Informed Consent for Thrombolytic Therapy for Patients With Acute Ischemic Stroke Treated in Routine Clinical Practice

Julie R. Rosenbaum, MD; Dawn M. Bravata, MD; John Concato, MD, MPH; Lawrence M. Brass, MD; Nancy Kim, MD; Terri R. Fried, MD

Background and Purpose—Little is known about informed consent for tissue plasminogen activator (tPA). Our objectives were to determine how frequently informed consent is obtained when tPA is given to stroke patients in clinical practice and whether the person providing consent (patient or surrogate) was the appropriate decision-maker.

Methods—This retrospective cohort included acute stroke patients given tPA in 10 Connecticut hospitals (1996–1998). Consent was defined as any documentation of discussion about risks and benefits of tPA. Patients had adequate decision-making capacity if they were alert, oriented, and without aphasia or neglect (patient was appropriate decision-maker). Patients with any of these deficits were considered to have diminished capacity (surrogate was appropriate decision-maker).

Results—Among 63 patients who received tPA, 53 (84%) had informed consent documented; 16/53 (30%) gave their own consent. Among patients with adequate decision-making capacity, 5/8 (63%) had consent by surrogate. Among patients with diminished capacity, 7/38 (18%) provided their own consent.

Conclusions—A substantial percentage of patients who received tPA for stroke had no consent documented. Surrogates often provided consent when the patients had capacity; conversely, patients with diminished capacity sometimes provided their own consent. Given the urgency and weight of the decision regarding tPA, more explicit informed consent and capacity assessment should be considered for treatment protocols. (Stroke. 2004;35:e353-e355.)

Key Words: cerebral ischemia □ informed consent □ mental competency □ thrombolytic therapy

Thrombolytic therapy with tissue plasminogen activator (tPA) decreases morbidity from acute ischemic stroke but is associated with potential risks, including hemorrhage and death. The American Heart Association Guidelines state that when considering tPA for stroke, “although a written consent is not necessary, patients and their families should be informed about the potential risks and benefits.” Shared decision-making between patient and physician is considered fundamental to quality medical care. Such decision-making and informed consent, its legal counterpart, both require that the patient has adequate information to participate in the discussion, has adequate mental capacity, and participates voluntarily. If the patient lacks capacity, then a surrogate should participate on the patient’s behalf.

Little is known about informed consent to tPA in stroke outside of the research setting. The objectives of this study were to assess how frequently informed consent is documented when thrombolysis is given to stroke patients in clinical practice, to describe who provides consent (patient or surrogate), and to assess whether the person who provides consent is the appropriate decision-maker.

Patients and Methods

This study involved secondary analysis of a retrospective cohort of patients who were given thrombolysis for acute stroke from 1996 to 1998 in 10 Connecticut hospitals; the methods of data abstraction have been described previously. Institutional review board approval was obtained from all hospitals.

We defined the presence of informed consent to include any documentation of a discussion with patient or proxy about risks and benefits of tPA (eg, a signature on a consent form, documentation about a discussion in the medical record). We recorded who provided consent (ie, patient or surrogate).

Our review found no documentation of assessment of patients’ decision-making capacity. We therefore used available clinical characteristics that might affect decision-making participation to infer whether patients provided appropriate consent. Patients were considered to have adequate decision-making capacity if they were documented to have all of the following: full alertness and orientation, and no evidence of aphasia or neglect. For patients with adequate capacity, the appropriate decision-maker was presumed to be the patient. Patients were considered to have diminished capacity...
TABLE 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=63</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range, y</td>
<td>39-92</td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>71±12</td>
<td></td>
</tr>
<tr>
<td>Race, white</td>
<td>52</td>
<td>83</td>
</tr>
<tr>
<td>Gender, female</td>
<td>34</td>
<td>54</td>
</tr>
<tr>
<td>Pre-existing speech deficit</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Admission NIHSS score, range</td>
<td>3-37</td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>15±6.7</td>
<td></td>
</tr>
<tr>
<td>Level of consciousness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alert</td>
<td>46</td>
<td>73</td>
</tr>
<tr>
<td>Lethargy</td>
<td>14</td>
<td>22</td>
</tr>
<tr>
<td>Coma</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Oriented</td>
<td>17</td>
<td>27</td>
</tr>
<tr>
<td>Any disorientation</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>No documentation</td>
<td>38</td>
<td>60</td>
</tr>
<tr>
<td>Neglect</td>
<td>17</td>
<td>27</td>
</tr>
<tr>
<td>Dysarthria</td>
<td>35</td>
<td>56</td>
</tr>
<tr>
<td>Aphasia</td>
<td>29</td>
<td>46</td>
</tr>
<tr>
<td>Patients with documented consent</td>
<td>53</td>
<td>84</td>
</tr>
<tr>
<td>Decision-making capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Diminished</td>
<td>44</td>
<td>70</td>
</tr>
<tr>
<td>Unknown</td>
<td>10</td>
<td>16</td>
</tr>
</tbody>
</table>

NIHSS indicates National Institutes of Health Stroke Scale.

when they had at least one of the following: less than full alertness, any disorientation, aphasia, or neglect. In this case, the appropriate decision-maker was presumed to be a surrogate.

Student t tests were used to compare differences in dimensional variables, and Fisher exact tests and χ² tests were used to assess binary variables. All calculations were performed using PC-SAS 6.12 (SAS Institute).

Results

Our cohort included 63 patients who received tPA for stroke (see Table 1 for baseline characteristics). Eighty-four percent (53/63) of patients who received tPA had informed consent documented. No differences were found between patients with and without consent (data not shown). Thirty percent (16/53) of patients gave their own consent, with surrogate decision-makers providing consent for 70%.

Fourteen percent (9/63) had adequate decision-making capacity (Table 1); 70% (44/63) had diminished decision-making capacity. For 16% (10/63), medical records lacked enough information to ascertain capacity. Among patients with consent and adequate decision-making capacity, 63% (5/8) had surrogates provide consent for them (Table 2). Among patients with consent and diminished capacity, 18% (7/38) provided their own consent. Two patients were comatose; surrogates provided consent.

Discussion

Two previous studies of informed consent for common medical procedures (eg, thoracentesis) found that consent documentation was present in 81% and 87% of the charts, respectively.8,9 Our study found a comparable rate (84%) for an intervention that carries greater risk, where one may have expected rates to have been higher. Informed decision-making by the patient should be part of any medical treatment but becomes most essential when the potential risks increase.5

Given the limited window of opportunity to administer tPA and the irreversibility of the consequences of stroke, one might consider the appropriateness of treating the patient without informed consent because of the emergency exemption to consent.10 Such exemptions are justified when: (1) there is widely accepted and incontrovertible evidence that the emergent therapy is likely to have a positive therapeutic result; (2) delay in treatment will almost certainly have adverse or irreversible consequences; (3) there are no alternative therapies available that would be nearly as safe and effective, but that would permit sufficient discussion regarding informed consent; and (4) treating physicians are confident that reasonable persons who, given this possible circumstance to consider in advance, would agree to the therapeutic intervention and agree to forgo explicit informed consent.

Although treatment with tPA may have meet criteria 2 and 3, it remains controversial whether tPA has yet reached the threshold in which there is widely accepted and incontrovertible evidence that this therapy is likely to have a positive therapeutic result. Despite the clinical benefit documented in the National Institute of Neurological Disorders and Stroke (NINDS) trial,1 data emerging from outside of the clinical trial setting suggest that the risk-to-benefit ratio may be less favorable when tPA is given in routine clinical practice.7,11 In fact, a recent evidence-based review of thrombolysis in stroke stated that “the data do not support the widespread use of thrombolytic therapy in routine clinical practice at this time.”12

Regarding criterion 4, the complexity of the information and urgency create a difficult decision-making situation. After discussing the risks and benefits of tPA, many patients or surrogates may defer to physicians to make decisions about treatment. Further research on eliciting treatment preferences of patients at risk for stroke may aid facilitation of this process.

Using a surrogate decision-maker should be predicated on an assessment of the patient’s decision-making capacity, which was poorly documented in charts. Our study suggests problems with the use of surrogate. They often provided consent when the patients had adequate decision-making capacity, and several patients with presumed diminished capacity provided their own consent. Several reasons may account for the discrepancies. For example, given the limited window of opportunity to treat with tPA and complexity of
the decision, some clinicians may have presumed that patients
would not be able to comprehend the issues, instead turning
to a surrogate, or patients may have asked family to decide.
Alternatively, patients with capacity may have been unavail-
able for consent discussions (eg, during brain imaging).
Our study is limited by relying on chart abstraction data to
assess the process of informed consent. Further, our re-
search findings may not reflect current practice given that the
study period was between 1996 and 1998.
Increasing the quality of informed decision-making regarding
tPA for acute stroke will involve greater attention to capacity
assessment for patients. Although the emphasis on improving
the use of tPA has previously focused on patient selection and
tPA administration, we have an obligation to involve patients
in their care. Future work should focus on capacity assessment
in the acute stroke setting to ensure that the most appropriate
parties participate meaningfully in the discussion.

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