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Stroke Center Certification: Where are we in 2009?

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Overview

Each year about 795,000 people in the United States will experience a new or recurrent stroke. About 600,000 of these events are first attacks, and 185,000 are recurrent attacks. Of all the strokes, 87% are ischemic, 10% are intracranial hemorrhage, and 3% are subarachnoid hemorrhage. On average, every 40 seconds someone in the United States has a stroke. Significant disparities exist within the US population, each year women have 55,000 more strokes than men, blacks have almost twice the risk of first-ever stroke compared with whites and Mexican Americans have an increased incidence of intracranial hemorrhage and subarachnoid hemorrhage compared with non-Hispanic whites, as well as increase incidence of stroke and TIA at younger ages. In 2005, stroke accounted for about one of every 17 deaths in the US or 143,579 individuals. Stroke ranks at number three among all causes of death, behind cardiovascular disease and cancer and is the leading cause of serious, long-term disability in the US. The estimated direct and indirect cost of stroke for 2009 is \$68.9 billion. (1)

Since the approval of iv tPA in 1995, a number of key initiatives supported by evidence-based medicine have led to the national, regional and local organization of previously fragmented stroke care into a more specialized hospital-based and stroke systems of care. These initiatives in organized stroke care have dramatically altered the landscape for stroke patients and providers.

Many factors are driving the centralization of acute stroke care in the United States. The recent development of formal certification for stroke centers is both a cause and an effect of this push. The certification process is still in evolution, and many different organizations, including State Legislatures, are involved. In addition, the relationship between primary stroke centers (PSCs, essentially intravenous tPA-capable facilities), and comprehensive stroke centers (CSCs, generally endovascularly-capable facilities) is not clear, in part owing to the lack of randomized trial data supporting current endovascular intervention for acute ischemic stroke. Nevertheless, the mandate to develop stroke systems of care will have an

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enormous impact on the future practice of neurointervention. The purpose of this brief review is to discuss the history and current status of stroke center certification and the development of stroke systems of care.

Primary Stroke Centers

The initial call for stroke center certification came from the Brain Attack Coalition in 2000 (2). The Brain Attack Coalition (BAC) was formed by Dr. Michael Walker, former director of Stroke, Trauma, and Neurodegenerative Disorders at the National Institute of Neurological Disorders and Stroke. The purpose of the BAC is to promote coordination between member organizations in order to improve the care of patients with stroke. The Society of NeuroInterventional Surgery is a member of this multidisciplinary group. Other members include representatives from the American Heart Association (AHA) and professional societies from Neurological Surgery, Neurology, Neuroradiology and Emergency Medicine. Based on a review of existing literature regarding the benefit of intravenous (iv) tPA, written care protocols, stroke units, acute stroke teams, and integrated emergency medical services (EMS), the BAC defined a list of recommendations for the establishment of primary stroke centers (PSCs). (Table 1)

The major goal of these recommendations was to improve the outcomes of stroke patients by increasing the appropriate utilization of iv tPA and standardizing their medical management. The main requirements for PSCs are 24/7 availability of an acute stroke team and neuroimaging, written care protocols for the treatment of acute stroke patients, integration with EMS and the Emergency Department, a Stroke Unit, and infrastructure to report outcomes and perform quality improvement. Neurosurgery services were not required on site, but had to be available within 2 hours, either by call or transfer. Ten quality metrics were initially identified for reporting purposes (since reduced to eight), and these include items such as deep vein thrombosis prophylaxis and discharge on anti-thrombotic therapy.

The call for the creation of PSC was subsequently endorsed by the AHA (3). Based on these recommendations and in collaboration with the AHA, the Joint Commission developed a PSC certification program that began certifying PSCs in December of 2003 (<http://www.jointcommission.org/CertificationPrograms/PrimaryStrokeCenters/>). As of October 1, 2009, over 600 PSCs have now been certified.

These efforts have been very successful in promoting the use of iv tPA in the United States (4, 5). Lattimore and colleagues at Suburban Hospital in Bethesda, MD, evaluated the use of thrombolytic therapy before and after the creation of a PSC (4). The primary new element was an on-call stroke team. In the year prior to the institution of an on-call service, 3 (1.5%) of ischemic stroke patients were treated with tPA. In the following 2-year period 44 of 420 ischemic stroke patients (10.5%) were treated with iv tPA ($P<0.0001$). Douglas, et al., correlated the 11 PSC criteria that had been recommended by the Brain Attack Coalition with iv tPA usage at 34 academic medical centers (5). Four elements strongly predicted increased tPA use: written care protocols, integrated EMS, organized emergency departments, and continuing medical/public education in stroke. Non-significant trends for increased use of tPA were seen at centers with an acute stroke team, a stroke unit, and rapid neuroimaging. In addition, the more elements present at a given institution, the more frequent the use of iv tPA. There is very good evidence that patient outcomes have been improved by this program (6).

In addition to the Joint Commission certification process, several states have also endorsed the BAC language for PSC and passed either legislation or regulations defining state-certified PSCs. These states include New York, Massachusetts and Florida.

Comprehensive Stroke Centers

The original BAC white paper identified PSCs as facilities that would be able to provide a more organized approach to stroke care as well as standardize some aspects of care for patients with acute stroke. The paper recommended several key elements of a stroke center that would improve patient care and outcomes. Most of the original key elements were adopted by both The Joint Commission (TJC) and States as requirements to become recognized PSCs. In 2004, the BAC published a second paper in which they set out the requirements for CSC (7). These centers differ from PSCs in that they are high-volume, tertiary care facilities with expertise in the care of patients with all forms of stroke and cerebrovascular disease. From the endovascular perspective, this expertise includes the ability to treat patients with intracranial aneurysms, subarachnoid hemorrhage-induced vasospasm, brain arteriovenous malformations, and ischemic stroke. Other important required elements of these centers are neurosurgical expertise, dedicated intensive care units, and 24/7 access to advanced neuroimaging. The rationale for CSCs is strong and is based on the success of similar models for trauma. (Table 2) The AHA has not formally endorsed the certification of CSCs yet, although a committee is working on recommendations (Comprehensive Stroke Center Task Force). A working group has developed a list of metrics that should be recorded and reported by CSCs for performance measurements. This document is being prepared for publication in *Stroke*. This is a first step towards a certification process, similar to the PSC development process. One source of resistance towards formal endorsement is the difficulty in defining the relative roles of PSCs and CSCs and how they would interact in a regional system of care. This is discussed more fully below. The Joint Commission has not yet launched a certification program for CSCs.

There is pending or passed legislation or regulations in nearly ten states now that endorses a tiered approach to stroke care with CSC recognition. These states include Washington, Virginia, Texas, Oklahoma, New York, New Jersey, Florida, Missouri, and Georgia. The certification of centers in these states would be performed by the state government.

Stroke Systems

The integration of PSCs and CSCs into a regionalized system of care is the current challenge. The coming decade will see the transition from primary stroke centers (PSC) as the focus of regional Emergency Medical Systems (EMS) systems of care to more complex hub and spoke models that involve comprehensive stroke centers (CSC) at their nexus. Local stroke systems of care have been developed that have preferentially transported stroke patients to tPA capable centers (8). Federal legislation, the STOP Stroke Act, if passed, will allocate funds and resources for implementing stroke systems of care. The American Heart Association white paper on stroke systems of care laid out four elements that have been widely adopted in state regulations (8). One element was to ensure rapid access to EMS and institute processes to develop, maintain, and measure these efforts. Formal education and testing of first-responders and 911 operators on the signs and symptoms of stroke is one example of such a process. Another was to require integration and communication between EMS and the triage mechanisms of PSCs. Suspected stroke patients generally bypass the usual triage mechanisms in an emergency department. This allows notification of the stroke team, pharmacy personnel, and scanner technologists prior to the arrival of a stroke patient.

The present challenge is the integration of CSCs into networks involving PSCs or other, less capable, facilities. One area of clear benefit for this model is for facilities that are willing and able to administer tPA but not capable of monitoring or dealing with complications of the treatment (primarily brain hemorrhage). Many tertiary care facilities have developed relationships with community hospitals to allow “drip and ship”. Telemedicine is emerging

as an enabling technology for this treatment paradigm (9). Several well-established Telemedicine networks already exist that facilitate the evaluation, treatment and, very often, transfer of acute stroke patients from mostly rural/remote hospitals to larger tertiary care centers. These hub and spoke telemedicine networks presently provide stroke consultation for rural hospitals in areas such as Michigan, Upstate New York, Western Pennsylvania, Massachusetts, and Eastern Georgia (11). The transfer of patients with hemorrhage and aneurysms to CSCs also fits well into a hub and spoke model.

The number of organized acute stroke systems is rapidly increasing. As of fall 2009, there are 1318 hospitals utilizing the Get With the Guidelines Stroke (GWTG-Stroke), part of the TJC certification process and a guideline-based program ensuring quality stroke treatment and prevention, as well as over 600 TJC Certified PSCs and over 200 state designated stroke facilities in the US. Furthermore, organized regional multi-state systems of care have been established or are being developed. Some of the best known examples are the Delta State Stroke Consortium (AL, AK, LA, MS, TN), Tri-State Stroke Networks (GA, NC, SC), Great Lakes Stroke Network (IL, IN, MI, MN, OH, WI) and Northeast Cerebrovascular Consortium (ME, NH, VT, MA, RI, NY, NE). In addition, several of the states that have passed legislation or written regulations have proposed a tiered approach similar to Trauma centers. These tiers include tPA capable (PSCs), tPA incapable, and CSCs. In Missouri, the current language in the draft regulations calls for EMS to bring a suspected stroke patient to any tPA capable hospital if symptom onset is within 3 hours. Between 3 and 6 hours, patients are to be transferred to level 1 (CSC) centers for consideration of intra-arterial (IA) therapy.

The two thorny issues for integration of CSCs relate to EMS rules for transportation of acute stroke patients to different tiers and for the role of IA intervention. Regarding the former, EMS rules generally mandate the nearest, closest, center. The problem with this rule is that patients taken to high volume, higher level centers will be more likely to receive iv tPA and more likely to get it faster. Regarding the latter, it is highly likely that intra-arterial intervention will be proven effective for selected patients with acute ischemic stroke. There are ongoing clinical trials, including the Interventional Management of Stroke (IMS) III trial directly comparing iv tPA alone to an iv/ia approach (10). If these trials are positive, transfer and triage rules will need to be revisited.

Summary

In summary, organized, regionalized, systems for improving the early recognition and treatment of patients with acute stroke have been widely and successfully implemented. The PSC designation and Joint Commission certification program has been a major driver in this effort. These initiatives have resulted in dramatic increases in the use of iv tPA and improved patient outcomes. CSC and more complex, tiered models of stroke care delivery are being developed. While the Joint Commission has not yet launched a CSC certification program, several states have passed legislation or regulations to form Stroke Systems similar to the Trauma model, with tiered levels of care and complex transfer rules. These systems will foster the use of endovascular intervention for ischemic and hemorrhagic stroke.

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Key Messages

Stroke Center certification is still in evolution, and many different organizations, including State Legislatures, are involved. The purpose of this brief review is to discuss the history and current

status of stroke center certification and the development of stroke systems of care.

The relationship between primary stroke centers and comprehensive stroke centers is not clear.

The mandate to develop stroke systems of care will have an enormous impact on the future practice of neurointervention.

Table 1
Major Elements of a Primary Stroke Center (2)

Patient care areas

- Acute Stroke Team (available 15 minutes of being called)
- Written Care Protocols (evidence-based and updated)
- Emergency Medical Services (integrated with stroke center)
- Emergency Department (familiar with protocols and team activation)
- Stroke Unit ^{*} (staffed by personnel with training in expertise with stroke)
- Neurosurgical services (available within 2 hours)

Support Services

- Commitment and support of medical organization; a dedicated stroke director
 - Neuroimaging services (CT or MRI available 24/7)
 - Laboratory services (available 24/7)
 - Outcome and quality improvement activities (database and quality improvement program)
 - Continuing medical education (ongoing staff and public educational programs)
-

^{*} A stroke unit is only required for those PSCs that will provide ongoing in-hospital care for patients with stroke

Table 2
Proposed Components of Comprehensive Stroke Center (7)

Recommendation	Optional
Personnel with expertise in the following areas	
Vascular neurology	Neuroscience intensive care
Vascular neurosurgery	Nursing director for stroke program
APN	
Vascular surgery	
Diagnostic radiology/neuroradiology	
Interventional/endovascular physician(s)	
Critical care medicine	
Physical medicine and rehabilitation	
Rehabilitation therapy (physical, occupational, speech therapy)	
Staff stroke nurse(s)	
RT	
Swallowing assessment	
Diagnostic techniques	
MRI with diffusion	MR perfusion
MRA/MRV	CT perfusion
CTA	Xenon CT
Digital cerebral angiography	SPECT
TCD	PET
Carotid duplex U/S	
Transesophageal echo	
Surgical and interventional therapies	
CEA (IA)	
Clipping of intracranial aneurysm	Stenting/angioplasty of extracranial vessels *
Placement of ventriculostomy	Stenting/angioplasty of intracranial vessels *
Hematoma removal/draining	
Placement of intracranial pressure transducer	
Endovascular ablation of IAs/AVMs	
IA reperfusion therapy	
Endovascular Rx of vasospasm	
Infrastructure	
Stroke unit [†]	
ICU	Stroke clinic
Operating room staffed 24/7	Air ambulance
Interventional services coverage 24/7	Neuroscience ICU
Stroke registry	
Educational/research programs	
Community education	Clinical research
Community prevention	Laboratory research

Recommendation	Optional
Professional education	Fellowship program
Patient education	Presentations at national meetings

* Although these therapies are currently not supported by grade IA evidence, they may be useful for selected patients in some clinical settings. Therefore, a CSC that does not offer these therapies should have an established referral mechanism and protocol to send appropriate patients to another facility that does offer these therapies;

[†] stroke unit may be part of an ICU.

Rx indicates therapy.