

Mechanical Thrombectomy: The Right Clinical, Economic, and Moral Decision For Your Hospital



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According to the most recent statistics on the Centers for Disease Control (CDC) website, stroke is still the 5th leading cause of death in the United States and the leading cause of serious long-term disability.¹ This is despite the significant progress made in the last 20 years in the development of the highly successful mechanical thrombectomy treatment for large-vessel occlusion stroke. We clearly lack the widespread deployment of this lifesaving and disability-sparing treatment. Full implementation of a mechanical thrombectomy service, however, will undoubtedly lower the negative statistics associated with stroke complications each year. There is not only a compelling clinical case for implementing this service, but also a strong business case to support it.

Understanding the clinical and business case of mechanical thrombectomies requires the acknowledgement of some basic information about stroke and the available treatments:

- Approximately 795,000 people in the U.S. experience a stroke each year.¹
- Thirteen percent (13%) are hemorrhagic strokes, which are caused by a bleed in the brain, most often from a ruptured blood vessel.
- Eighty-seven percent (87%) (691,500) are ischemic strokes, which are caused by a blockage in a blood vessel in the brain, usually a blood clot that either formed in the vessel or traveled from elsewhere in the body.
- Approximately 24-46% (165,960 to 318,090) of ischemic strokes are caused by large-vessel occlusions (LVOs).²
- LVOs are responsible for 90% of all ischemic stroke deaths and 60% of long-term disability.³
- Stroke-related costs in the U.S. came to nearly \$46 billion between 2014 and 2015.⁴

After recognizing that large-vessel occlusions account for the majority of both stroke deaths and long-term disability, treatment of these strokes should be our highest priority. Yet focus is still heavily tilted toward administration of tissue plasminogen activator (tPA). This does not mean that there should not be measures focused on the fast administration of tPA, but there should be just as much focus on the identification of LVOs, especially while patients are being assessed for possible tPA administration.

For those who are unfamiliar with tPA, it is a thrombolytic or “clot buster,” which is administered intravenously (IV) and breaks up the clot causing the blockage in the brain. Prior to the invention of tPA, we had very little treatment for stroke. Patients came into the hospital with stroke symptoms, which were confirmed by a computed tomography (CT) scan. We then waited and provided supportive care. Once the stroke was done extending and the patient was stable, we could send the patient for rehabilitation. The hope was that the patient would eventually retrieve some of their lost function. With the advent of tPA in the mid 90’s, there was finally a treatment that might be able to dissolve the clot and stop the extension of the stroke, thus leaving the patient with the need for significantly less rehabilitation.

But if this treatment has been available since the mid 90’s, then why are we still seeing stroke as the leading cause of long-term disability? There are multiple reasons. To begin, tPA has a very short window of effect, from about 3 to 4.5 hours after a patient is “last known well,” meaning the last time they were without any stroke symptoms. Most patients simply do not arrive in the hospital emergency department (ED) within this window of time, and of those who do, there are a considerable number who are not eligible for tPA. This is due to one of tPA’s many exclusion criteria, including a known bleeding issue or recent surgery. There are also many hospitals that are not prepared to administer tPA.

The treatment of stroke has experienced significant progress in many states with emergency medical services (EMS) bypass laws that allow EMS to bypass facilities that cannot treat stroke and instead take patients directly to a stroke-certified facility where tPA can be administered. These stroke-certified facilities have significantly improved the rate of administration for eligible patients who arrive within the required timeframe. However, the most significant issue is that tPA alone is simply not very effective for LVOs, with only a 10-13% recanalization rate.⁵

What is the answer? Mechanical thrombectomy. Mechanical thrombectomy is a minimally invasive procedure where a clot retriever device is threaded up through a catheter (typically inserted into an artery in the groin and up through the body) until

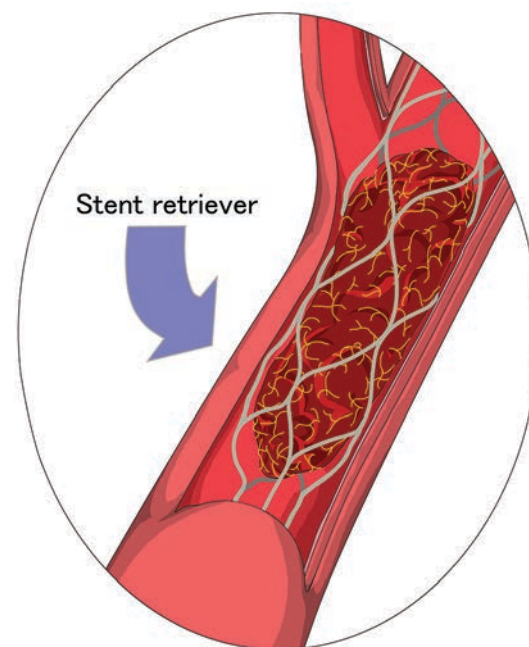


Figure 1. Mechanical thrombectomy is a minimally invasive procedure where a clot retriever device is threaded up through a catheter until it reaches just past the clot in the brain.

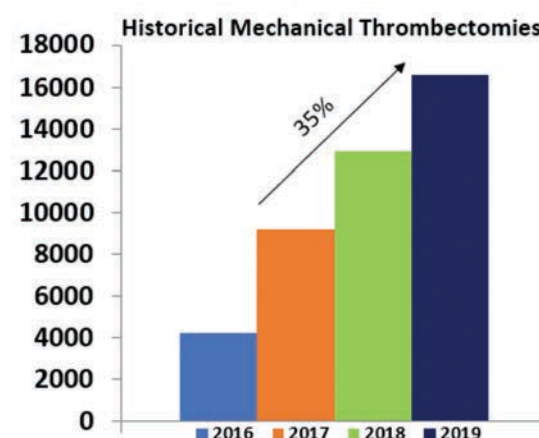


Figure 2. There is an increasing volume of strokes and data are expected to show an even greater increase in volume for 2020 and 2021.

Source: Medicare claims data.

it reaches just past the clot in the brain. Using x-ray guidance, the clot retriever is then opened and pulled back to capture the clot and remove it from the body. This procedure has a much longer treatment window than tPA, with the current standard being up to 24 hours, depending on the potential for salvageable brain tissue. This potential is based off brain imaging studies done upon arrival at the stroke center ED.

From 2015 to 2018, there were 8 extremely successful clinical trials for mechanical thrombectomy. In fact, the last 2 trials, DAWN and DEFUSE3, were so successful that both were stopped early, meaning no additional tests had to be conducted to prove the efficacy of mechanical thrombectomy. A recent overview of meta-analyses of thrombectomy trials⁶ indicate that for every 100 patients treated, approximately 40 patients will have a less

Hospital-Based Contribution Margin Comparison

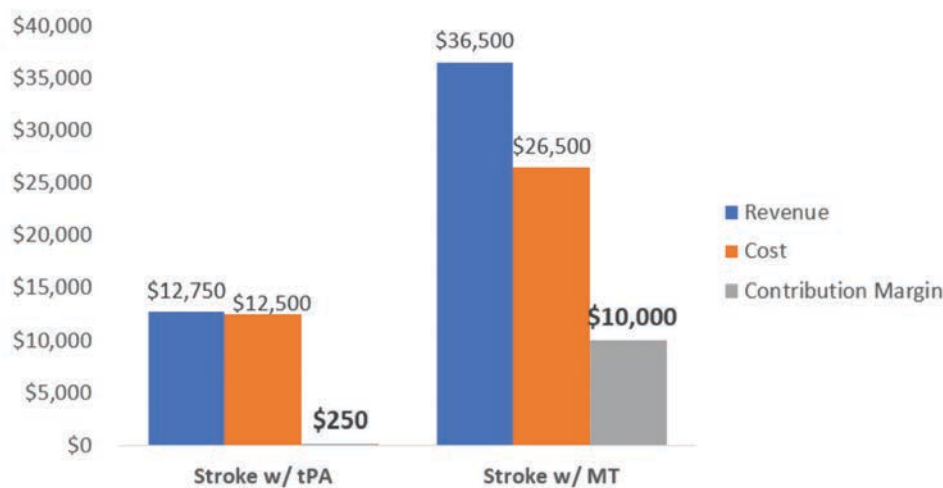


Figure 3. There is a \$10,000 contribution margin for mechanical thrombectomy, while a tPA-treated stroke comes in around \$250.

Source: Medicare claims data.

disabled outcome and an additional 23 patients will achieve an independent outcome. Mechanical thrombectomy is the gold standard for treatment of large-vessel occlusion stroke, yet less than 50% of patients with LVOs receive this treatment. If you recall from the statistics above, the estimated annual number of large-vessel occlusions ranges from 165,960 to 318,090, yet Mission Thrombectomy 2020+, a global non-profit committee of the Society of Vascular and Interventional Neurology (SVIN), estimates the total number of mechanical thrombectomies performed in 2019 was in the 70,000 to 80,000 range.⁷

The main issue around mechanical thrombectomies stems from lack of access. Organizations need to undertake the clinical and business analysis necessary for the implementation of mechanical thrombectomy services. There is a very clear case that mechanical thrombectomy is the right thing to do for patients. Watching an increased number of stroke patients leave your facility with little or no need for physical rehabilitation is amazingly gratifying. However, many facilities fear the cost of implementing thrombectomy services, due to several myths related to its finances. There are several assessments and plans that need to be completed in determining thrombectomy feasibility, including a market analysis for the potential thrombectomy volume (including the distance to other thrombectomy-capable stroke centers), an evaluation of the current stroke infrastructure within the facility, and the creation of a comprehensive recruitment plan for the required interventionalists needed to perform the procedure. In addition, potential interventional lab space needs to be evaluated. The necessary space can include building a new lab, but more often it involves creating a plan for shared space within an interventional radiology or the cardiac cath lab.

Mechanical Thrombectomy Financials

The sound business case surrounding mechanical thrombectomy is often the most surprising aspect. There is still considerable, untapped volume in many markets, since the industry has been unable to achieve the 50% mark of procedures being performed. There is an aging population, with all baby boomers on track to cross the 65-year age threshold in 2030. Incidentally, most strokes affect those over 65 years of age, which clearly indicates a continued upward trajectory for thrombectomy volume. A review of Medicare claims data shows a consistently increasing volume of strokes from 2016 through 2019. Given the American Heart Association / American Stroke Association's publication of the "Update to the Guidelines for the Early Management of Acute Ischemic Stroke in October of 2019," in which the window expanded up to 24 hours for mechanical thrombectomy treatment, the expectation is that data revealed in 2020 and 2021 will show an even greater increase in volume.

The assessment of potential volume is another surprise for organizations that Corazon supports. For example, a recent thrombectomy implementation, the client was expecting roughly 24 or 25 cases in a year, given the fact that about 1 to 2 patients per month were being transferred out to the comprehensive stroke center for thrombectomy services. In their first year, this facility has completed 77 mechanical thrombectomies. What was learned is that an organization may think they are fully aware of the potential volume of large-vessel occlusions, but once the thrombectomy service is implemented, the heightened focus produces volume that matches the projected incidence rate for LVOs.

The contribution margin of thrombectomy procedures is notable, as few procedures hit the \$10,000 level. This is especially significant when compared with the contribution margin of a tPA-treated stroke,

which comes in around \$250. It is clear that there is not only a compelling clinical justification for implementing mechanical thrombectomy services, but also a viable business case.

The aforementioned financial business analysis focuses on the individual facility, and so it should not be overlooked that stroke costs the U.S. economy approximately \$46 billion dollars annually. Associated costs include the cost of healthcare services, medicines to treat stroke, and missed days of work. Improving the treatment of LVO strokes and thereby decreasing the long-term disability could have a profound affect on the overall costs to treat stroke in the United States.

Until there is an appropriate expansion of mechanical thrombectomy services, the industry will continue to struggle to have a meaningful impact on stroke deaths and disabilities. The first and most essential step is for organizations to undertake an evaluation to determine feasibility and gauge where it makes sense to begin implementation. ■

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