Informed Consent for Intravenous Tissue Plasminogen Activator in New York State Designated Stroke Centers

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Objective: Our objective was to assess informed consent procedures for intravenous tissue plasminogen activator in acute stroke among New York State (NYS) Department of Health (DOH) designated stroke centers. *Methods:* A 13-question survey stratified by 0- to 3-hour and 3.0- to 4.5-hour treatment windows was used to determine the type of consent or if no consent was required. *Results:* Of the 117 hospitals, 111 responded (95%). All 111 hospitals provided treatment within the 3-hour window, whereas 97 (87%) provided treatment beyond the 3-hour window ($P < .001$). For hospitals that did provide treatment, there was a difference between the percentages of hospitals requiring consent (verbal or written) within 3 hours (82%) and beyond 3 hours (92%) ($P = .04$). Of the hospitals requiring consent, there was a difference in the type of consent: 31 of 91 (34%) required written consent within the 3-hour window, whereas 57 of 89 (64%) required written consent beyond the 3-hour window ($P < .001$). Within both treatment windows, 98% accepted a health-care proxy or surrogate in lieu of the patient. Of the hospitals with less than 500 beds, 11 of 81 (14%) did not require consent within the 3-hour treatment window, compared to hospitals with 500 or more beds where 9 of 30 (30%) did not require consent within the 3-hour treatment window ($P < .05$). Beyond the 3-hour treatment window, hospitals with more than 500 beds required written consent—2-fold increase "compared to less than 3 hour window" ($P < .05$). Fifty-five percent of the hospitals were academic, whereas 45% were nonacademic. Academic status was not related to the type of consent in either window. *Conclusions:* Significant variability exists in the types of informed consent based on hospital bed size and treatment windows across NYS DOH designated stroke centers.
Key Words: Tissue plasminogen activator—acute ischemic stroke—informed consent—thrombolysis—stroke centers.

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Despite the success of the 1995 National Institute of Neurological Disorders and Stroke (NINDS) study using intravenous (IV) recombinant tissue plasminogen activator (tPA) within 3 hours in acute ischemic stroke (AIS)[1] and its subsequent Food and Drug Association approval, there has been some reluctance to use tPA in the estimated 800,000 ischemic strokes per year.[2] Successful expanded use of tPA up to 4.5 hours in selected patients with AIS in the European Cooperative Acute Stroke Study (ECASS III)[3] led the American Heart Association/American Stroke Association[4] and the American Academy of Neurology to revise their guidelines in 2009 to provide more patients with an opportunity to receive potential benefits from this effective therapy with updated treatment guidelines. The Food and Drug Administration, however, did not approve the expanded time window in 2011,[5,6] which led to further controversy and "off-label" connotation.[7] Kleindorfer et al demonstrated that from July 1, 2005, to June 30, 2007, 64% of the nation's hospitals did not provide thrombolytic therapy with IV-tPA[8] and the nationwide utilization is less than 5% in Medicare patients.[8,9] However, relatively little is known about statewide hospital stroke practice patterns concerning informed consent with tPA within the 0- to 3-hour window and beyond and the extent of quality assurance follow-up.

We developed a voluntary questionnaire sent to all New York State (NYS) Department of Health (DOH) designated stroke centers regarding their approach to consent procedures. This survey was designed to collect information about the types of consent obtained at the various designated stroke centers from August to September 2014.

Methods

A 13-question, multiple-choice survey was created (Appendix) to study current informed consent and quality assurance procedures for tPA among all 117 NYS DOH designated stroke centers. Stroke coordinators received a standardized e-mail for their voluntary responses with the intent to share the aggregated information with all hospitals. Blinded responses were submitted to the SurveyMonkey website and there was a reminder e-mail sent 1 month after initial contact made by NYS DOH or American Heart Association/American Stroke Association staff to clarify a response in 5 separate cases.

Statistical Analysis

The survey data were descriptive and categorical. Chi-square tests of association were used to assess the relationship between consent (written or verbal discussion versus none required) and the 6 demographic measures. Tests were 2-sided with a level of significance set at a P value less than .05. Statistical Package for the Social Sciences (version 22.0, IBM Corp., Armonk, New York) was used to analyze the data.

Results

Of the 117 identified designated stroke centers, 111 (95%) responded. The demographic characteristics of the responding designated stroke centers are presented in Table 1. The percentages of hospitals with 250 beds or less, 251-500 beds, or more than 500 beds were 33%, 40%, and 27%, respectively. There was a wide range of hospital annual volume of ischemic stroke discharges and patients treated with IV-tPA. A modest excess of hospitals (55%) was academic (teaching). The percentages of hospitals that were urban, suburban, or rural were 49%, 42%, and 9%, respectively.

Consent procedures for IV-tPA within and beyond the 3-hour window are presented in Tables 2 and 3. There was a significant difference between the numbers of hospitals that provided treatment within and beyond the 3-hour windows: all 111 hospitals provided treatment within the 3-hour window, whereas 97 (87%) provided treatment beyond the 3-hour window ($P < .001$). For the hospitals that did provide treatment, there was a difference between the percentages of hospitals requiring consent (verbal or written) within 3 hours (82%) and beyond 3 hours (92%) ($P = .04$). Of the hospitals requiring consent,

Table 1. *Hospital demographics*

Demographics	n (%)
Number of beds	
250 or less	37 (33.3)*
251-500	44 (39.6)
Greater than 500	30 (27.0)
% of patients from skilled nursing facility/ long-term care facility	
0-25%	56 (72.7)
26-50%	18 (23.4)
Greater than 50%	3 (3.9)
Annual volume of ischemic stroke discharges	
0-100	21 (19.8)
101-300	47 (44.3)
Greater than 300	38 (35.9)
Annual volume of patients treated with tissue plasminogen activator	
0-10	36 (33.6)
11-30	46 (43.0)
31-50	17 (15.9)
Greater than 50	8 (7.5)
Type of hospital	
Academic (teaching)	59 (55.1)
Nonacademic	48 (44.9)
Hospital location	
Rural	10 (9.4)
Suburban	45 (42.0)
Urban	52 (48.6)

*Percentage of hospitals that provided a response to the question.