Improving Delivery of Acute Stroke Therapy
The TLL Temple Foundation Stroke Project

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Background and Purpose—Only a small minority of acute stroke patients receive approved acute stroke therapy. We performed a community and professional behavioral intervention project to increase the proportion of stroke patients treated with approved acute stroke therapy.

Methods—This study used a quasi-experimental design. Intervention and comparison communities were compared at baseline and during educational intervention. The communities were based in 5 nonurban East Texas counties. The multilevel intervention worked with hospitals and community physicians while changing the stroke identification skills, outcome expectations, and social norms of community residents. The primary goal was to increase the proportion of patients treated with intravenous recombinant tissue plasminogen activator (rTPA) from 1% to 6% of all cerebrovascular events in the intervention community.

Results—We prospectively evaluated 1733 patients and validated 1189 cerebrovascular events. Intravenous rTPA treatment increased from 1.38% to 5.75% among all cerebrovascular event patients in the intervention community (P<0.01) compared with a change from 0.49% to 0.55% in the comparison community (P=1.00). Among the ischemic stroke patients, an increase from 2.21% to 8.65% was noted in the intervention community (P=0.02). The comparison group did not appreciably change (0.71% to 0.86%, P=1.00). Of eligible intravenous rTPA candidates, treatment increased in the intervention community from 14% to 52% (P=0.003) and was unchanged in the comparison community (7% to 6%, P=1.00).

Conclusions—An aggressive, multilevel stroke educational intervention program can increase delivery of acute stroke therapy. This may have important public health implications for reducing disability on a national level. (Stroke. 2002; 33:160-166.)

Key Words: education ■ emergency medical services ■ stroke, acute ■ thrombolytic therapy

In June 1996, the US Food and Drug Administration (FDA) approved intravenous recombinant tissue plasminogen activator (rTPA) for acute ischemic stroke. Treatment needs to begin within 3 hours of symptom onset. The approval was based largely on the 2 combined National Institute of Neurologic Disease and Stroke (NINDS) Acute Stroke Studies.1 Including the risk of intracranial hemorrhage, these studies suggested that the use of intravenous rTPA resulted in at least a 30% relative benefit in reducing disability from stroke. Consensus statements from the American Heart Association,2 American Academy of Neurology,3 and American College of Chest Physicians4 supporting the use of intravenous rTPA were published (grade A recommendations). Although these leading organizations published these statements supporting the use of intravenous rTPA for acute ischemic stroke, some individuals have expressed reservations in editorial format.5 Despite the published data, consensus statements, and guidelines, only a very small minority of acute stroke patients currently receive intravenous rTPA for acute ischemic stroke nationally.

Speculations regarding the cause of the low treatment rate include a long delay time for hospital presentation6–15 and reluctance among physicians to treat patients.16 The TLL Temple Foundation Stroke Project was organized to determine whether an aggressive, scientifically based behavioral intervention could increase the proportion of stroke patients treated with FDA-approved acute stroke therapy within a representative community.

Methods

The study used a quasi-experimental comparison group design within 2 communities.17 The intervention was located in the com-
munity of the sponsoring agency. The comparison community was chosen to provide matched hospitals and similar nonurban demographic characteristics. Both communities were in East Texas, and they did not have overlapping media orbits. Each community was far enough from Houston that referral to Houston for acute stroke care was prohibitive without an initial stop at a local hospital. The intervention community contained 5 hospitals in Angelina, Nacogdoches, and Shelby counties in Texas. The comparison community contained 5 hospitals in Jefferson and Orange counties in Texas. In 1998, the intervention community comprised an estimated 160 833 residents (77% non-Hispanic white). The comparison community contained an estimated total of 332 676 residents (66% non-Hispanic white). A neurologist was on staff in 4 of 5 intervention hospitals and in all comparison hospitals. All 10 hospitals had 24-hour emergency departments and protocols for emergent head CT imaging. Both communities had full 911 emergency medical services (EMS).

This project had 2 prespecified phases. Phase I ran from February 1998 through October 1998; phase II ran from January 1999 through March 2000. In phase I, baseline data collection occurred in the intervention and comparison communities, and the intervention was developed. The community process relied on information from focus groups with stroke patients and caregivers to identify issues contributing to delay times for hospital presentation. A local community advisory board was formed in the intervention community to provide community-specific information relevant to the intervention. A random-digit dialed telephone survey (n = 656) was conducted with adults in both intervention and comparison communities to assess factors related to intention to react rapidly to signs of stroke.

The data obtained during phase I were used in a systematic process of intervention development. The planning data suggested that simply providing knowledge of stroke symptoms and asking patients to call EMS for these symptoms was unlikely to be effective. Targeting outcome expectations, stroke recognition skills and self-efficacy, and perceived community norms and removing community-specific barriers were thought to be critical to reduce delay times and get patients to the hospital quickly after stroke symptom onset. Additionally, published information on factors influencing delay time for acute stroke presentation—15 and suggested systems approaches—20 were used for intervention planning.

The community intervention relied on role modeling of response to stroke symptoms in both mass and small media. Mass media strategies included billboard advertising, radio and television public service announcements, and news stories. "Small" media included brochures and posters (Figure 1). In addition, volunteers were trained in stroke recognition and reaction and in turn trained coworkers. Community figures were used as role models to show calling 911 immediately for stroke symptoms and to demonstrate that responding to stroke immediately can result in a better outcome (Figure 1). Community members were also encouraged to be assertive in asking the physician about TPA if taken to the emergency department for stroke symptoms, thereby providing a cue to act for healthcare providers who were initially reluctant.

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assuming a 30% stroke mortality rate. A sample size of 249 in the intervention group was needed in both phases to detect the desired difference with 80% power and \( \alpha = 0.05 \). Before the study began, we decided to run phase I for 9 months and phase II for 15 months to meet sample size estimates and to give the intervention time to reach the population. The other primary outcome measures were the proportion of ischemic stroke patients treated with intravenous rTPA and the proportion of patients treated who met label eligibility criteria for intravenous rTPA for acute ischemic stroke. Although the study was powered to detect change in the intervention community only, a comparison community was also examined in parallel to determine whether change in the proportion of patients treated with intravenous rTPA for acute ischemic stroke had occurred.

Secondary outcome measures were (1) a change in the proportion of patients treated with intravenous rTPA in phase II compared with phase I in the intervention community relative to the comparison community; (2) a reduction in delay time from symptom onset to hospital arrival in the intervention community in phase II compared with phase I; (3) mention of consideration of the use of intravenous rTPA in physician notes in the hospital chart in the intervention community; (4) an increase in the proportion of stroke patients treated with intravenous rTPA with progressing month of the intervention; and (5) prespecified exploratory analyses that included a breakdown of eligible candidates into those treated, those not treated because of in-hospital delay, and those not treated for unknown reasons.

Data collected in this study were entered into Microsoft Access. Measurements out of range were identified, checked with the hard copy, and corrected if needed. The verified data were then transferred into a SAS database, and analyses were performed with SAS, version 8. Descriptive statistics of demographic variables, risk factors, and clinical symptoms of stroke patients were calculated for each phase, separated by intervention and control groups. For dichotomous variables, Fisher’s exact test was applied to examine the homogeneity of the distribution between the intervention and control communities within each phase. For continuous variables, a 2-sample \( t \) test was used for the similar assessment.

To study the intervention effect on the proportion of intravenous rTPA treatment (a secondary outcome) and on the proportion of patients presenting within 2 hours of symptom onset, the Breslow-Day test for homogeneity of odds ratios was applied. The trend comparisons of delay time (treated as a continuous variable) over 2 phases were performed with general linear models. Because of the skewness of the delay time distribution, this outcome was first logarithmically transformed before the analyses were carried out.

This study was approved by the University of Texas at Houston Committee for the Protection of Human Subjects and by each individual hospital. Subjects signed informed consent before being interviewed.

### Results
During the study, 1733 patients were screened positive for a presenting symptom suggestive of stroke. Of these, 1189 were validated as having had a cerebrovascular event (ischemic stroke, intracranial hemorrhage, or transient ischemic attack). Table 1 presents the demographic and clinical information for validated stroke patients by phase and community. Table 2 presents the primary outcome measure of proportion of intravenous rTPA treatments among all cerebrovascular pa-

<table>
<thead>
<tr>
<th>Table 1. Demographic and Clinical Information for Validated Stroke Patients by Phase and Community</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>(n=218)</td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
</tr>
<tr>
<td>Mean (SD) age, y</td>
</tr>
<tr>
<td>Female sex, %</td>
</tr>
<tr>
<td>Nonwhite race, %</td>
</tr>
<tr>
<td>High school graduate, %</td>
</tr>
<tr>
<td>No insurance, %</td>
</tr>
<tr>
<td><strong>Risk factors, %</strong></td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>CAD</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>Current tobacco use</td>
</tr>
<tr>
<td>Previous stroke</td>
</tr>
<tr>
<td><strong>Clinical</strong></td>
</tr>
<tr>
<td>Mean SBP, mm Hg</td>
</tr>
<tr>
<td>Mean DBP, mm Hg</td>
</tr>
<tr>
<td>Motor symptoms, %</td>
</tr>
<tr>
<td>Sensory symptoms, %</td>
</tr>
<tr>
<td>Language symptoms, %</td>
</tr>
<tr>
<td>Visual symptoms, %</td>
</tr>
<tr>
<td>Neurological examination, %</td>
</tr>
</tbody>
</table>

CAD indicates coronary artery disease; SBP, systolic blood pressure; and DBP, diastolic blood pressure.
patients, ischemic stroke patients, and candidates eligible for treatment. Using any of the 3 denominators gives a significantly greater proportion of patients treated with intravenous rTPA in phase II compared with patients treated in phase I in the intervention community. No significant increase in treatment was noted in the comparison community.

The first secondary outcome measure compared the change in proportion of all cerebrovascular event patients treated from phase I to phase II in the intervention community with the change in proportion of patients treated in the comparison community. These proportions were not significantly different ($P=0.30$). Similar comparisons for ischemic stroke patients and TPA candidates also did not detect a significant change ($P=0.35$, $P=0.11$, respectively). This study would need considerably more subjects and probably multiple communities to demonstrate such a difference.

Table 3 presents delay time information for both phases and both communities. Delay time information was available in 68% of cases, similar to that found in other community efforts.25 Delay time to hospital presentation decreased in both communities over time. Breslow-Day tests for homogeneity of the odds ratios failed to demonstrate a significant relationship of the intervention in increasing the proportion of patients arriving within 2 hours of symptom onset. Similarly, a reduction in mean delay time could not be ascribed to the effects of intervention when the trends of delay over 2 phases were compared by use of general linear models.

The third secondary outcome measure was mention in the chart about candidacy for intravenous rTPA. This did not change between phases. In the intervention community, consideration of the use of intravenous rTPA was mentioned in the chart in 8.4% of cerebrovascular event patients in phase I and 7.6% in phase II. In the comparison community, it was 7.1% in phase I and 7.6% in phase II.

The fourth prespecified secondary outcome measure was determination of a potential time lag for the full effect of the intervention. We examined the trend for the proportion of ischemic stroke patients treated by month in each community. Figure 2 demonstrates this relationship. Logistic regression analysis did not demonstrate an increase in the proportion of ischemic stroke patients treated with intravenous rTPA over time of the intervention ($P=0.91$).

The results of how eligible candidates were handled by phase and community are shown in Figure 3. In phase II, eligible intravenous rTPA candidates in the intervention community experienced less hospital delay and less unexplained nontreatments. There was little change between the two phases in the comparison community. Protocol violations were found in 13% of patients receiving rTPA among phase II patients in the intervention community. Among the few treated patients in the comparison community and those treated in phase I in the intervention community, none of the patients were treated outside protocol specifications.

**Discussion**

This study provides evidence that aggressive professional and community education may increase the rate of use of FDA-approved acute stroke therapy. This increase was seen in a representative nonurban community. The comparison location did not see an increase in treatment during the same time interval. Although intravenous rTPA remains the only FDA-approved acute stroke therapy, animal investigations suggest that other thrombolytic or neuroprotective approaches are likely to have short time windows for efficacy and safety. Intra-arterial thrombolytic administration may play a role at select centers but will also require prompt hospital presentation and triage.25 Effective community and professional education and motivation for expedient treatment are likely to be important for successful acute stroke treatment regardless of the agent administered.

**TABLE 2. Primary Outcome Measure of Proportion of Intravenous rTPA Treatment for All Cerebrovascular Event Patients, Ischemic Stroke Patients, and Candidates Eligible for Treatment**

<table>
<thead>
<tr>
<th>Community</th>
<th>Phase I (n=424)</th>
<th>Phase II (n=765)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cerebrovascular patients (ischemic stroke, transient ischemic attack, intracranial hemorrhage)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>3/218 (1.38%)</td>
<td>23/400 (5.75%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Comparison</td>
<td>1/206 (0.49%)</td>
<td>2/365 (0.55%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Ischemic stroke patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>3/136 (2.11%)</td>
<td>23/266 (8.65%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Comparison</td>
<td>1/141 (0.71%)</td>
<td>2/233 (0.86%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Eligible candidates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>3/22 (14%)</td>
<td>23/44 (52%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Comparison</td>
<td>1/15 (7%)</td>
<td>2/36 (6%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*Fisher’s exact test.

**TABLE 3. Delay Time Information by Community and Study Phase**

<table>
<thead>
<tr>
<th>Proportion of Patients Presenting Within 2 Hours of Symptom Onset</th>
<th>Delay Time Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>Phase I, %</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
</tr>
<tr>
<td>All cerebrovascular events (ischemic stroke, intracranial hemorrhage and TIA)</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>26.5</td>
</tr>
<tr>
<td>Comparison</td>
<td>21.4</td>
</tr>
<tr>
<td>Ischemic stroke</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>28.1</td>
</tr>
<tr>
<td>Comparison</td>
<td>20.7</td>
</tr>
</tbody>
</table>

*Compares log delay time data.
The professional component of the intervention likely had the largest impact. Treatment of eligible candidates increased from 14% in phase I to 52% in phase II in the intervention community. The multilevel professional intervention used individual contact and explanation of acute stroke guidelines with emergency department physicians. This process allows adoption of therapeutic advances after the opportunity to review and interact with a peer health professional. This enhances knowledge, self-efficacy, and outcome expectations. This method has previously demonstrated a robust effect. Paramedics, physicians, and emergency department staff were allowed to practice acute stroke treatment during mock “stroke codes,” which facilitated self-efficacy. Academic detailing was an important part of the intervention. The health educator and physician-investigators made regular trips to emergency departments and high-volume primary care physicians to remind them of acute stroke therapy. Messages were repeated through high-quality graphic presentations, and positive reinforcement was used to modify behavior.

In the present study, delay time to hospital presentation decreased significantly in both intervention and comparison communities from phase I to phase II. We did not monitor background stroke awareness campaigns in either community. This may have been important to determine why delay time decreased in both communities. Both communities are served by the same American Heart Association affiliate, and none of the hospitals in either community advertised stroke services during the study period. This secular trend of reduced delay time may have resulted from general increased public awareness of the importance of time in acute stroke. The discrepancy of reduced delay time without increased treatment may imply a barrier in the comparison community. In poststudy discussions with community neurologists, no barriers that differed from the intervention community were readily apparent.

Examinations of the delay time data may indicate that the community intervention was unsuccessful because delay time reductions in the intervention community did not exceed those in the comparison community. However, the professional and community interventions were inextricably linked in this project. One feature of the community behavioral intervention was to encourage potential stroke patients to ask for TPA in the emergency department and to suggest that paramedics radio ahead with a potential “TPA stroke patient.” The effectiveness of these efforts is difficult to measure in isolation, although several physicians reported that patients asked for specific treatment. Medical personnel (doctors, nurses, and paramedics) were introduced to colleagues and patients who had used and received the treatment successfully. Stories in the media and public service announcements were frequently discussed between patients and doctors. In this way, the community intervention diffused throughout the professional community and likely explains in part the improved treatment of eligible candidates by physicians. Figure 3 shows that among the eligible candidates, the group that was not treated because of delay or for unknown reasons was shifted to treated patients after the intervention. For those who remained untreated, emergency department physicians told us that they remained concerned about treating patients without the support of accepting primary care physicians who would care for the patient in the immediate post-rTPA period. As the intervention progressed, we found
that local primary care doctors were critical to supporting treatments in the emergency department. The number of eligible candidates was greater in phase II than phase I because phase I ran 9 months and phase II ran 15 months and because delay times were reduced in both communities. We cannot explain why the proportion of eligible candidates was lower in phase I in the comparison group, but the difference was not significant.

The results shown in Figure 2 were disappointing. We hoped that the effect of the intervention would increase over time. Instead, we found no trend. This may suggest that the intervention must continue for sustained benefits, but longer follow-up is needed to test this theory.

Early efforts to reduce delay time to hospital presentation for acute stroke used a long time window as a target. In North Carolina, investigators were able to increase the proportion of patients presenting within 24 hours from stroke symptom onset from 37% to 86% after community-wide education.29 An NIH consensus group, however, considers 2 hours to be the target upper limit time to hospital presentation to accomplish intravenous rTPA treatment within 3 hours of symptom onset.30 Indeed, recent evidence suggests that the effectiveness of intravenous rTPA in reducing disability is clearly time dependent. Patients treated within 1 hour of symptom onset are ~4 times more likely to recover back to independent function compared with those treated just before the 3-hour time window expires.31 Convincing physicians that stroke is a medical emergency may be difficult. A multicenter study reported that faced with a 3-hour time window, physicians are likely to treat just before this window expires rather than treat early-presenting patients immediately. “Door to needle time” can be quite short for those presenting late and quite long for those presenting early.32

Community interventions must begin with a target. Only a few percent of EMS calls are initiated by the patient.33 The target for the behavioral intervention then becomes the family and coworkers. Studies attempting to limit delay time for hospital presentation for acute myocardial infarction have not shown consistent results.34–40 The recently published Rapid Early Action for Coronary Treatment (REACT) study34 randomized 10 community pairs in the United States and, following a baseline phase, used a well-organized, thorough community intervention program to reduce prehospital delay. Although appropriate EMS use was increased, delay time to hospital presentation was not changed by the intervention.

The present study is limited by its nonrandomized design. The funding agency requested that the intervention be carried out in its community. A comparison community was sought by the investigators to be a geographic and demographic community match blinded to prehospital delay information or attitudes regarding rTPA among community physicians. The study data collection methods were hospital based because outcome measures were arrival time and treatment. The intervention, however, was aimed at the entire community. We matched hospitals by size. Although all 5 intervention community hospitals were used in this study, data from only 5 of the comparison community hospitals were needed to achieve a comparable sample size. Furthermore, the study did not examine EMS documentation to see whether the frequency or appropriateness of 911 usage was affected. For an individual subject, the study ended after a decision was made to treat or not treat the patient with intravenous rTPA. There is information on the safety and efficacy of intravenous rTPA.1,41–45 This study was not intended to examine outcome after intravenous rTPA but rather to determine whether the use of FDA-approved acute stroke therapy could be increased appropriately in a nonurban environment. Indeed, the rate of protocol violations in the intervention community in phase II was less than that previously reported.45 Nevertheless, the lack of outcome data prohibits a cost-effectiveness analysis. Allocation of resources to treat stroke may be better served by stroke prevention strategies, but this requires further study.

Effective acute stroke therapy goes above and beyond rTPA and includes preventing medical complications and other therapies as illustrated by the successes of stroke units.46 The present study is relevant to the 61 million US residents who reside in nonurban areas47; generalizing these results to urban populations may be inappropriate. An alternative view would suggest that if this program was successful in nonurban East Texas, it is likely to have an impact in areas with greater population densities that include closer distances to the hospital, more healthcare services, and expanded media opportunities. Future studies are needed to confirm these findings. Urban areas may benefit from replicating the professional intervention and parts of the community intervention of this project. In addition, future work should be performed in a multicenter, randomized design that incorporates monitoring of secular trends in both communities. Furthermore, cost analysis and outcomes and community and professional surveys that monitor the reasons why components of the intervention were or were not successful should be included.

Acknowledgment

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