocol deviations in this cohort, although the high rate of deviations with and without neurology consultation illustrates the further need for quality improve-

A total of 119 patients had 152 deviations. For blood pressure, a posttreatment deviation was >2 consecutive readings out of range taken 15 minutes apart.

Neurological consultation was not found to be associated with decreased protocol deviations in this cohort, although the high rate of deviations with and without neurology consultation illustrates the further need for quality improvement. It appears acute stroke treatment guidelines can be followed by emergency physicians without immediate neurological consultation could achieve faster treatment times without compromising compliance with major inclusion criteria. Because our investigation evaluated cases that occurred over a relatively lengthy time period (1996 to 2005) and that the overall door-to-treatment times were relatively long, our ability to detect this effect may have been limited. This type of system would require support from the institution and local neurologists. Such support would ensure that the protocol is in line with best practices for acute stroke and that patients would receive proper posttreatment care or transfer to an institution that can provide it. The prompt availability of advice would be crucial for cases that are not straightforward or fall outside of the protocol.

This investigation has several important limitations. Charts reviewed were a consecutive series of thrombolytic-treated patients with stroke who were retrospectively reviewed. Consultations with neurology that caused patients to not receive treatment would thus not be included here, although this could conceivably include patients who could have been treated and those who should not have been treated. In some cases, the care may have been discussed with a neurologist or stroke expert despite this not being apparent on later review of the chart. We did not compare functional outcomes between the groups given the small sample size. Finally, the absolute number of cases in which no consultation was documented is relatively low, which limited our ability to detect a difference. This also prevented us from being able to make meaningful comparisons regarding symptomatic intracranial hemorrhage rates.

In summary, we found no significant differences in protocol deviation rates in tPA-treated patients with stroke among those with and without neurologist consultation. Most protocol deviations were related to timing; nontiming deviations were low for both groups. Further study of emergency physician-directed acute stroke care may be warranted.

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Disclosures

None.

References


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