Regionalization of Stroke Systems of Care Along the Trauma Model

Kyle M. Fargen, MD, MPH; Edward Jauch, MD, MS; Pooja Khatri, MD, MSc; Blaise Baxter, MD; Clemens M. Schirmer, MD, PhD; Aquilla S. Turk, DO; J Mocco, MD, MS

The burden of stroke is indisputable. Stroke is the fourth leading cause of death and the leading cause of major disability in the United States, and affects ≈800,000 people every year.1 Of these events, ≈87% are acute ischemic strokes, or ≈700,000 per year. Furthermore, stroke accounts for ≈200,000 deaths and results in an estimated $73 billion cost to the United States healthcare system annually,2 the single highest Medicare reimbursement entity for long-term adult care. Interventions that positively impact the outcome of ischemic stroke would be of tremendous value to both patients and society at large.

Although improvements have been made with increased public awareness, enhanced prehospital triage systems, and hospital stroke certification programs, recent studies suggest that acute ischemic stroke reperfusion interventions (both intravenous and intra-arterial) remain significantly underused.3 In most community settings, only 5% of patients with acute stroke actually receive intravenous recombinant tissue-type plasminogen activator (r-tPA) therapy.3,4 Furthermore, advanced stroke care goes beyond acute reperfusion with intravenous or intra-arterial techniques: for patients who develop significant infarcts, subsequent care, such as dedicated neuro-intensive management, intracranial pressure monitoring and control, decompressive surgery, or hemorrhage evacuation are all potentially critical aspects of managing ischemic or hemorrhagic strokes that can significantly affect patient outcome. These resources are often found only at comprehensive stroke centers (CSCs).

Intra-arterial therapies, such as intra-arterial (IA) thrombolysis or mechanical thrombectomy, have emerged as a means of restoring perfusion after large vessel occlusion and have exhibited excellent recanalization and outcome measures in recent prospective trials.5–13 Although 3 randomized trials published in 2013 demonstrated no added benefit to IA intervention compared with intravenous tPA alone,14,15 the randomized controlled trials the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN), the Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion With Emphasis on Minimizing CT to Recanalization Times Trial (ESCAPE), and Extending the Time for Thrombolysis in Emergency Neurological Deficits–Intra-Arterial Trial (EXTEND-IA) have recently completed and all 3 demonstrated significantly improved outcomes in those patients undergoing IA therapies compared with medical management for confirmed large vessel occlusion.11–13 These trials will probably galvanize the stroke community into the widespread acceptance of the routine use of IA treatments going forward. Finally, it is worth noting that recent randomized trials have experienced well-documented challenges in patient enrollment. One element in recruitment difficulty is hypothesized to be because of the decentralization of stroke care, as trial enrollment and management is a resource-intensive process that many small centers are unable to successfully maintain. For these aforementioned concerns, a renewed discussion of regionalized stroke care is necessary.

A recent policy statement from the American Heart Association/American Stroke Association on stroke systems of care summarized the current status of stroke systems and the need for an integrated, regionalized network of care.17 To build on this concept, we propose a model for stroke care borrowed from the widely successful regionalized trauma care model in use within the United States.

Emergence of Stroke Centers

In 2000, the Brain Attack Coalition (BAC) published a proposal calling for the development of primary stroke centers (PSCs) as a means of improving stroke care throughout the United States.18 Recommendations were generated from an extensive literature review followed by consensus agreement from the coalition members. On the basis of this literature review and discussion, institutions designated as PSC would possess acute stroke teams, stroke units, written care protocols, integrated emergency response systems, availability of

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Department of Neurosurgery, University of Florida, Gainesville (K.M.F.); Departments of Emergency Medicine (E.J.) and Radiology (A.S.T.), Medical University of South Carolina, Charleston; Department of Neurology and Rehabilitation Medicine, University of Cincinnati Neuroscience Institute, OH (P.K.); Department of Radiology, Erlanger Health System, Chattanooga, TN (B.B.); Department of Neurosurgery, Geisinger Health System, Danville, PA (C.M.S.); and Department of Neurosurgery, Mount Sinai Medical Center, New York (J.M.).

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Correspondence to Kyle M. Fargen, MD, MPH, PO Box 100265, Gainesville, FL 32608. E-mail kyle.fargen@neurosurgery.ufl.edu

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computed tomography and radiology interpretation 24 hours a day, rapid laboratory testing, and strong administrative support. The investigators concluded that the establishment of PSC had the potential to improve the care of patients with stroke and hopefully improve stroke outcomes. Since 2003, the Joint Commission and several state agencies have identified and designated PSC that fulfill these requirements. Several studies evaluating hospitals designated as PSC both before and after implementation of formal protocols, or compared with nonstroke center hospitals, have revealed improved performance and patient outcomes with PSC designation.19–23

In 2005, the BAC released a second proposal calling for the development of CSCs with the capability of providing advanced and emergent interventions for patients with ischemic and hemorrhagic stroke.24 The BAC defined CSC as a facility or system with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat patients with stroke who require a high intensity of medical and surgical care, specialized tests, or interventional therapies.24 Using similar methodology, the BAC identified many key areas supported by evidence-based medicine that would be important for the delivery of the wide variety of specialized care needed by patients with stroke at a CSC. These include healthcare personnel with specific expertise in neurosurgery and vascular neurology; advanced neuroimaging capabilities, such as cerebral angiography; surgical and endovascular techniques, including clipping and coiling of aneurysms, carotid endarterectomy, and IA therapies; and other specific infrastructure elements, such as a dedicated neurointensive care unit. The coalition argued that the development of a national system with CSC serving as regional hubs would probably improve outcomes of patients with stroke and complex cerebrovascular diseases. At present, pilot CSC performance measures are being tested in the hospitals that have already achieved CSC status.

During the past 10 years, the number of PSC has increased considerably. Currently, there are well >1000 PSC in the United States. In addition, anywhere from 100 to 250 hospitals are anticipated to gain CSC status in the coming years.17 Obtaining PSC or CSC status is advantageous to most hospitals for several reasons. Stroke center status is a significant marketing and public relations title that serves as an excellent advertising tool for hospitals. Second, the reimbursement for stroke care is significant, with the average Centers for Medicare and Medicaid reimbursement for medical management of stroke ranging between $4500 and $10,500 and for IA treatment of acute occlusion between $20,000 and $50,000.25 Because of these factors, many hospitals are actively seeking neurologists and interventional neuroradiology-trained physicians to meet Joint Commission requirements for stroke center designation. This push is leading to an increasing number of community hospitals, many with low stroke volumes, achieving PSC certification or seeking comprehensive accreditation.

**Stroke Centers: the More the Better?**

Although enhancing access to stroke care is a major goal of the BAC, many stroke professionals are concerned about the optimal number and distribution of PSC and CSC in the United States.26–28 On one hand, small community hospitals having the infrastructure and means to treat acute strokes may decrease the time to intravenous r-tPA treatment and probably have a positive effect on stroke outcomes for that particular institution. On the other hand, low-volume hospitals that only nominally meet Joint Commission infrastructure requirements may, despite their individual improvement, still have worse outcomes than alternative hospitals with experienced stroke physicians who more routinely treat high-acuity patients with cerebrovascular disorders. Ideally, every hospital in the United States would be a CSC, each equipped with state-of-the-art highly skilled and experienced neurologists, intensive care units and neurocritical care physicians, advanced cerebrovascular imaging and neuroendovascular capabilities, and neurosurgeons. Unfortunately, this ideal is far from reality and not feasible. Even if such an infrastructure were created, there would not be sufficient numbers of patients to ensure adequate treatment volumes that have repeatedly been shown to correlate with overall quality of care.29–34 The importance of adequate patient volume to overall outcomes has been well documented both in neurovascular care, such as in the treatment of cerebral aneurysms11,35 and in carotid stenosis,36,37 as well as in similar emergent disease processes, such as percutaneous coronary intervention38,39.

Grigoryan et al28 performed a nationwide inpatient sample database analysis of participating hospitals and evaluated the number of stroke-related procedures performed at each institution. The results of the analysis indicated that few hospitals in the United States were meeting the procedure volume necessary, based on previous trial experience requirements for operator inclusion (such as those for the Asymptomatic Carotid Atherosclerosis Study or the International Subarachnoid Aneurysm Trial), to ensure satisfactory operator experience. The authors concluded that this analysis indicates that specialized regional stroke centers are needed to ensure that the physicians caring for patients with stroke are meeting adequate procedural volume to maintain operator competency. This is consistent with several studies that have suggested that morbidity and complications from endovascular or open surgical procedures are lower at high-volume centers.29–31 Similarly, there is evidence to suggest that higher volume stroke centers are associated with higher rates of good outcomes compared with lower volume centers.32–34 These studies provide a convincing argument that appropriately equipped centers with physicians and staff who routinely treat stroke have better outcomes than centers that treat only small numbers of such patients.

Similar sentiments are expressed among leaders of the neurointerventional community who perform IA stroke interventions. On the basis of the number of patients with acute stroke who are candidates for IA interventions per year, estimated at ≈11 to 20,000, and the number of neurointerventional proceduralists active in the United States (=800 practitioners), the average number of acute strokes treated by an interventionalist is only 14 per year, or 1 case every 3 to 4 weeks.26 At best, other recent estimates have suggested that the number of IA stroke cases per year is no more than 22,000 per year.27,28 Additional expansion of practicing neurointerventional proceduralists would likely further reduce the number of procedures performed by such practitioners each year, dramatically reducing the practical experience

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(and associated competency) of treating physicians. This concern has led many stroke experts to suggest that the training of neurointerventional proceduralists be halted temporarily.26

**Limiting the Number of Stroke Centers**

Why are too many PSC and CSC a bad thing? Leaders in the field argue that there are several reasons that the number of stroke centers treating patients with stroke be limited to a finite number based on incidence-based epidemiological analyses. Most importantly, as previously stated, the number of patients who require high-level care (neurocritical care units, hemicraniectomy, IA therapy, etc) is limited. Therefore, as the number of centers providing such care increases, the number of annual cases cared for at each institution decreases, threatening the satisfactory maintenance of physician and healthcare provider competencies, as well as satisfactory volume to support appropriate infrastructure and care delivery systems. In addition, as the number of proceduralists increases each year, there are economic pressures for both hospitals and physicians to find and treat patients with cerebrovascular disorders, biasing centers to perform potentially unnecessary procedures as opposed to conservative management strategies,28 as has been seen with stenting for heart disease.41,42 Furthermore, similar pressures may lead to low-volume centers keeping and treating more patients as opposed to transferring these patients to high-volume centers, potentially leading to worse stroke outcomes. Finally, concern exists that the increasing number of community hospitals treating patients with cerebrovascular disorders, providing some degree of stroke care significantly contributes to the slow enrollment of patients into important field-defining trials that are crucial to the development of new treatments.43,44 By strictly controlling the number, quality, and distribution of centers performing such therapies, enrollment in important randomized trials may be optimized.

An important corollary to stroke care in the United States is that of percutaneous coronary intervention for ST-segment-elevation myocardial infarction. It is well substantiated that modern, regionalized trauma systems have improved injury-related mortality by using this paradigm.48–59 Furthermore, there are data suggesting that patients treated at level-1 centers also have improved functional outcomes after an injury.60–62 with higher patient volumes associated with better outcomes.63 It is generally thought that the marked improvements in morbidity and mortality with regionalized trauma systems are secondary to more patients with the most severe injuries being treated at level-1 trauma centers and because of a reduction in the time from injury to definitive treatment through rapid triage and transport.59 In fact, the 2 consistent requirements to the optimization of trauma outcomes seem to be (1) tertiary trauma care and (2) reduced prehospital time after an injury.59

It should be noted that current trauma systems are not without their own financial conflicts. Traditionally, trauma hospitals have been considered generally unprofitable because of the high proportion of Medicaid and uninsured patients served, often resulting in significant losses in reimbursement.64,65 In fact, trauma center closure has been a common phenomenon because of such losses during the past 2 decades;65 hospitals receiving supplemental indigent care payments may be more likely to weather these financial pressures.66 Further complicating this burden is that hospital costs are usually larger at higher tiered trauma centers and a minority of trauma patients continue to be overtriaged and sent inappropriately to higher levels of care than needed.67

**Regionalization of Trauma Care**

Many experts consider the publication of Accidental Death and Disability: the Neglected Disease of Modern Society66 in 1966, by the Committee on Shock and Committee on Trauma of the Division of Medical Sciences of the National Academy of Sciences/National Research Council, as the landmark event that sparked modern regionalized trauma care. This document drew attention to the magnitude of the trauma burden in the United States, both in terms of morbidity and mortality as well as economic losses, and called for strong government leadership to improve the coordination of trauma care, as well as the development of the Institute of Trauma. Shortly thereafter, Congress responded with the National Highway Safety Act of 1966, legislation that called for the expansion of ambulance and helicopter services for the transport of injured patients and revamping of emergency medical care systems. The first statewide trauma systems emerged in the 1970s. In 1971, the American Medical Association proposed a hierarchical classification scheme for hospitals based on their size, expertise, and ability to care for trauma patients. In 1976, the Committee on Trauma released a report documenting the essential requirements for trauma hospitals, one of which was participation in regionalized trauma systems.57

During the past 40 years, increased attention to, governmental funding of, and legislation for trauma systems has led to remarkable changes in the way trauma patients are managed. Modern trauma systems focus on the rapid stabilization, optimal triage, transport, and definitive management of trauma patients by channeling appropriate patients through a regulated, integrated, region-based network. Those with the greatest need for tertiary care are stabilized at lower level centers then transported expeditiously to hospitals with the capability of offering maximal care. There is overwhelming evidence demonstrating that modern, regionalized trauma systems have improved injury-related mortality by using this paradigm.58–59 Furthermore, there are data suggesting that patients treated at level-1 centers also have improved functional outcomes after an injury60–62 with higher patient volumes associated with better outcomes.63 It is generally thought that the marked improvements in morbidity and mortality with regionalized trauma systems are secondary to more patients with the most severe injuries being treated at level-1 trauma centers and because of a reduction in the time from injury to definitive treatment through rapid triage and transport.59 In fact, the 2 consistent requirements to the optimization of trauma outcomes seem to be (1) tertiary trauma care and (2) reduced prehospital time after an injury.59

Triage of the Poly-Trauma Patient

Although the evaluation of the trauma patient begins with the assessment and stabilization of the patient in the field, the basis for the practices that are performed from start to finish lies in planned, orchestrated steps. Guidelines for the field assessment
Regionalization of Trauma Care Systems: A Blueprint for Stroke Care?

As of May 2010, ≈200 level-1 centers were active in the United States. Slightly higher numbers of level-2 (≈250) and level-3 (≈375) centers were active during this time. Overall, 1 level-1 or -2 center is present for every 610,000 people in the United States. In 2005, an estimated 84% of all US residents had access to a level-1 or -2 trauma center within 60 minutes, by ambulance or helicopter; nearly 45 million members of the US population, predominantly living in rural areas, did not have such access within an hour of event.

The National Trauma Data Bank, the American College of Surgeons-sponsored trauma registry and the largest national database for trauma, reported 773,000 trauma incidents from 744 individual trauma centers in 2011. Of the 744 centers, 228 were level-1 and 251 were level-2. Of the 773,000 events, 600,000 were defined by injury severity scores of ≤15 and 164,000 as severity of ≥16 (generally accepted as the definition of a major injury or poly-traumatic injury), with 8900 not reported. Because most major or poly-trauma patients are treated at either level-1 or -2 centers, estimated mean hospital admissions can be calculated. Therefore, for all 744 trauma centers reporting, each hospital sees, on average, ≈1040 minor or major trauma patients per year. Furthermore, each level-1 or -2 center treats ≈340 major or poly-trauma patients annually.

Similar to the poly-trauma patient, patients with stroke are often critically ill, require specialized care, and have a finite time window wherein life-saving therapies can be initiated. In poly-trauma patients, the golden hour represents the first 60 minutes after sustaining multitrauma; such patients are more likely to survive if they receive definitive treatment within this 60-minute time frame. Similarly, patients with stroke have a finite period of time before ischemic penumbra becomes unsalvageable infarct. Although this time window has not yet been strictly defined, the importance of timely treatment in predicting outcome after stroke has been consistently demonstrated, highlighting the severe sensitivity of neurons to ischemia and the potential for permanent, devastating losses of function with delay in diagnosis or intervention. For instance, it has been estimated that ≈2 million neurons die during each minute of ischemia. Stroke patients with large clot burdens are less likely to benefit from intravenous r-tPA alone. Furthermore, a complication of thrombolytic therapy is intracranial hemorrhage that may require neurosurgical evaluation and intracranial pressure management. Such complex stroke management requires intricate multidisciplinary decision making that would probably be maximized at centers with dedicated stroke care teams (involving dedicated emergency medicine, neurology, neurosurgery, radiology, intensive care, and rehabilitation physicians). So, although treatment with intravenous r-tPA can and should be initiated as soon as possible, patients with severe stroke should be triaged and transported expeditiously to regional stroke centers (if also available in close proximity) with vascular neurology, neuroendovascular, neurosurgical, and advanced intensive care capabilities, to facilitate endovascular, critical care, or neurosurgical management as necessary.

Currently, stroke care is fragmented and operates in a pseudoregionalized system. Unlike the systematic development and refinement of trauma systems, stroke systems evolved based on local needs in an uncoordinated manner lacking systematic oversight and control. It was recently estimated that there is 1 PSC for every 412,000 people in the United States. In most instances, rural hospitals that evaluate a new patient and recognize the patient’s need for tertiary stroke care contact the tertiary center for emergency transfer. Usually, rural centers obtain brain imaging as well. In this scenario, the receiving physician often provides assistance in patient management, offering advice to the treating physician so that the patient can be adequately treated while en route for definitive care. Frequently, this involves initiating intravenous r-tPA and then emergently transferring the patient to a tertiary stroke center, commonly referred to as drip-and-ship. Currently, ≈1 of every 6 patients with stroke in the country receive their stroke care in this manner. Drip-and-ship treatment may be associated with lower hospital costs as well as a higher probability of patients being treated at a tertiary center, although improved outcomes have not yet been definitively demonstrated. Telemedicine is another means, whereby rural hospitals may communicate and discuss patient information for triage within hub-and-spoke stroke referral systems. Oftentimes telemedicine consultation involves real-time video conferencing as well as teleradiology, whereby the consulting physician may evaluate the patient’s imaging and determine the best course of action. Frequently, telestroke results in transfer from a spoke, rural hospital to a hub hospital, which usually is a tertiary care hospital with CSC capabilities.

This pseudoregionalized system, although well intentioned, is often fragmentated and often overlapping and redundant. This decentralization may contribute to some patients who are candidates for intravenous, IA, decompressive surgery, or other advanced therapies from actually receiving them because...
of triage to centers lacking expertise in these treatments. Furthermore, there is no regulated and standardized means by which hospitals with limited stroke resources diagnose, refer, and transfer patients with acute ischemic stroke to tertiary stroke centers.

The development of modern-day, regionalized trauma systems required years to achieve maturity. However, modern regionalized trauma systems are now recognized as a fundamentally necessary, impactful, cost-effective, and patient-centric paradigm that optimizes outcome after major injury. With stroke, we are just beginning to appreciate both the need and the benefits to stroke systems. The similar time window for life-saving therapies, need for specialized physicians and critical care staff, and potential requirements for state-of-the-art facilities in both stroke and trauma make a solid argument that stroke care would benefit from adopting well-evidenced algorithmic regionalized approaches currently used for the trauma patient.

Although the focus of this article is predominantly on developing a regionalized system that promotes optimization of stroke care through the use of stroke centers of excellence, it is important to note the role of the community hospital in this system. The overall goal of the proposed system is to improve care of patients with stroke at all hospitals, not just designated stroke centers. This integrated system would, therefore, provide a 2-way street for education, feedback and training between community hospitals and larger centers. Furthermore, this system would also allow community hospitals to continue to care for appropriate patients with stroke, as well as care for those patients who have been evaluated or stabilized at stroke centers and no longer need tertiary-level care. Through a regionalized, orchestrated system, community hospitals would continue to play an important role in post-stroke care and rehabilitation as well as in managing acute patients with less severe strokes, and would benefit from consultation or telestroke conferencing with higher volume centers with stroke specialists.

Possible Solutions

Currently, there is no clear singular solution to the under-use of reperfusion therapies and CSC resources. However, we suggest a concerted effort is needed, as was necessary for the regionalization of trauma, incorporating all major stakeholders: patient advocacy groups, organized medicine, and governmental bodies and payers, to reevaluate the US current fragmented system of stroke care and aid in the development of a coordinated regionalized network. As in the case of trauma, this may require significant legislative efforts.

In an integrated system of care, use of validated prehospital stroke scales, such as the Los Angeles Motor Scale79,80 (LAMS) and the Cincinnati Prehospital Stroke Scale (CPSS),81 that provide a standardized means for emergency medical service or emergency physicians to rapidly diagnose stroke-like symptoms, initiating triage into the regionalized stroke model is critical. Both the scales are simple, 3-factor assessments of gross neurological function: LAMS assesses facial symmetry, arm drift and grip strength, whereas CPSS assesses facial symmetry, arm drift, and speech. The LAMS has a sensitivity of ≈65% to 81% and a specificity of 87% to 89% in detecting acute ischemic large vessel occlusions82—the patient population most likely to require advanced medical, surgical, or interventional care. With the use of such screening tools, patients requiring advanced care could be directed to preidentified CSCs in rapid fashion, bypassing nearby less equipped stroke facilities.

With appropriate volumes and fixed patient transportation expectations, these CSCs can use prehospital notification and efficiencies of scale to improve the rates of time sensitive care—one might hypothesize that the resulting care would be even quicker, across the entire population, than the current system. Although certainly this is only a hypothesis, the overwhelming success of the trauma system provides a strong indicator that such efforts would be rewarded with improved care to the stroke population as a whole. On the basis of trauma data estimations, 85% of the US population is within 1 hour of either ambulance or helicopter transport to the ≈500 level-1 or -2 trauma centers in the United States.80 In both heart attack and stroke paradigms, high-volume centers have repeatedly demonstrated much shorter door to treatment times as compared with low-volume centers.83,84 Might that difference alone make up any differences in transport time? Might it not be worth trading 15 minutes of extra transport time to arrive at a center that consistently administers intravenous tPA within 30 minutes of arrival as compared with the national average of 55 minutes, or consistently expeditiously performs IA revascularization, as well as ensuring that the physicians and nurses have extensive experience in caring for the critically ill patient with stroke after they have received emergent therapies? Furthermore, because efficiencies of scale become evident and transport networks become more consistent, might not further opportunities for shortened treatment times be realized? As previously stated, these are hypotheses, however, with the trauma experience as a guide, its consideration seems worth the effort.

Conclusions

Acute ischemic stroke is the fourth leading cause of death and the leading cause of major disability in the United States, yet stroke care remains suboptimal with limited numbers of patients receiving the treatments they need. Furthermore, stroke hub-and-spoke networks are fragmented and poorly organized and under-regulated. Although defining PSCs has led to broadly improved outcomes, defining a regionalized stroke system of care with a limited number of high-volume, highly experienced CSCs, well integrated into a regional system of care, is the critical next step. Using highly evidenced US regional trauma systems as a blueprint, we encourage a similar regionalized system for stroke care in the US. Limited but well coordinated numbers of CSC can supply the US population with the necessary comprehensive stroke coverage, whereas promoting improved outcomes by maximizing neurological, medical, neurosurgical, critical care, and procedural experience. Most importantly, regulation establishing, promoting, and incentivizing robust and integrated stroke systems will be required to support the development of any proposed stroke system.

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