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## The Need for Increased Access to Mechanical Thrombectomy for Large Vessel Occlusion Strokes in the US

By Michelle Luffey

Large vessel occlusions account for up to 46% of acute ischemic strokes, which place large areas of the brain at risk for irreparable damage if not treated appropriately within a designated recommended timeframe. Furthermore, these types of stroke cause disproportionately high rates of post-stroke death and disability when compared to other types of Ischemic stroke, 95% and 62%, respectively.

Over the past few years, study data has demonstrated the efficacy of endovascular thrombectomy for improving clinical outcomes in patients with large vessel occlusions (LVOs), which has significantly impacted the treatment recommendations for the large and growing patient population that suffers from LVOs. In response to the study data and results, in October of 2019, the American Heart Association / American Stroke Association published the 2019 Updates to the *Guidelines for the Early Management of Acute Ischemic Stroke* in which the window for mechanical thrombectomy expanded from the prior six-hour recommendation to up to 24 hours for LVO patients. However, even with the longer timeframe potential for this procedure, nearly two years later many patients who could benefit from this therapy are still not receiving it.

The Question is "Why?"

<u>Corazon</u> believes the number one reason is a lack of access. In many areas across the US, there are simply not enough established thrombectomy-capable centers to ensure availability to this life-saving / life-altering treatment.

Unlike the significant proliferation of Percutaneous Coronary Intervention centers that popped up across the country over the last 30 years, there has been a much slower rate of implementation for neuro-intervention. There are of course significant differences in the overall volume of patients who need PCI versus those who may need mechanical thrombectomy, though the similarities in these two procedures are many.

In 2018 there were approximately 965,000 PCI procedures performed, therefore the 2,600 (approximate) PCI centers across the country makes mathematical sense. When looking at potential volume for mechanical thrombectomy, the numbers are significantly smaller. There are roughly 800,000 strokes per year in the US, with 87% being ischemic in nature. This equates to about 696,000 ischemic

type strokes. And with the LVO incidence ranging from 24% up to 46%, the overall potential for mechanical thrombectomy is somewhere in the range of 167,000 to 320,000 patients annually who could or should receive interventional treatment.

However, annual US thrombectomy volumes are not even close to 167,000 in number, the lowest end of the range for potential candidates. In 2016 there were only 13,010 thrombectomies completed yet the stroke rate was not significantly less than that of today. The shorter six-hour window certainly played a part in the smaller volume, but even that could not fully account for the low case volume performed. According to Mission Thrombectomy 2020+, a global non-profit committee of the Society of Vascular and Interventional Neurology (SVIN), the total number performed was still only estimated in the 70,000 to 80,000 range in 2019.

The numbers tell the story: We still have a long way to go to provide this beneficial and recommended treatment to all patients in need.

It is difficult to calculate the actual number of Comprehensive Stroke Centers or Thrombectomy Capable Stroke Centers, as there is not a nationally-maintained list. A recently-published study from the UT McGovern Medical School indicated that of the 1941 stroke centers in 2017, only 713 were able to perform mechanical thrombectomy, and only 19.8% of the US population had direct access to EVT (endovascular therapy or mechanical thrombectomy) within 15 minutes. And there was just an incremental increase to 30.9% who had access within 30-minutes.

In alignment with the researchers at UT and the Mechanical Thrombectomy 2020+ committee, Corazon strongly believes that there are two critical paths to take in order to increase access to this treatment: (1) Implementing statemandated bypass laws that direct EMS providers to take patients with suspected large vessel occlusion strokes directly to a thrombectomy-capable stroke center, and (2) By implementing more stroke program expansions so as to include thrombectomy services where community need, geography, or other factors indicate.

Get Ahead of Stroke, which is an organization founded by the Society of Neurointerventional Surgery (SNIS), is working to drive state legislative changes aimed at ensuring patients who are screened positive for LVO in the field are transported to stroke centers with mechanical thrombectomy capability, even if that means bypassing a primary stroke center.

We repeatedly hear the phrase "Time is Brain," and best-practice hospitals without thrombectomy services DO attempt timely patient transfer, but despite these efforts, studies have shown that patients transferred before thrombectomy have worse outcomes than those taken directly to a thrombectomy capable center. In fact, a study from just last year concluded that patients with a suspected LVO should be redirected to a comprehensive stroke center if the additional delay to receiving IV thrombolytic (tPA) is <30 minutes in an urban area and <50 minutes in a rural area.

But, program expansion is still necessary overall. In order for bypass laws to be effective for optimal treatment, there is still the additional need to implement more thrombectomy capable centers. The UT researchers indicated that flipping 10% of the high-volume non-thrombectomy stroke centers to thrombectomy-capable could result in an additional 23 million Americans having timely access to this life saving treatment. That's raising the total access to about 27% of the population, a major improvement from today, though still not enough. Should we not be working towards providing this access to a very high majority, if not all, Americans?

We know from the many studies conducted that thrombectomy is the superior treatment for LVOs and is now considered the gold standard despite the still very limited availability. The outcomes speak for themselves: for every 100 patients treated with thrombectomy, approximately 40 will have a less disabled outcome than with Intravenous thrombolysis (tPA), and nearly 23 more will achieve an independent outcome as a result of treatment.

We should no longer sit back and view this lack of access as acceptable. As healthcare professionals, we need to advocate for what's best for patients, therefore hospitals across the country need to be looking at the clinical, operational, and financial feasibility of implementing thrombectomy services. Programs that offer coronary intervention are already well-positioned to consider neuro-intervention. In fact, many sites have capitalized on the similarities between heart attack (MI) and brain attack (stroke) and have found ways to operationalize shared interventional space.

This strategy is not without its challenges but given the need to advance stroke care within the neuroscience service line, building from a foundation of excellence in cardiovascular intervention or surgery is a prime place to start.

The country does not need as many neuro-interventional sites as cardiovascular, but doubling the number that is currently in place wouldn't even cover the need; adequate access would still be lacking.

A degree of assessment is necessary to determine whether or not it is appropriate for a facility to implement thrombectomy services, as evaluation of the current stroke treatment infrastructure, the potential thrombectomy volume, the distance to other thrombectomy capable centers and the ability to recruit the required manpower are essential to the process. Understanding the current market dynamics and the potential for case volume and future growth will set the stage for a successful interventional service.

And, in consideration of coronary interventional cases moving to the outpatient setting, some hospital-based labs could have capacity – backfilling with thrombectomy cases is one option to consider for optimized operational efficiency.

These next 10+ years will likely result in a large increase in the stroke burden on hospitals, as most strokes afflict patients over the age of 65. Hospitals should start NOW to consider neuro expansion. As the Baby Boomers cross the 65-year age threshold, the population of those at highest risk for stroke is only going to increase, with all of the members of that generation reaching that age bracket by 2030.

All of the industry statistics, clinical study results, and anecdotal and reported program data suggest that a future increase in the need for thrombectomy services is imminent. Hospitals that work now to consider this offering will be best positioned to handle the future needs of their community.



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