Changing Demographics at a Comprehensive Stroke Center Amidst the Rise in Primary Stroke Centers

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Background—The creation of The Joint Commission primary stroke centers (PSCs) has increased access to acute stroke care in metropolitan areas. We hypothesized that the rise in PSCs in the Houston area was associated with demographic changes and decreased trial enrollment at our comprehensive stroke center.

Methods—Consecutive admissions to the UT Houston stroke team from January 2005 to June 2011 were reviewed for demographic and clinical information. Patient characteristics were compared across years. Logistic regression was performed to assess the odds of admission per year.

Results—During the 6.5-year study period, there were 6623 admissions. Admissions increased each year. The proportion of patients transferred from other hospitals to our Comprehensive Stroke Center increased from 24.6% in 2005 to 45.5% in 2011. The number of The Joint Commission PSCs in the greater Houston area increased from 2 to 15. The percentage of large artery occlusions fell from 32.9% in 2005 to a low of 16.4% in 2010, whereas minor strokes (National Institutes of Health Stroke Scale, 0–5) increased from 37.4% in 2005 to 48.6% in 2011. Among stroke patients presenting within 3 hours, study enrollment fell from 45.8% in 2005 to 19.3% in 2011.

Conclusions—We observed a temporal association between the changes in our patient demographics and the number of The Joint Commission PSCs in Houston. The number of large artery occlusions decreased over time, whereas the number of mild strokes increased. In addition, the number of patients enrolled into clinical trials substantially decreased. Increased access to stroke care at PSCs may be associated with changes in patient demographics and clinical trial enrollment at our center. (Stroke. 2013;44:1117-1123.)

Key Words: acute stroke ■ clinical trials ■ organized stroke care ■ regionalization of stroke care ■ stroke care

Optimal therapy of acute stroke requires rapid identification of patients, efficient treatment algorithms, and coordinated inpatient care. In 2000, the Brain Attack Coalition (BAC) published recommendations for the establishment of Primary Stroke Centers (PSCs) at hospitals that have the resources to provide therapy for acute stroke.1 PSCs were intended to increase use of intravenous tissue plasminogen activator (t-PA) for eligible patients and serve as the building blocks of a multitiered acute stroke care system, modeled after the US trauma care system. Using recommendations of the BAC, The Joint Commission (TJC), in collaboration with the American Stroke Association, began certifying hospitals as PSCs on a national level in November 2003. As of May 17, 2011, 835 hospitals across the United States have been certified (personal communication with Jean Range, Executive Director of Disease Specific Care Certification, TJC).

Although PSCs should provide high-quality care, patients with complex stroke types, severe deficits, or multiorgan disease may require and benefit from specialized care and technological resources not available at a typical PSC.2 Thus, in 2005, the BAC published recommendations for Comprehensive Stroke Centers (CSCs). They described a CSC as a facility with the necessary personnel, infrastructure, and expertise to diagnose and treat stroke patients who require a higher intensity of care or interventional therapies than PSCs can provide. CSCs were intended to parallel level-1 trauma centers as tertiary referral centers. The BAC suggested that CSCs would act as a resource for other facilities in their region and encourage CSCs to participate in research to develop new therapies and advance the field of vascular neurology.3 National processes now exist for certifying CSCs, although many academic tertiary care centers have likely functioned as CSCs according to the BAC recommendations.3

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The public health impact of TJC PSC certification is a topic of ongoing investigation. Studies have demonstrated a modest mortality benefit and a marked increase in t-PA utilization compared with noncertified hospitals. However, little is known about the impact of PSCs on the patient population presenting to PSCs with CSC capabilities, and consequently, whether such changes might affect clinical trial enrollment at PSCs with CSC capabilities. We hypothesized that the types of strokes admitted to our academic tertiary care center with comprehensive stroke capabilities have been changing, and that the number of patients transferred from other hospitals to our center have substantially increased in the face of the growing number of TJC PSCs in our region. This study examines the demographics of the stroke patients admitted to our stroke service over time, in relation to our rates of clinical trial enrollment.

Methods

A retrospective cohort study was performed on consecutive patients admitted to the University of Texas in Houston Stroke Team from January 2005 to May 2011 using prospectively acquired registry data collected by medical doctors trained as data abstractors, using detailed instructions and a data dictionary. Definitions in the data dictionary are consistent with those previously published. Intracerebral hemorrhage (ICH), ischemic stroke (IS), and transient ischemic attack (TIA) patients admitted to our stroke service were included, regardless of whether they presented directly to our hospital or were transferred from another facility. Patients with subdural hematoma or subarachnoid hemorrhage were excluded, as well as strokes that occurred while admitted for another diagnosis.

The greater Houston area has a population of nearly 6 million, which is 25% black and 37% Hispanic. Memorial Hermann-Texas Medical Center is a not-for-profit 812-bed tertiary care teaching hospital with a dedicated 10-bed stroke unit and a dedicated 32-bed neurological/neurosurgical intensive care unit. The greater metropolitan region is served mainly by the Houston Fire Department Emergency Medical Services (EMS), which serves as the major source of patients for our facility. The UT Stroke Team pager is activated from the field when EMS personnel suspect stroke, as well as by the Emergency Department (ED), immediately when patients with stroke symptoms present. The on-call team (a vascular neurologist and an in-house resident) evaluate the patient and treat with thrombolytics according to the published American Heart Association and Food and Drug Administration guidelines. All patients seen by the stroke team are admitted to the CSC at Memorial Herman Hospital.

For the purposes of this study, data on age, sex, race/ethnicity, date and time of symptom onset or date and time the patient was last seen normal, date and time of ED arrival (for ED admissions), date and time of admission (for transfer patients and direct admissions), transfer status, treatment with IV t-PA, intrartrial therapy, stroke mechanism by TOAST classification, stroke severity as measured by the National Institutes of Health Stroke Scale (NIHSS), stroke location on computerized tomography or MRI, and nonobservational clinical trial enrollment were obtained from the prospectively collected UT Houston Stroke Registry, in addition to participants’ self-reported history of hypertension, hyperlipidemia/dyslipidemia, coronary artery disease, and smoking history. Time from symptom onset to arrival was calculated as the number of minutes that elapsed from the onset of stroke symptoms (or last seen normal time) until the patient’s arrival in the ED. Door-to-needle was calculated as the time elapsed from ED arrival to administration of IV t-PA. Minor stroke was defined as an admission NIHSS from 0 to 5.

The Texas Hospital Inpatient Discharge Public Use Data File was used to determine the number of infarcts discharged from PSCs without CSC capabilities and PSCs with CSC capabilities in the greater Houston area from 2008 to 2011. Infarcts were defined as International Classification of Diseases-9 codes 433, 434, or 436.

Statistical Analysis

Proportions are reported for categorical data, and measures of central tendency (mean±standard deviation or median with range) are reported for continuous data. Patient characteristics were compared among years using analysis of variance and χ² tests (or nonparametric equivalent) for continuous and categorical variables, respectively. Logistic regression was performed on variables of interest to assess the odds of particular types of patients being admitted per year. The first year of the study, 2005, was the reference group. This provided information on the change in odds of admission over time.

Results

During the 6.5-year period, 6623 patients were admitted to the UT Stroke Team (median age 63, 50.4% women, 33.2% black, 15.5% Hispanic, median NIHSS 6). More than half of admissions were IS (n=3457), 23.2% were ICH (n=1534), 8.3% TIA (n=550), 0.5% isolated intraventricular hemorrhage (n=31), 0.2% cerebral venous sinus thrombosis (n=12), and 15.7% nonstroke diagnosis (n=1037).

Overall, IS patients had a median age of 65 years (TIA, 64; ICH, 61), 47.9% were women (TIA, 57.8%; ICH, 44.5%), 32.6% were black, and 13.5% were Hispanic (TIA, 33.9% black and 16.0% Hispanic; ICH, 32.7% black and 20.2% Hispanic). IS patients had a median NIHSS of 7, and ICH 14. Among IS, 33.5% were cardioembolic, 23.3% large artery, 15.3% small vessel, 8.3% other, and 19.5% unknown pathogenesis. Forty percent of IS were classified as minor (NIHSS, 0–5). Less than one third of IS admissions were transfers (TIA, 15.1%; ICH, 51.4%).

Although the total number of admissions increased each year, this increase was largely attributable to an increase in the number of transfers from outside hospitals (Figure 1). In 2005, 24.6% of admissions to the stroke service were transfers. By 2011, the proportion of transfer patients had increased to 45.5%. Approximately 1 in 3 transfer patients had ICH, ranging from 28.8% in 2007 to 46.3% in 2011. Table 1 depicts patient demographics for all stroke types by year.

IS subtypes changed substantially over the study period. As illustrated in Table 2, the percentage of large artery occlusions (LAO) fell from 32.9% in 2005 to a low of 16.4% in 2010, whereas minor strokes (NIHSS, 0–5) increased from 37.4% in 2005 to 48.6% in 2011. Overall, one third of IS patients were treated with IV t-PA (24.3% via drip and ship). Over time,
IV t-PA treatment rates at our center remained statistically unchanged, ranging from 30% in 2005 to 37% in 2011; however, among acute ischemic stroke patients presenting within 3 hours of symptom onset, study enrollment fell from 46% in 2005 to 19% in 2011. Although other methods of administering thrombolytics to acute stroke patients (ie, drip and ship) appear to be maintaining our treatment rates, few of these patients appear to be eligible for time-dependent acute stroke therapy trials, whereas 20% of these trials had 3-hour windows during the study period.

From 2005 to 2011, the number of TJC-certified PSCs in the greater Houston area rose from 2 to 15. Figure 2 shows the proportion of LAOs, minor strokes, and patients enrolled in a clinical trial each year at our center compared with the number of hospitals that have attained TJC PSC accreditation. According to the Texas Hospital Inpatient Discharge Data, the number of patients with infarcts discharged from PSCs without comprehensive capabilities increased each year from 2008 to 2011 (Figure 2). Of the 3 area PSC hospitals with CSC capabilities, the proportion of infarcts discharged from our facility increased from 29% in 2008 to 39% in 2011.

Table 3 illustrates the odds of particular types of patients admitted to our stroke service for each year compared with patients admitted in 2005. Compared with 2005, patients in 2011 were more likely to have been transferred from an outside facility (odds ratio [OR], 2.55; 95% confidence interval [CI], 2.01–3.24), more likely to have a minor stroke (OR, 1.57; 95% CI, 1.16–2.13), and less likely to present with an LAO within 3 hours of symptom onset (OR, 0.47; 95% CI, 0.25–0.88). The odds of enrolling patients that presented within 3 hours of symptom onset in a clinical trial in 2011 were 29% of those in 2005 (OR, 0.29; 95% CI, 0.16–0.54). This finding remained
significant even after adjusting for time from last seen normal to ED arrival (OR, 0.35; 95% CI, 0.24–0.50).

**Discussion**

To the best of our knowledge, this is the first study to report a shift in the admission demographics of an academic tertiary care center in a metropolitan area, where the number of TJC PSCs has been increasing. Our study found that since 2005, our center has seen an increase in the number of transfer patients, the majority of which were ICH cases. Among IS patients, the proportion of LAOs has decreased over time, whereas the number of mild strokes has increased. Compared with 2005 to 2007, when our center enrolled 28% to 30% of all acute IS patients in clinical trials, since 2008, enrollment rates have dropped to 8% to 14%. Although this work does not provide direct causal evidence, the clear temporal relationship observed in the increase in the number of TJC PSCs in the greater Houston area and our changing patient demographics cannot be overlooked. It is plausible that increased regional access to specialized stroke care, in the form of TJC PSCs, is partially responsible for the changes we observed in patient demographics at our center. In support of this hypothesis, we found the number of patients with infarcts discharged from TJC PSCs has increased each year between 2008 and 2011. These data support our impression that the number of IS patients being taken to TJC PSCs is increasing over time. The changes in our patient admissions may thus be attributable, in part, to transport of patients by EMS to the nearest PSC which, in turn, preferentially requests transfer of ICH cases to our center, whereas keeping patients with IS.

There may be other causes for the changes seen in our patient demographics and clinical trial recruitment. It is possible that there has been a change in the incidence of stroke pathogenesis within the greater Houston area, making the observed demographic changes unrelated to PSCs; however, this would not be in keeping with the stable population trends recently reported for large vessel, cardioembolic, and small vessel IS pathogenesis (Brett Kissela, University of Cincinnati, personal communication). Our observed decrease in the number of IS patients being taken to TJC PSCs in the greater Houston area, is partially responsible for the changes we observed in patient demographics at our center.
in clinical trial enrollment is complicated by changes in the number and type of clinical trials offered at our center over time. Although some of our previous trials are no longer active (eg, Caffeinol/Hypothermia, SAINT II/NXY-059), many have been active since 2005 and remain active in later stages of testing (eg, Argatroban, Clotbust, Hypothermia). Overall, little change has occurred in the number or nature of acute stroke therapy trials conducted at our institution during the study period. The focus for IS remains on treatment of LAO in the acute period.

Some of the loss of more severe acute IS cases could be related to competition from the 2 other stroke centers in the region with neurointerventional capabilities, which are also conducting clinical trials. We found that the 3 centers with neurointerventional capabilities, the proportion of IS patients discharged from our center increased by 10% from 2008 to 2011. Thus, it does not appear that our center is losing patients to neighboring stroke centers with comprehensive stroke capabilities.

The decreased proportion of IS patients with LAO evaluated at our center has important clinical and academic consequences. LAOs are associated with worse outcomes when compared with other stroke subtypes, and studies have shown that IV t-PA alone may not be adequate to achieve recanalization after LAO.22,33 Although still currently under investigation, intraarterial therapies have significantly higher recanalization rates, extended treatment windows, and are approved by the Food and Drug Administration as devices to achieve recanalization. Even if PSCs are capable of treating eligible patients with IV t-PA, very few in our area have 24/7 catheter angiography and access to intraarterial recanalization approaches. There is also a great need for clinical trials evaluating more advanced treatment options, including new mechanical devices, combined IV and IA thrombolysis, and other adjuvants (eg, Argatroban, Clotbust, neuroprotective strategies). If patients with LAO are preferentially treated at PSCs that keep rather than transfer acute stroke patients, they will be denied the opportunity to participate in clinical trials with 3-hour time windows (eg, Argatroban, Clotbust, ICTUS C).

However, we observed an increase in the number of admitted patients with ICH at our center, in large part, because of the increased transfer of ICH cases from outside hospitals. These trends also have important consequences. Ideally, this would translate to improved recruitment for ICH trials (eg, STOP-IT, IMPACT, ATACH-II, SHRINC). In practice, however, we observe that the restrictive time window of these trials does not always allow for trial enrollment in patients transferred to our facility. It also means that CSCs, in conjunction with their neurosurgical and neurocritical care teams, must be prepared and resourced to handle the increasing volume of ICH cases transferring from outside facilities; ICH is associated with greater LOS, greater need for intensive care unit care, and higher hospital costs.17 Similarly, our observation that minor strokes may be increasing has other implications. It may translate to rapid recruitment in trials testing lytic and antiplatelet therapies in minor stroke but may necessitate resources, such as observation units and rapid access clinics, for immediate stroke workup. The reasons for this increase

| All transfers | Ref | 0.96 (0.75–1.21) | 1.03 (0.83–1.29) | 1.49 (1.20–1.85) | 2.05 (1.66–2.53) | 2.2 (1.79–2.71) | 2.55 (2.01–3.24) |
| Transferred ICH cases | Ref | 1.52 (0.75–1.79) | 1 (0.66–1.52) | 1.9 (1.27–2.84) | 2.56 (1.74–3.75) | 2.83 (1.93–4.15) | 3.99 (2.51–6.34) |

Table 3. Odds Ratios and 95% Confidence Intervals for Stroke Admissions Among Patients Presenting Each Year to the UT Stroke Team

| Large artery occlusion | Ref | 0.86 (0.64–1.15) | 0.91 (0.69–1.20) | 0.49 (0.38–0.67) | 0.44 (0.32–0.59) | 0.41 (0.30–0.56) | 0.55 (0.38–0.78) |
| Large artery occlusion where LSN to arrival under 3 hours | Ref | 0.67 (0.42–1.09) | 0.91 (0.57–1.44) | 0.41 (0.24–0.69) | 0.28 (0.16–0.49) | 0.41 (0.24–0.68) | 0.47 (0.25–0.88) |

The row entitled “All Transfers” includes all types of stroke. The row entitled “Transferred ICH Cases” includes only ICH. The remaining rows describe only infarcts. The row entitled “ICH” includes only ICH. The remaining rows describe only infarcts.

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Age ≥80 y Ref | 0.83 (0.63–1.11) | 0.88 (0.68–1.15) | 0.97 (0.74–1.25) | 0.89 (0.69–1.16) | 0.91 (0.70–1.18) | 0.99 (0.73–1.34) |

IAT Ref | 0.8 (0.52–1.24) | 0.67 (0.44–1.02) | 1.01 (0.68–1.50) | 0.78 (0.52–1.17) | 0.62 (0.40–0.98) | 0.64 (0.34–1.21) |

The row entitled “All Transfers” includes all types of stroke. The row entitled “Transferred ICH Cases” includes only ICH. The remaining rows describe only infarcts.

ED indicates Emergency Department; IAT, intraarterial therapy; ICH, intracerebral hemorrhage; LSN, last seen normal; NIHSS, National Institutes of Health Stroke Scale; and t-PA tissue plasminogen activator.

Six months of data (1/11–6/11). P values were derived using logistic regression to assess the odds of particular types of patients being admitted per year.
in minor strokes remain unclear but may reflect previously reported population increases in medication use for treatment of stroke risk factors.18

If the changes in demographics at our center are generalizable to other centers, such findings carry the potential to impact the feasibility as well as the cost of future clinical trials. CSCs will be impaired in their mission to develop new stroke therapies without eligible trial subjects. We therefore believe that PSCs must participate in research devoted to the development of new therapies for acute stroke. Although PSCs are not likely to have sufficient resources to participate in all acute stroke trials, partnerships with CSCs should be encouraged. The goal should be to identify eligible subjects and facilitate appropriate transfers to CSCs. Such regional partnerships would ensure that potentially eligible subjects are offered enrollment in trials and promote cooperation between PSCs and CSCs. These partnerships may take the form of telemedicine, commando teams from the CSC that travel to neighboring PSCs, or hub–spoke complexes with shared research and information technology resources. These partnerships would also assist policy makers in developing regionalized stroke care systems and ensure rapid access to appropriate therapies for all. Accreditation committees should encourage these partnerships, and PSCs should invest in staff and resources to participate in clinical trials. Alternatively, clinical scoring systems could be used by EMS to identify patients in the field with LAOs for triage to CSCs.19 In fact, efforts are already underway at the University of California San Diego Stroke Program to form a task force in their area to formulate a county-wide policy that would triage patients to CSCs based on stroke severity (Thomas Hemmen, personal communication).

The delivery of stroke care in other countries may provide some important observations from which to consider other solutions. For example, a recent observational study from the Netherlands demonstrated that a centralized model, in which EMS and general practitioners transported patients directly to one central stroke center, resulted in more patients arriving within 4.5 hours when compared with a decentralized model, in which stroke victims were treated at local community hospitals. Earlier arrival resulted in higher t-PA treatment rates in the centralized model. Similarly, in some regions of Canada, EMS brings patients with suspected acute stroke to regional stroke centers that have interventional capabilities and participate in clinical trials.20 Centralized systems of acute stroke care in areas outside of the United States may be contributing to the successful trial enrollment seen in these countries.21

This study has some limitations, including the retrospective design and single-center experience. Although we believe that the associations between patient referral patterns and simultaneous decrease in trial enrollment are important and relevant observations, our study cannot draw a direct causal link between the increase in patient discharges from area TJC PSCs and decrease observed in trial enrollment at our center. Unfortunately, we were unable to report the proportion of patients at our site or at area TJC PSCs that would have been eligible for a clinical trial.

In conclusion, our results represent the experience of a single academic tertiary stroke center. Interestingly, this change appears to be temporally related to the growing number of TJC PSCs being accredited in our metropolitan area. Although it is not possible, using our data, to know if the increasing accreditation of PSCs in our area is the cause of our changing demographics, our findings suggest that there are changes in the types of patients presenting to our center. Other academic tertiary centers are witnessing similar changes in their patient demographics corresponding to the rise of TJC PSCs in their metropolitan area (Scott Kasner, University of Pennsylvania, personal communication). Further investigation is necessary to determine whether the demographic changes we are reporting are more widespread in the United States and other countries. In addition, the patterns we observed may prove important for other countries that are developing stroke systems of care and tiered stroke center systems. If confirmed at other academic stroke centers, regional changes in stroke care should be considered to ensure that acute stroke therapies are offered to appropriate patients and to facilitate development of new stroke therapies through participation in clinical trials.

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Disclosures

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