Chapter 3
Importance of a Comprehensive Approach

Raymond D. Turner

Stroke is the second leading cause of death worldwide and the foremost cause of disability [1]. For over a decade and a half, the Brain Attack Coalition (BAC) has been developing recommendations for the treatment of stroke, and the Joint Commission has been certifying centers based on these recommendations [2]. These guidelines are designed to improve access and triage decision making for patients in efforts to obtain the best possible population-based clinical outcomes. The current highest level of Joint Commission certification is Comprehensive Stroke Center (CSC).

Defining Comprehensive Stroke Center

In general, a certified CSC has the necessary facilities, personnel, processes, and expertise to manage stroke patients, with the goal of optimizing population-based patient outcomes. Part of this certification requires that the approved centers have the ability to track data, identify positive and negative trends, and modify the processes in the patient care pathway in order to optimize standardized outcomes. While centers are approved for 2 years, it is important to note that there is an interim analysis at 1 year. The Joint Commission is regularly reviewing and updating the requirements based on patient outcome data and expert recommendation. The most current detailed CSC requirements can be found at https://www.jointcommission.org/certification/advanced_certification_comprehensive_stroke_centers.aspx.

In order to track quality metrics, the AHA/ASA put out a scientific statement detailing 26 metrics that should be used across all CSCs [3]. They are divided into

R. D. Turner (✉)
Department of Neurosurgery, Medical University of South Carolina, Charleston, SC, USA
e-mail: turnerrd@musc.edu

A. M. Spiotta et al. (eds.), *Management of Cerebrovascular Disorders*,
https://doi.org/10.1007/978-3-319-99016-3_3

three disease categories: ischemic stroke, aneurysms (ruptured and unruptured), and non-trauma-related hemorrhagic stroke and AVMs (ruptured and unruptured). The metrics address all phases of the care pathway, from triage and initial management to critical care through rehab, as well as the participation in clinical research studies. Due to a lack of data, currently there are little-to-no benchmarks established for quality metrics that centers need to achieve, particularly in regard to complication rates. However, there are goals that are set related to timing of triage and treatment.

The effectiveness of the certification in reducing mortality and morbidity has yet to be elucidated. Most recently in the USA, the impact of stroke mortality improved from the third to fourth leading cause of death. The AHA/ASA attributed this improvement to a multitude of factors, such as changes in interventions, improvement in stroke prevention, and risk factor modifications, particularly hypertension. However, it is important to note that the CSC program certification is relatively new, and while there are approximately 100 joint commission CSCs, there are other centers functioning like a CSC that are in the queue for certification site visit. Therefore, it is likely premature to see any measured effect in a large population analysis [4].

Disease-Specific Considerations: AIS

There are several core measures that have been identified with best practices for triage and management of acute ischemic stroke. The initial triage of all suspected stroke patients should begin with the NIHSS. Utilization of this scale standardizes the examination of the patient and is a predictor of stroke outcomes. All suspected strokes should also obtain a non-contrast CT scan of the brain. Based on clinical imaging and laboratory data, patients who qualify for intravenous thrombolysis with tPA should receive this without delay. The standardized goal is to administer this drug within 60 min upon arrival to the hospital. All suspected large vessel occlusions (LVO) should be referred to neuro-endovascular surgeons for evaluation for mechanical thrombectomy.

Triage: Primary Versus Comprehensive

There is currently a debate regarding the triage of patients at the EMS level. Should a patient be transported directly to a CSC or to a PSC? Obviously, if the CSC is a shorter transport, patients should triage to the CSC. This argument likely holds true for when they are equidistant. However, it is unknown at this point if there is a time cutoff that would dictate improved value by accepting a slightly longer transport time in order to reach a CSC over a PSC. In some cases, particularly those patients with low likelihood of harboring LVO, either PSC or CSC, may be appropriate. However, this discussion has ramifications in patients with LVO. There are several endeavors

underway at the EMS triage level that will try to correlate a noninvasive "in the field" exam or study that will predict patients who have LVO from those who do not.

IV tPA + EVT Versus EVT Alone

There have been several retrospective studies published looking at the outcomes of suspected LVO patients, those treated with IV tPA and endovascular therapy (EVT) vs ETV alone. The Catalan Stroke Code and Reperfusion Consortium reported in stroke that their observational study of >1100 patients demonstrated no difference in good outcomes (mRS 0–2) at 3 months [5]. A meta-analysis of six randomized control trials also demonstrated the observation that IV tPA did not impact the rate of good outcome in mechanical thrombectomy patients with large vessel occlusion [6]. A third group published their experience with 90 consecutive patients demonstrated so significant difference in good outcomes; however the cost of treatment favored ETV alone vs IV tPA + ETV ($33,810 vs $40,743; $p = 0.02$) [7].

While these studies are of interest and trigger good academic debate, it is important to note their primary limitation is that these are really two different treatment groups. While these studies generally had similar demographics, stroke severity, etc., in all studies, patients presenting within the IV tPA-recommended guidelines received that therapy. Therefore, the ETV-only groups are patients with AIS presenting later by comparison to the tPA group, or were disqualified for other reasons; yet their imaging suggested that they may receive benefit if they revascularized the patient with ETV. Therefore, the ETV group may have a propensity for better outcomes due to a number of factors, such as good collateral flow. Nevertheless, this fuels the academic fire to consider a head-to-head RCT of EVT with or without tPA, especially if similar good outcomes and avoidance of bad outcomes can be obtained for lower socioeconomic costs.

Disease-Specific Considerations: Aneurysms

It has been shown that large volume centers that treat aneurysms are able to obtain better outcomes compared to low volume centers. The analysis of the California hospitals demonstrated that in-hospital mortality was lower at the higher volume centers; however length of stay and charges were higher [8]. Barker et al. reported that high volume centers were more likely to discharge patients to home after elective aneurysm surgery, there was a trend toward lower mortality, and length of stay was not significantly different [9]. Analysis of ruptured and unruptured aneurysms in New York state demonstrated lower morbidity and mortality in high volume centers [10]. Hoh et al. demonstrated that high volume endovascular centers had lower morbidity and mortality rates compared to low volume centers [11].

One key issue with these studies and others is the lack of standardized definition of high volume vs low volume. Furthermore, the data of these studies were largely obtained in the late 1990s and early 2000s, well prior to the formation of CSC designations. This is confounded by the issue that some of these studies set the benchmark for a high volume center as low as eight procedures per year for a hospital or three procedures per year for a surgeon. The CSC requirement (currently) for approved centers is 15 aneurysm procedures per year. These case minimums have changed over the years, but in essence acknowledge that there is practical experience required to have optimized population-based outcomes [12]. Grigoryan et al. looked at the implications of case minimum requirements, which determined that very few centers (at that time) qualify for CSC certification, making the argument that cerebrovascular disease should be treated in regionalized centers [13].

Another consideration for the treatment of cerebral aneurysms, among other diseases (AVMs), is the specific members of the team caring for the patient. MUSC delineated the experience of developing a comprehensive approach to cerebral aneurysm care from the traditional independent approach [14]. Creating a single team of open and endovascular-trained neurosurgeons, interventional neuroradiology, and neuro-critical care specialists, the group saw an increase in patient volume, increase in case mix index (a measure of severity of the patient's comorbidities), lower length of stay, and lower mortality rates with a comprehensive team approach.

Disease-Specific Considerations: ICH

Intracranial hemorrhage is a complex disease that is typically secondary to poor management of chronic physiological conditions, such as hypertension and diabetes. However, in some cases, underlying vascular etiologies such as vascular malformations or aneurysms may be present. Approximately 30% of patients will have an increase in ICH following the ictal bleed [15]. Patient's medical conditions may also be complicated by the use of anticoagulation. For example, reversal of vitamin K antagonists has historically been limited to combinations of vitamin K and fresh frozen plasma; however recent evidence suggests that four-factor prothrombin complex concentrate may be superior [16]. Stopping and reversing these medications for the benefit of the patient in terms of ICH management must be balanced with the risk of why they are on those medications prior to the hemorrhage. For example, stopping the prophylactic aspirin in a patient with ICH is a relatively easy risk/benefit analysis; however managing the anticoagulation in a patient with a left ventricular assist device (LVAD) and ICH is a more challenging scenario.

While management of ICH guidelines assists with the decision analysis of these patients, their complexity may require additional experience and expertise [17]. Aggressive intracranial pressure monitoring, surgery, and seizure treatment are not uncommon in the acute care of these patients whose mortality and morbidity are significant. Given the complex and diverse decision analysis required to treat these

patients, a comprehensive team approach of neuro-critical care, neurosurgery, and vascular neurology is required to optimize the components of treatment.

Beyond CSC: Comprehensive *Systems* of Care

While the current state of stroke designation is focused on hospital-based accreditation, population-based approaches need to be considered in the ability to deliver optimal care across a geographical area. These systems of care will differ across the USA, as the geographical constraints and opportunities to access healthcare differ in the various environments (urban, rural, etc.). The other consideration is the cerebrovascular disease that requires treatment. Acute ischemic stroke is extremely time sensitive; however a small ICH may not be as critical.

The FAST-MAG study looked at routing suspected acute ischemic stroke patients to the nearest primary stroke center vs the nearest adult ER in the Los Angeles County area. They found that volume increased at the PSCs without sacrificing prehospital care time. However, this is in a confined geographical area where there were 29 PSCs by the end of the study enrollment. This is a very different scenario if you live in Wyoming, where there is only one PSC at the time of this writing.

This is important because while the number of endovascular patients with aneurysms and AVMs have remained stable, there has been an increase in endovascular treatment of AIS since the trials demonstrated superior outcomes to IV tPA alone at the end of 2014 and early 2015. From an access to care standpoint, this is now critical to consider as the patients who need the most urgent care are the largest growing treatment eligible population in cerebrovascular disease. However, training new physicians takes time, and if there is a large increase in the large number of endovascular surgeons to treat AIS, it will inevitably dilute the volumes each physician treats of the other cerebrovascular disease. While correlating high volume to better outcomes has not been established for AIS, it has been demonstrated for diseases such as aneurysms. It is possible that without novel access and care delivery platforms, we could be sacrificing the outcomes of one disease (aneurysms) to meet the need of another (AIS).

There are several models being implemented currently to address these issues. Stroke mobiles are currently in service in Cleveland, Houston, Memphis, and Chicago and are used to assist in triage and CT imaging in the field rather than at a hospital, moving the decision point from in-hospital to the point of first contact. The MUSC group in Charleston is creating a single physician team, including triage and treatment processes across multiple healthcare systems, concentrating expertise within a finite group of doctors, rather than a single hospital. Others, such as in Charlotte, are creating multiple teams of experts at each hospital. While no one solution will prevail, innovation solutions will eventually help model out the best approaches given the needs and resources of a particular area. This is an extremely dynamic time in the treatment of cerebrovascular disease, and the only certainty is how we optimize workflow will like continue to evolve.

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