

# Racial disparities in refusal of stroke thrombolysis in Chicago

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## Abstract

### Objective

To evaluate race differences in tissue plasminogen activator (tPA) refusal among eligible patients with acute ischemic stroke (AIS) in Chicago.

### Methods

Using the Get With The Guidelines–Stroke registry data from 15 primary stroke centers between January 2013 and June 2015, we performed a retrospective analysis of patients with AIS presenting to the emergency department within 4.5 hours from symptom onset. Patient or proxy refusal was captured as a reason for nonadministration of tPA to eligible patients in the registry. We assessed whether tPA refusal differed by race using logistic regression.

### Results

Among 704 tPA-eligible patients with AIS, tPA was administered to 86.2% (black race, 82.5% vs nonblack race, 89.5%;  $p < 0.001$ ). Fifty-three (7.5%) tPA refusals were documented. Refusal was more common in black vs nonblack patients (10.6% vs 4.8%;  $p = 0.004$ ). In multivariable analysis, the following were associated with tPA refusal: black race (adjusted odds ratio [OR] 2.5, 95% confidence interval [CI] 1.3–4.6), self-pay status (adjusted OR 3.23, 95% CI 1.2–8.71), prior stroke (adjusted OR 2.11, 95% CI 1.14–3.90), age (adjusted OR 1.04, 95% CI 1.02–1.07), and NIH Stroke Scale score (adjusted OR 0.94, 95% CI 0.90–0.99).

### Conclusions

Among tPA-eligible patients with AIS in Chicago, over 7% refused tPA. Refusal was more common in black patients and accounted for the apparent lower rates of tPA use in black vs nonblack patients. Further research is needed to understand barriers to consent and overcome race–ethnic disparities in tPA treatment for AIS.

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## Glossary

AHA = American Heart Association; AIS = acute ischemic stroke; CI = confidence interval; DTN = door-to-needle; ED = emergency department; GWTG = Get With The Guidelines; IQR = interquartile range; NIHSS = NIH Stroke Scale; OR = odds ratio; PSC = primary stroke center; QUESTS = Quality Enhancement for Speedy Thrombolysis in Stroke; tPA = tissue plasminogen activator.

Since its approval for use in patients with acute ischemic stroke (AIS) in 1996, the rate of tissue plasminogen activator (tPA) administration to eligible patients has steadily increased.<sup>1</sup> The development and dissemination of stroke centers in the United States and hospital-based quality improvement initiatives including the American Heart Association (AHA)'s Target Stroke program have played an important role in appropriate and timely tPA use in patients with AIS.<sup>2</sup> Yet despite these efforts, tPA utilization for AIS nationwide remains suboptimal, ranging between 3% and 7%,<sup>3,4</sup> and with lower rates among black than nonblack patients.<sup>5</sup>

Indeed, racial and ethnic disparities have been observed in all aspects of stroke, including prehospital care, acute treatment with tPA, and poststroke outcomes.<sup>6</sup> For example, black patients are more likely to die and be disabled after stroke and half as likely to receive tPA compared to non-Hispanic white patients.<sup>7,8</sup> Black patients are 20% less likely to arrive by emergency medical services and are less likely to achieve door-to-needle (DTN) times <60 minutes.<sup>9,10</sup> Racial disparities in tPA utilization persist even at primary stroke centers (PSCs).<sup>5</sup>

In a qualitative study at 2 large Chicago hospitals, we previously reported that obtaining consent may contribute to delays in DTN time and tPA refusal.<sup>11</sup> Refusal of tPA may result from patient or caregiver uncertainty about the risks and benefits of tPA. These observations led to the development and dissemination of standardized informed consent pocket cards to Chicago hospitals participating in the regional Quality Enhancement for Speedy Thrombolysis in Stroke (QUESTS) initiative.<sup>12</sup> Recently, more refined decision aids have been developed to assist clinicians with the informed consent process for tPA.<sup>13</sup> However, empiric data on the prevalence of tPA refusal is sparse<sup>14</sup> and no data exist on race-ethnic disparities in tPA refusal. Building upon these studies and our prior observations at Chicago hospitals, we hypothesized that race-ethnic disparities exist in tPA refusal among tPA-eligible patients at 15 QUESTS-participating PSCs in Chicago.

## Methods

### Study population

We performed a retrospective analysis of patients with AIS discharged from 15 Chicago PSCs (table e-1, [links.lww.com/WNL/A104](https://www.ahajournals.org/doi/full/10.1161/STROKEAHA.116.0104)) between January 2013 and June 2015.

All of the participating hospitals contribute data to the AHA Get With The Guidelines (GWTG)-Stroke registry (Quintiles, Inc., Cambridge, MA). GWTG-Stroke is a national quality improvement program focused on guideline-driven care in stroke patients.<sup>15</sup> As part of QUESTS,<sup>12</sup> each hospital agreed to share the data and report results in aggregate form. All data were entered by coordinators at each hospital without central adjudication, interpretation, or review. A GWTG-Stroke superuser account, managed by the AHA/American Stroke Association, was created to monitor and aggregate the regional data.

Patients with a primary diagnosis of AIS who presented to the emergency department (ED) within 4.5 hours from symptom onset were included. We excluded patients with documented medical contraindications to tPA upon arrival to the ED, patients who developed stroke symptoms after hospital arrival, and patients with incomplete documentation (e.g., missing arrival or tPA treatment times or initial NIH Stroke Scale [NIHSS] scores). Reasons for not administering tPA included medical contraindications (e.g., blood pressure control or inability to determine eligibility based upon medical history), hospital factors (delay in arrival or diagnosis), as well as patient/family refusal.<sup>16</sup>

### Variable of interest

Since multiple reasons may have been documented for not administering tPA for any one patient, we defined tPA refusal when it was the only documented reason for the purposes of analysis.

### Covariates

Other relevant covariates captured in the GWTG-Stroke registry included age, sex, race/ethnicity, health insurance status, mode of arrival, arrival and admission time data, and initial NIHSS score. We simplified race-ethnicity into 3 categories: African American or black, Caucasian or white, and other (including Hispanic, Asian, Native American, undetermined, and not documented). Medical history included the presence of atrial fibrillation/flutter, coronary artery disease, diabetes mellitus, heart failure, hypertension, smoking status, prior stroke, and prior TIA.

### Statistical analysis

All data analyses were performed using the Statistical Package for the Social Sciences (SPSS 24.0; IBM, Armonk, NY). Descriptive statistics are expressed as means with SD or medians with interquartile ranges (IQRs), as appropriate, for

continuous variables and frequencies for categorical variables. A test for trend was performed to evaluate change in rate of refusal by quarter during the study period. To compare demographic or clinical characteristics between patients with and without tPA refusal, we performed univariable tests using  $\chi^2$  tests for categorical variables and *t* tests or Mann-Whitney *U* tests for continuous variables, as appropriate. Variables were selected for the multivariable models based on univariable association ( $p < 0.15$ ) with tPA refusal. To determine independent factors contributing to tPA refusal, separate multivariable logistic regression analyses were performed using a stepwise elimination approach to create a parsimoniously adjusted model with less susceptibility to overfitting and a probability of F-to-remove  $\geq 0.1$ . Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were estimated from the final models. The model fitness was assessed using the Hosmer-Lemeshow test. A *p* value  $< 0.05$  was considered significant in final models.

### Standard protocol approvals, registrations, and patient consents

All participating hospitals were required to comply with local regulatory and privacy guidelines and, if necessary, to secure institutional review board approval.

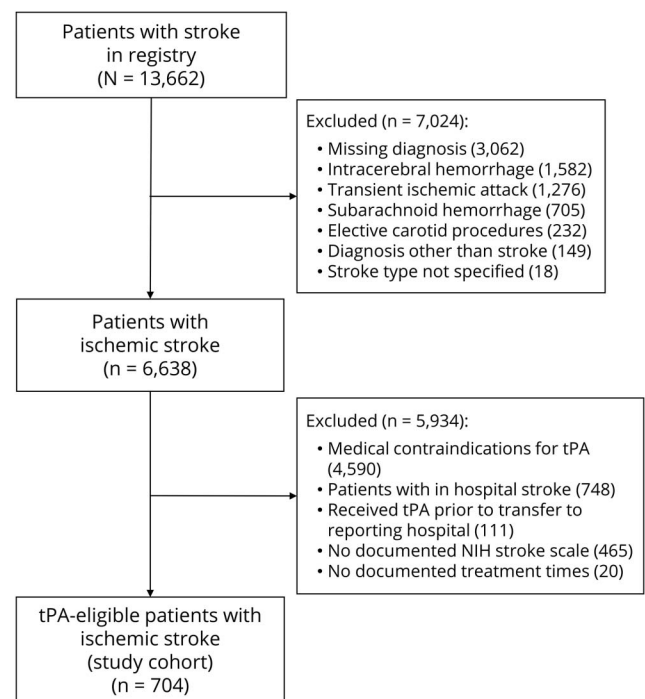
## Results

Of the 13,662 patient records in the regional registry during the study period, 704 (5.2%) AIS patients without documented medical contraindications to tPA were identified (figure). Sixteen patients (4 black, 12 nonblack) with documented refusals also had documented medical contraindications to tPA (e.g., recent surgery, uncontrollable blood pressure) and were not included in the study cohort.

Patient characteristics of the study cohort are described in table 1. The mean age was  $67.2 \pm 15.5$  years, 49.9% were female, and 47.0% were black. Eighty-six percent ( $n = 607$ ) of eligible AIS patients received tPA (82.5% black vs 89.5% nonblack,  $p < 0.001$ ). Fifty-three (7.5%) patients or their proxies refused treatment with tPA. The rate of tPA refusal did not change by quarter over the study period ( $p = 0.522$ ).

The rate of refusal was higher in black compared to nonblack patients (10.6% vs 4.8%,  $p = 0.004$ ). Refusal rates were also higher in patients with a history of prior stroke (12.9% vs 6.1%,  $p = 0.005$ ) and older patients ( $69.8 \pm 13.3$  vs  $64.2 \pm 15.8$ ,  $p = 0.013$ ). The median NIHSS was 9 (IQR 5–15) compared to 9 (3.5–13) in patients without and with tPA refusal ( $p = 0.089$ ), respectively. There was no difference in the rate of refusal ( $p = 0.197$ ) or race ( $p = 0.583$ ) among patients presenting within 3 hours of symptom onset and patients arriving between 3 and 4.5 hours. There were no differences by sex or by arrival mode between patients who refused and those who received tPA (table 1). Based on significance in univariable analysis, we included the following variables in a multivariable model of refusal: age, race, self-pay status, prior stroke, NIHSS

**Figure** Flowchart of study cohort assembly



tPA = tissue plasminogen activator.

score, and hypertension. On multivariable analysis, black patients (or their proxies) were more likely to refuse tPA (adjusted OR 2.48, 95% CI 1.34–4.61; table 2). Other factors contributing to tPA refusal included self-pay status (adjusted OR 3.23, 95% CI 1.2–8.71), prior stroke (adjusted OR 2.11, 95% CI 1.14–3.90), age (adjusted OR 1.04, 95% CI 1.02–1.07), and NIHSS score (adjusted OR 0.94, 95% CI 0.90–0.99).

## Discussion

Among tPA-eligible AIS patients at 15 PSCs in Chicago, 7.5% did not receive tPA because of patient or proxy refusal. While the observed tPA refusal rate in Chicago is consistent with other single-center studies (4.2%–6.9%),<sup>14,17</sup> we found that black patients were more than twice as likely to refuse tPA compared to nonblack patients. Indeed, the observed disparity in tPA administration, an absolute 7% difference in black vs nonblack patients, was nearly all attributable to higher refusal rates in black patients (5.8% absolute difference). These data suggest that cultural and community barriers to tPA consent, especially in black communities, warrant further investigation.

Current professional guidelines state that explicit, though not written, informed consent is indicated when providing tPA to eligible AIS patients.<sup>18,19</sup> Informed consent is more frequently obtained from patient surrogates than acute stroke patients

**Table 1** Stroke patient characteristics and comparison of demographic, medical, and clinical data between those who refused vs those who did not refuse tissue plasminogen activator

	Study cohort (n = 704)	No refusal (n = 651)	Refusal (n = 53)	p Value
Age, y, mean (SD)	67.2 (15.5)	64.2 (15.8)	69.8 (13.3)	0.013
Female, n (%)	351 (49.9)	328 (93.4)	23 (6.6)	0.328
Race, n (%)				0.016
Black	331 (47.0)	296 (89.4)	35 (10.6)	
White	313 (44.5)	298 (95.2)	15 (4.8)	
Other	60 (8.5)	57 (95.0)	3 (5.0)	
EMS arrival, n (%)	497 (70.6)	458 (92.2)	39 (7.8)	0.620
Insurance status, n (%)				0.053
Self-pay	42 (6.0)	36 (85.7)	6 (14.3)	
Medicaid	75 (10.7)	73 (97.3)	2 (2.6)	
Medicare	209 (29.7)	190 (90.9)	19 (9.1)	
Private	259 (36.8)	237 (91.5)	22 (8.5)	
Other	119 (16.9)	115 (96.6)	4 (3.4)	
Medical history, n (%)				
Hypertension	481 (68.3)	439 (91.3)	42 (8.7)	0.076
Diabetes mellitus	182 (25.9)	167 (91.8)	15 (8.2)	0.672
Hyperlipidemia	185 (26.3)	176 (95.1)	9 (4.9)	0.110
Prior stroke	147 (20.9)	128 (87.1)	19 (12.9)	0.005
Current smoker	114 (16.2)	104 (91.2)	10 (8.8)	0.583
Coronary artery disease	108 (15.3)	97 (89.8)	11 (10.2)	0.255
Atrial fibrillation	96 (13.6)	89 (92.7)	7 (7.3)	0.925
Prior TIA	46 (6.5)	42 (91.3)	4 (8.7)	0.756
NIHSS, median (IQR)	9 (5–16)	9 (5–16)	9 (3.5–13)	0.089
Onset to arrival time in min, median (IQR)	59 (36–98)	58 (36–97)	62 (38.5–119.5)	0.270

Abbreviations: EMS = emergency medical services; IQR = interquartile range; NIHSS = NIH Stroke Scale.

themselves because of a perceived lack in capacity<sup>20</sup> and are often initiated by physicians in the ED. However, challenges to informed consent for tPA may stem from cognitive impairment or aphasia due to current or prior stroke, lack of availability of proxies, or misunderstanding potential risk–benefit ratios.

Providing informed consent requires effective communication among health care providers, patients, and their surrogates. Our data also imply a need to tailor the informed consent process to individual patient and cultural characteristics.<sup>21</sup> Some patients may not be aware that tPA is an approved medical treatment and not an investigational drug, that treatment benefits are time-dependent, and that overall benefits outweigh risks.<sup>22</sup> Although socioeconomic differences between black and white patients may

contribute to health care disparities, they only explain a portion of the disparities.<sup>23,24</sup> Social determinants of health, such as residential environments,<sup>25</sup> social support,<sup>26</sup> and knowledge of available therapies,<sup>27</sup> affect outcomes after stroke. Disparities may also be due to varying levels of health literacy among black vs nonblack patients. Though some have noted that health literacy for stroke treatments is poor in general,<sup>28</sup> health numeracy is suboptimal especially in elderly patients, minorities, and those with lower education and socioeconomic status.<sup>29</sup> Racial and ethnic disparities in health communication, heavily influenced by health literacy and numeracy, are known to exist in clinical situations such as acute stroke.<sup>30,31</sup> Another possible factor, institutional mistrust in health care, is also higher in black compared to non-Hispanic white patients and may contribute to tPA refusal.<sup>32</sup>

**Table 2** Factors contributing to refusal of tissue plasminogen activator in multivariable analysis<sup>a</sup>

	Odds ratio	95% CI	p Value
Age, y	1.04	1.02–1.07	<0.001
Black race	2.48	1.34–4.61	0.004
Self-pay status	3.23	1.20–8.71	0.020
Prior stroke	2.11	1.14–3.90	0.018
NIHSS score	0.94	0.90–0.99	0.011

Abbreviations: CI = confidence interval; NIHSS = NIH Stroke Scale.  
<sup>a</sup> Final model excluded hypertension; Hosmer-Lemeshow  $\chi^2$  8.39,  $p = 0.397$ .

To satisfy the time constraints of administering tPA in patients with AIS, strategies to improve patient or proxy understanding of the indication, risks, and benefits of tPA in a timely manner, such as use of structured oral presentations and visual aids,<sup>33</sup> have been described.<sup>34</sup> Recently, more detailed tools have been developed to aid AIS patients and their proxies in tPA decision-making.<sup>13,35</sup> One decision aid, for example, uses a mobile phone application to provide probabilities of independence and death following stroke treatment based on patient characteristics (e.g., age, sex, NIHSS).<sup>35</sup> Another, the Rapid Evaluation for Stroke Outcomes using Lytics in Vascular Event (RESOLVE) tool, uses 3 printed pages of patient-facing materials that include a description of ischemic stroke along with 2 pages of population and individual-level data regarding risks and benefits of tPA.<sup>13</sup> Future strategies to tailor informed consent conversations will need to achieve satisfactory information exchange in a culturally appropriate manner while avoiding unnecessary treatment delays or refusals, which could result in poorer outcomes. Some have advocated a different approach, framing the discussion as informed refusal rather than informed consent.<sup>36</sup> Regardless of the framing, the discussion must ensure key elements (e.g., assessing capacity or evaluating comprehension) are addressed within the time constraints of acute stroke care and tailored to the needs of black and other minority populations. Community participatory efforts such as the ongoing Patient-Centered Outcomes Research Initiative–funded Community Engagement for Early Recognition and Immediate Action in Stroke (CEERIAS) in Chicago, which aims to adapt public education in acute stroke recognition and action to cultural and neighborhood factors, could provide the methodologic framework to tailor informed consent discussions based on community and stakeholder input.

Besides race differences in tPA refusal, we confirm a prior observation that tPA refusal was inversely related to stroke severity.<sup>14</sup> We also identified self-pay status and history of prior stroke as independent factors related to tPA refusal. Payer status and socioeconomic status are highly correlated, and lower socioeconomic status has been associated with

worse outcomes and mortality from stroke.<sup>37</sup> There has not been a demonstrated link, though, between socioeconomic status and tPA rates in AIS.<sup>38,39</sup> As with mild stroke patients, prior stroke survivors may refuse tPA due to misperceived risks of disability. In addition, we cannot exclude the possibility that prior stroke patients with language or cognitive deficits may have been unable to clearly provide informed consent for tPA. Clearly, further research with specific attention to the informed consent process needs to be conducted to confirm our findings and to establish causal relationships.

The study has several limitations. First, the data represent practice at 15 PSCs in Chicago and therefore may not be generalizable to other regions or practice settings. Second, as a retrospective analysis of data quality improvement initiative, the study is limited by voluntary clinician and hospital reporting of tPA refusal. While consecutive patient capture and data entry are strongly recommended by the Chicago regional stroke advisory committee and were incentivized by QUESTS during the study period, we cannot exclude the possibility of missing cases and sampling occurring at some participating hospitals. Third, while pocket cards to standardize tPA consent discussions were provided to all 15 PSCs, we cannot be certain these were used in each tPA-eligible patient or know specifically what led to tPA refusal. Fourth, the accuracy of the registry data was not independently validated, especially for documentation of tPA refusal, though a prior audit of the GWTG-Stroke registry demonstrated excellent data quality overall.<sup>40</sup> Finally, we excluded 16 patients who refused tPA but also had medical contraindications since it is impossible to know whether tPA refusal was the primary reason for not administering tPA or whether refusal was influenced by those other contraindications. We also did not consider initial refusal with subsequent delayed receipt of tPA. Thus, our results may underestimate the rate of any tPA refusal and its effect on treatment rates and times.

Among tPA-eligible AIS patients in Chicago, 7.5% refused tPA, with refusal occurring more frequently in black than nonblack patients. Refusal nearly completely accounted for the race–ethnic disparity in tPA treatment rates between black and nonblack patients. Besides quantifying the prevalence of tPA refusal, our data affirm the need and potential effect of a culturally tailored shared decision-making aid for informed consent.

### Author contributions

Scott J. Mendelson: study concept and design, acquisition of data, analysis and interpretation of data, critical revision of manuscript for intellectual content. Neelum T. Aggarwal: critical revision of manuscript for intellectual content. Christopher Richards: critical revision of manuscript for intellectual content. Kathleen O'Neill: acquisition of data. Jane L. Holl: analysis and interpretation of data, critical revision of manuscript for intellectual content. Shyam Prabhakaran: study concept and design, acquisition of data, analysis and

interpretation of data, critical revision of manuscript for intellectual content, study supervision.

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# Racial disparities in refusal of stroke thrombolysis in Chicago

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## Study question

Are there racial disparities in patient refusal of tissue plasminogen activator (tPA) administration for acute ischemic stroke?

## Summary answer

African American patients are more likely to refuse tPA administration than are patients of other races.

## What is known and what this article adds

Racial disparities have been observed in all aspects of stroke care in the United States, including the use of tPA. This study provides evidence that racial disparities in patient refusal of tPA are a contributing factor to disparities in tPA usage.

## Rationale, design, and data collection method

To determine whether racial disparities in patient refusal of tPA exist, the study accessed the American Hospital Association's Get With The Guidelines registry for retrospective data.

## Participants and setting

The study analyzed data for 704 tPA-eligible patients who presented at any of 15 primary stroke centers in Chicago between January 2013 and June 2015.

## Recruitment/sampling strategy

The analysis included all tPA-eligible patients who presented within 4.5 hours of the onset of acute ischemic stroke symptoms, had complete data available, and were symptomatic prior to hospital arrival.

## Data analysis method

Racial disparities in tPA refusal were analyzed via multivariable logistic regression analyses.

## Main findings

tPA refusal was more common among African American patients than among non-African American patients (10.6%

Factor	Adjusted OR (95% CI)	p
African American ethnicity	2.48 (1.3–4.6)	0.004
No insurance	3.23 (1.20–8.71)	0.020
Prior stroke	2.11 (1.14–3.90)	0.018

Abbreviations: CI = confidence interval; OR = odds ratio.

vs 4.8%;  $p = 0.004$ ). The table shows the most important factors contributing to tPA refusal in the multivariable logistic regression analysis, which included African American ethnicity.

## Implications

Further research on cultural and community barriers to tPA consent among African American patients is warranted. Also, the informed consent process should be tailored to the cultural characteristics of patients.

## Bias, limitations, and generalizability

The results may not be generalizable to nonmetropolitan areas or practice settings other than primary stroke centers. The study may be limited by nonreporting of data, possible noncompliance with standardized consent discussion procedures, and the lack of independent validation of the accuracy of the registry data. There are also ways in which the study may have underestimated tPA refusal.

## Study funding/potential competing interests

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