

Thrombectomy stroke centers: The current threat to regionalizing stroke care

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The Joint Commission (JC), in collaboration with the American Heart Association (AHA), recently announced a new stroke center certification for Thrombectomy Capable Stroke Centers (TSCs).¹ The criteria for TSC accreditation are less stringent than those for existing Comprehensive Stroke Centers (CSCs) with focus specifically on the delivery of endovascular acute *ischemic* stroke care. The accrediting organizations state that this designation originated in response to the 'need to identify rigorous standards for performing endovascular thrombectomy procedures'.¹

There is no dispute of the value in identifying rigorous endovascular thrombectomy standards. Unfortunately, this new designation does not meet a reasonable threshold for rigor. Although these centers may be thrombectomy 'capable', the evidence suggests that the process and numerical requirements currently proposed for accreditation are insufficient to yield the favorable patient outcomes reported in recent randomized controlled trials. Further, the new guidelines do not call for adequate resources to support the comprehensive care of emergent large vessel occlusion (ELVO) stroke patients. Concerns were recently raised by the Brain Attack and Cerebrovascular Coalitions about this new designation.

Consistently successful treatment of the most severely affected stroke patients requires not just *capability*, but *excellence* as well. It is possible that TSCs

may have value in specific systems of care and/or limited parts of the country with unique geographic and urban spatial considerations. For instance, incorporation of hospitals under this designation might serve an unmet regional need or strengthen an existing spoke and hub model within a unified hospital enterprise. Even in such circumstances, requirements should ensure that TSCs are staffed with experienced and specialized stroke/critical care neurologists and neuroendovascular surgeons who are supported by services capable of delivering high-level periprocedural care. If hospital facilities are allowed to pursue this designation independent of regional considerations or existing networks, it is highly likely that large vessel stroke patients would unknowingly receive second-tier stroke care when top-tier care is readily available within their own community or region.

The Joint Commission has been criticized for a variety of challenges related to its accreditation programme. Stroke certification is not an exception. It is our belief that the JC and AHA's failure to adequately respond to feedback from professional societies is concerning and undermines their entire effort.

The editorial board of JNIS urges consideration of the following tenets and processes. Incorporation of these points would serve to better integrate the TSC designation into broader stroke networks:

Thrombectomy capable centers should be staffed by neuroendovascular practitioners who perform adequate volumes of mechanical thrombectomy procedures.

In recent years, the neuroendovascular surgery specialty and its parent organizations (Neuroradiology, Neurology, Neurosurgery) have exhibited a patient-centric, highly collaborative relationship to advance common goals of stroke care. This group aims to ensure that practitioners are adequately trained to perform neuroendovascular procedures and maintain the skills necessary in managing ELVO patients and related disease processes. This is based on a thorough understanding of stroke systems of care and numerous

studies highlighting the importance of procedural volume.²⁻⁵ A recent paper published in *Stroke* outlined the metrics and criteria for *Committee on Advanced Subspecialty Training (CAST) Neuroendovascular Fellowship Certification*.⁶ In this document, the minimum acute ischemic stroke treatment numbers mandatory for each trainee (30), are substantially higher than those required for thrombectomy capable certification (each neurointerventionalist at a TSC needs to perform only 12 mechanical thrombectomies over the previous year).¹ The TSC volume requirements are unclear and harbor two major shortcomings:

THEY STIPULATE THE MINIMUM NUMBER OF PROCEDURES PER CENTER, BUT DO NOT ACCOUNT FOR FLEXIBILITY OF TEAMS COVERING MULTIPLE CENTERS

We believe that the number of mechanical thrombectomies performed by a practitioner at a specific TSC is less important than the aggregate number of thrombectomy procedures performed by the practitioner over the course of the year. Furthermore, the operators need to have demonstrated dedication to neurointerventional procedures and management of the associated diseases. The strength of the process relies on the comprehensive management of ELVO patients. This includes pathophysiology, context of clinical presentation, nuances of medications, blood pressure parameters, management of complications and physiology of acute large vessel stroke. In the same light that it does not make sense for neuroendovascular surgeons to perform procedures outside of their expertise, similarly, it does not make sense to have practitioners not trained in neuroendovascular procedures perform mechanical thrombectomy.⁷

THE TSC VOLUME REQUIREMENTS DO NOT RECOGNIZE OVERALL THRESHOLDS THAT CENTERS MUST MEET (NOT PER PRACTITIONER) TO DEVELOP COMPETENT SYSTEMS OF CARE

If a center has one neurointerventionalist, the current requirements state that the center need only perform 12 annual thrombectomies. This reflects an overly simplistic view of the breadth of services needed for these severe strokes. The thresholds also reveal a significant lack of understanding regarding the global processes involved in these patients' care. A center that performs only 12

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Editor's column

thrombectomies (or 24 for that matter) will not have adequate programmatic experience. This proficiency is needed to ensure excellent ED throughput, skillful medical management, advanced/timely imaging, neurointensive care expertise, supportive services (PT, Swallow studies, etc.), and rehabilitation expertise for these severe stroke patients. Focusing solely on the neurointerventionalists' case volumes ignores the broader institutional commitment and needs critical to the process.⁸

While perhaps attractive for organizations that produce revenue through certification, a call schedule and a shelf stocked with stent retrievers do not constitute a successful thrombectomy center. In the large randomized controlled stroke trials reported in the *New England Journal of Medicine* in 2015,⁹⁻¹³ successful patient outcomes were achieved through efficient systems of care, robust operator training/experience, and careful peri-procedural patient management.¹⁴ Indeed, these studies let prominent organizations immersed in the care of ELVO patients to declare that mechanical thrombectomy is the standard of care. Any benefit derived from thrombectomy lies not necessarily in the presence of a stent-trieter, but more so in the ability and experience of the team caring for the patient. An endovascular surgeon with a stent retriever doing 12 thrombectomies a year is no different than a casual golfer with a fancy Big Bertha driver. Hitting the ball long and straight down the fairway takes more than a fancy club and some nice golf spikes.¹⁵

The idea that TSCs could be covered by specialists without dedicated neuroendovascular training or executed efficiently without well-planned hospital processes of care diminishes the complexity of care delivery to the most critically ill acute stroke patients. Direct prospective evidence would help support these logical inferences and serve to control the quality of stroke systems in the future. Recent studies have demonstrated a positive effect of public reporting on patient mortality and related clinical outcomes.¹⁶ Public data reporting would ensure that certified stroke centers are delivering the type of care that our patients and their families expect. In the absence of this data, however, we should not feel empowered to lower patient care standards below that generated by the evidence-based studies supporting thrombectomy procedures. The processes, experience, and expertise of the centers that participated in the large randomized trials were the reason for the procedure's success. Thus, the onus needs to be on the medical community

to demonstrate that lower standards can still result in adequate care. We believe, and evidence to date suggests, that they cannot. To promote dilution of quality based on evidence extrapolated from high volume centers, is not only counterintuitive, but could potentially cause significant patient harm.

Thrombectomy capable centers should exist within stroke systems of care. Regionalization of centers should be considered along with concerns of geography and proximity to comprehensive stroke/tertiary care centers. If all TSCs were able to perform mechanical thrombectomy procedures and peri-operative care with efficiency and outcomes similar to that of the CSCs, this would not be a problem for our patients. In such a case the primary issue would be societal cost concerns. However, inequality of care among treating centers will be practically assured by lack of rigor in the accreditation process. There will be a wide range of quality at hospitals in close proximity to one another (CSCs vs TSCs). In the case of hotels or food service providers, the superior product (either by experience or price) would eventually attract more customers and a capitalistic market would determine the fate of the individual providers. When too many coffee franchises open in close proximity in a large city, market demands re-establish the provider sustainability over short periods of time. This natural balance would not be realistic in the proposed stroke center model, as the patient (consumer) does not have any choice as to where he/she receives stroke treatment. The presence of multiple TSCs/CSCs in a dense area, without the most rigorous of requirements for every center, would detract from patient outcomes by directing patients away from centers providing the highest levels of care. A constant influx of patients at the facilities that meet criteria, but do not have the same high level of expertise, would dilute overall large vessel stroke care and regress patient outcomes towards the mean.

As previously stated, the profoundly positive treatment effect of mechanical thrombectomy was proven in high volume centers in the published randomized controlled trials. There is no clear evidence that this effect would persist in lower volume centers (even those meeting a pre-determined threshold). Well-designed care delivery models exist for the emergent triage of patients with acute, life threatening trauma. Severely injured patients are triaged to the most advanced/capable centers (Level 1) and, most importantly, accreditation is dependent

on resources and population density.¹⁷ Individuals treated at high volume Level one trauma centers have better overall functional outcomes.^{18,19} The acute stroke community can learn from the organization of trauma care systems and from the steadfast commitment of the surgical community to adhere to the standards that have demonstrated success.²⁰

Logistics should be considered regionally. A system that provides benefit to an urban population may not be practical in rural areas and vice versa. Practically speaking, it may be worthwhile to have TSCs in rural areas or those lacking adequate densities of CSCs. In these locations, the centers meeting minimum criteria for mechanical thrombectomy procedures would not be directing patients away from CSCs but rather would be providing valuable resources to an underserved geographic region. Further, if optimal systems can be developed under a single healthcare organization, it could be beneficial to have TSCs in the same region as CSCs. This could be true even in densely populated, urban locations, provided an actual population-based need exists. In this scenario, clear workflow and treatment paradigms could be developed. The TSCs could be staffed with high volume proceduralists and adequate periprocedural support. Algorithms could be developed that ensure efficient transfer of patients/disease processes from TSCs to affiliated CSCs, when the TSCs do not have the required expertise or infrastructure. While the current guidelines call for an established relationship with a CSC, the nature of the CSC-TSC relationship is not adequately clarified. This would be less concerning for patient care if rigorous standards were kept, however, as rigor declines the magnitude of the problem increases. No clear roadmaps or logical computations exist to govern the number of TSCs needed to serve particular regions. As a result, financial incentives, community recognition, and perceived hospital credibility will all likely contribute to establishment of co-localized and redundant facilities.

Stroke center designation by specific disease type requires accurate screening and triage. The requisite screening tools do not exist at the present time to properly triage ELVO patients. The current clinical state and paradigm does not include screening tools and methods with the requisite sensitivity/specificity to reliably differentiate large vessel stroke from other neurological/neurosurgical/neurovascular emergencies.²¹ In the proposed system, it is highly likely that patients, clearly better served at tertiary centers, would be routed to

TSCs not equipped to handle these disease processes. Perhaps even more concerning, the lack of specificity of current triage tools and the expanding time window of thrombectomy (currently established with level 1 evidence at 24 hours) will effectively result in a majority of potential stroke patients being triaged to a TSC or CSC. As a result, small vessel strokes may rarely present to non-TSCs/CSCs. The fear of losing the ability to care for the majority of stroke patients will drive every hospital to attempt to obtain TSC accreditation. A hemiplegic patient with an NIH stroke scale of 10 does not present with a specific large or small vessel stroke diagnosis. To artificially delineate ELVO from small vessel stroke or intracerebral hemorrhage is not patient focused but rather, centered on hospital and certifying organization concerns. Without an 'EKG-equivalent' tool for stroke, the complexity and demands made on first responders to determine stroke severity in the field currently stands as a significant challenge. Adding a third stroke center designation would likely only exacerbate this challenge.

Thrombectomy Capable Centers may occupy an important niche within larger stroke systems of care in the future. They have the potential to broaden the footprint of effective and beneficial endovascular stroke treatment. These centers could greatly benefit ELVO patients in areas where tertiary centers are not available or when incorporated into efficient care delivery systems with structured support and clear treatment algorithms. However, in order for TSCs to be beneficial to patients, it is critical to establish and maintain high standards of procedural expertise and peri-procedural care.

Further, the regional allocation of these centers must be an absolute requirement before incorporation into the broader stroke system of care.

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