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

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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 nonconsultation 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

The use of intravenous tissue plasminogen activator (tPA) in ischemic stroke has been demonstrated to decrease disability; however, the limited availability of timely neurological consultation may contribute to lack of adoption in widespread community practice. The temporal urgency in stroke diagnosis and tPA administration makes the emergency department the focal point of most acute stroke treatment.

Only 15% of all ischemic strokes present for medical attention within the 3-hour treatment window, and of these cases, only 15% to 25% receive tPA treatment. Many patients with ischemic stroke arriving within the 3-hour treatment window are ineligible for tPA due to contraindications based on tPA protocol guidelines.

It is common practice for emergency medicine physicians to consult a neurologist before tPA administration. In prior investigations, protocol deviation rates have been associated with increased complications and mortality. The presence of both a standard protocol for acute stroke in the emergency department and a vascular neurologist on the hospital staff lowered in-hospital mortality for patients with ischemic stroke. However, it is unclear whether consultation before treatment is critical in preventing deviation from protocol guidelines given the time pressures associated with drug delivery along with variability in the response times of consultants. In this study, we evaluated the hypothesis that pretreatment specialist consultation would be associated with fewer protocol deviations.

Methods

Retrospective analysis of 273 consecutive tPA-treated patients with acute stroke at 4 hospitals from 1996 through 2004 was performed to evaluate the safety of the community use of tPA for stroke. The characteristics of the hospitals are provided in Table 1. The primary outcome studied in this secondary analysis was presence of a...
Table 1. Hospital Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location, city</td>
<td>Ann Arbor</td>
<td>Ann Arbor</td>
<td>Flint</td>
<td>Jackson</td>
</tr>
<tr>
<td>Urban/rural/suburban</td>
<td>Suburban</td>
<td>Suburban</td>
<td>Urban</td>
<td>Rural</td>
</tr>
<tr>
<td>Hospital beds (2004)</td>
<td>792</td>
<td>529</td>
<td>463</td>
<td>411</td>
</tr>
<tr>
<td>Adult ED visits per year (2004)</td>
<td>50 918</td>
<td>65 259</td>
<td>54 707</td>
<td>52 500*</td>
</tr>
<tr>
<td>Neurology residency</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Teaching hospital</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Total ED visits*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ED indicates emergency department.

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 x²). 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-
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-
er a deviation but the medical record did not reflect this. before treatment in the 5 patients in whom this was consid-
er other reasons; it is highly likely that glucose was checked
process improvement. Few treated patients were ineligible for
deviations may be especially amenable to reduction through
volvement of neurology in many cases. The vast majority of
followed by emergency physicians without immediate in-
Neurological consultation was not found to be associated
ment deviation rates were 18.9% in the nonconsultation group
sultation group and 9 in the consultation group. The pretreat-
Type of Deviation No. Percent No. Percent

<table>
<thead>
<tr>
<th>Pretreatment</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms not severe</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Time &gt;180 minutes</td>
<td>10</td>
<td>27%</td>
<td>36</td>
</tr>
<tr>
<td>Recent myocardial infarction</td>
<td>1</td>
<td>3%</td>
<td>1</td>
</tr>
<tr>
<td>Recent major surgery</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Prior intracerebral hemorrhage/subarachnoid hemorrhage</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Blood pressure not &lt;185/110 mm Hg at time of treatment</td>
<td>1</td>
<td>3%</td>
<td>7</td>
</tr>
<tr>
<td>If on heparin, activated partial thromboplastin time normal</td>
<td>1</td>
<td>3%</td>
<td>0</td>
</tr>
<tr>
<td>Platelet count &gt;100 000</td>
<td>0</td>
<td>0%</td>
<td>5</td>
</tr>
<tr>
<td>Glucose&gt;50 mg/dL (deviations include not tested)</td>
<td>0</td>
<td>0%</td>
<td>5</td>
</tr>
<tr>
<td>No seizure at onset</td>
<td>1</td>
<td>3%</td>
<td>4</td>
</tr>
<tr>
<td>Posttreatment including hospitalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No antplatelet use for 24 hours</td>
<td>3</td>
<td>8%</td>
<td>27</td>
</tr>
<tr>
<td>No anticoagulant use for 24 hours</td>
<td>3</td>
<td>8%</td>
<td>16</td>
</tr>
<tr>
<td>Blood pressure maintained &lt;180/105 mm Hg for 24 hours*</td>
<td>7</td>
<td>19%</td>
<td>21</td>
</tr>
</tbody>
</table>

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.

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 improvement. It appears acute stroke treatment guidelines can be followed by emergency physicians without immediate involvement of neurology in many cases. The vast majority of pretreatment deviations involved timing, which is generally a less concerning deviation than blood pressure management or extensive ischemic changes on pretreatment CT. The timing 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 considered 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 demonstrate a difference between the door-to-treatment times in the consultation and nonconsultation groups, although we had suspected that treating patients without awaiting consultation might have produced more efficiency. The efficacy of tPA for stroke was subsequently demonstrated in selected patients between 3 and 4.5 hours, potentially mitigating the seriousness of this type of deviation.10

Because relatively small improvements in treatment times (ie, 10 to 15 minutes) could have clinical importance,11 it is possible that a system in which the initial process is conducted within a protocol by the emergency physician 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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