Advances in ELVO Access and Management

An overview of the development and evolution of techniques and devices aimed at expediting effective and efficient delivery of endovascular stroke therapies.

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Acute ischemic stroke (AIS) remains the leading cause of long-term disability in the United States with approximately 795,000 individuals afflicted in the United States every year.[1] Direct medical costs of stroke are upwards of $17 billion, and the cost in terms of human suffering remains high, with more than 50% of stroke patients requiring discharge to a rehabilitation or skilled nursing facility. Up to one half of AIS is related to emergent large vessel occlusion (ELVO), most commonly of the internal carotid artery (ICA) or middle cerebral artery. Until recently, intravenous tissue plasminogen activator given within 4.5 hours of symptom onset was the only treatment approved by the US Food and Drug Administration, and early randomized trials of endovascular stroke therapy failed to demonstrate benefit. More recently, however, multiple trials have now unequivocally established the clinical benefit associated with mechanical thrombectomy for certain well-selected patients with ELVO. The improved results observed in these trials were due to both increased understanding of patient selection as well as the use of newer, more effective treatment devices.[1-3]

This article reviews the evolution of endovascular devices for treatment of ELVO, presenting the strengths and limitations of recent technologies and current efforts toward further improving interventional capabilities.

ENDOVASCULAR THROMBECTOMY TECHNIQUES

Initial attempts at endovascular stroke management ranged widely in search of devices and techniques that would successfully recanalize the occluded vessel. First came intra-arterial administration of thrombolytics. The Prolyse in Acute Cerebral Thromboembolism (PROACT) trial showed that administration of the thrombolytic agent was associated with successful recanalization, which was subsequently confirmed by the PROACT II study, with a 66% rate of recanalization in patients undergoing thrombolysis.[4,5]

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This was followed by use of first-generation clot retrieval devices, including the Merci device (Stryker Neurovascular). The Mechanical Embolus Removal in Cerebral Ischemia (MERCI) trial demonstrated successful recanalization (TIMI 2 or 3) associated with good neurological outcome (modified Rankin Scale [mRS] score of 0–2) in 46% of patients compared to 10% without recanalization (TIMI 0).[6] Subsequently, use of aspiration systems, such as the Penumbra aspiration system (Penumbra, Inc.), were designed to prevent distal embolization while effectively removing thrombus. The prospective Penumbra pivotal stroke trial reported a recanalization rate (TIMI 2–3) of 81.6%, and the postmarket experience of the Penumbra system trial (POST) had a successful recanalization rate in 87% of patients.[7,8] The successes demonstrated with each of these techniques laid the groundwork for subsequent device and technique developments.

Over the past several years, endovascular thrombectomy techniques have evolved and improved. The

latest thrombectomy devices and techniques have significantly improved the rates and speed of vessel revascularization. The most common modality employed in the recent positive ELVO trials was mechanical thrombectomy using stent retrievers. Solitaire (Medtronic, Inc.) and Trevo (Stryker Neurovascular) are the two stent retrievers approved for use in the United States. Although Solitaire was used exclusively in the SWIFT-PRIME, EXTEND-IA, and REVASCAT trials, both Solitaire and Trevo, and in some cases, direct aspiration, were included in the MR CLEAN and ESCAPE trials. These trials established the key role of mechanical thrombectomy for selected patients presenting within 6 hours of onset, with stent retrievers being the most well established and evaluated. The differential effectiveness and efficiency of stent retrievers remains unclear, as these studies have not yet been performed.

The focus has now started to shift toward optimizing the mechanical thrombectomy procedure by improving first-pass effectiveness and speed while reducing emboli in distal or nonaffected territories. This direction has resulted in the evaluation of a variety of new strategies, such as shifting from simply deploying a guide catheter in the high cervical vessel to using balloon guides or large-bore distal aspiration in conjunction with stent retrievers, as well as direct aspiration as a first pass technique (ADAPT). These competing and sometimes complementary strategies remain an area of tremendous interest and are currently being evaluated in prospective randomized trials, with particular focus on clinical as well as various cost-effectiveness measures.

PREVENTING IATROGENIC CLOT EMBOLIZATION

During the course of thrombectomy, clot breakdown and embolization can occur in as many as 2% to 17% of cases, which can be a major source of perioperative morbidity and mortality.[9] Recently, instead of a conventional guide catheter, the use of a balloon guide catheter has been shown to reduce the risk of distal embolization. Among ELVO patients treated with stent retrievers, balloon guide catheters have also been associated with higher recanalization rates.[10] These effects are thought to be due to antegrade flow arrest induced by the inflated balloon guide catheter, which helps to reduce the distal migration of fragmented clots that have been mobilized by the stent retrievers.

One newer embolic protection concept, the Lazarus Effect Cover (Medtronic, Inc.), incorporates a nitinol braided mesh that surrounds a stent retriever to help prevent clot embolization. As the stent retriever is withdrawn, the mesh inverts to enclose the stent and protect the clot from fragmentation. Studies have compared rates of recanalization and embolization in new territories between the Cover and conventional stent retrievers, used either in conjunction with a conventional guide catheter or balloon guide catheter. Successful recanalization was achieved more frequently in the Cover group than in either comparison group.[11] Furthermore, embolization occurred less frequently in the Cover group compared with traditional stent retrievers (0% vs 25% for the guide catheter group and 15% for the balloon guide group).

ALTERNATIVES TO TRADITIONAL ACCESS

Despite advances in the devices deployed at the clot face, for a certain percentage of ELVO patients, even reaching the lesion remains challenging. Vasculopaths tend to have difficult access, including tortuous and distorted vessels, as well as other obstacles, such as tandem occlusions. Several devices and techniques have been successfully employed to overcome these challenges.

The inability to navigate tortuous vessels and type III arches and stably deliver a guide catheter can prematurely abort attempted thrombectomy. New guidewire technologies, such as the ZigiWire (Vascular Solutions, Inc.) establish a progressively stable guidewire support system. This system works by allowing the clinician to independently navigate a series of floppy wires into the target vessel that, in combination, form a secure support wire platform that is compatible for use with catheters that accept standard 0.038-inch guidewires.

Access issues extend into the intracranial vasculature. Newer intermediate and aspiration-type catheters, such as the Sofia Plus (MicroVention Terumo), Ace 64 (Penumbra, Inc.), Cat-6 (Stryker Neurovascular) and Arc (Medtronic, Inc.) have been specifically designed to overcome limitations of previous generations of devices that may have difficulty navigating tortuous smaller vessels of the intracranial space. The ability to more quickly and easily deliver large-bore catheters to the clot face could expand treatment options with ADAPT or aspiration alone.

Direct Common Carotid Puncture

Traditional transfemoral approaches have two important problems, especially in elderly patients who are most prone to ELVO: (1) difficult vascular anatomy (eg, type III arch, tortuous cervical vasculature) that may otherwise preclude cerebral access and (2) "shaggy" arches that result in an increased risk of embolic complications. Direct carotid puncture

addresses both of these issues by bypassing tortuous anatomy and gives ready access to the intracranial vasculature. The Silk Road device (Silk Road Medical) facilitates direct carotid access along with flow reversal. Case studies using the device for elective carotid artery stenting suggest that perioperative outcomes are similar to those of carotid endarterectomy. Direct carotid access is also possible using the traditional Seldinger technique with standard access sheaths. Standard ELVO devices may be deployed through either access platform. However, as most ELVO devices are made with groin access in mind, the ergonomics of manipulating long devices in the shorter spaces afforded by carotid access can be awkward. Nonetheless, several case reports have verified direct common carotid artery puncture as a technically acceptable alternative in cases wherein transfemoral access is not possible.

Emergent Carotid Artery Stenting

Tandem occlusions involving an acute cervical ICA occlusion in addition to a more distal intracranial occlusion can pose access challenges. Although the techniques and sequence of maneuvers has not been extensively studied, in these difficult cases, the proximal occlusion is typically treated first, using either angioplasty or stenting. A carotid stent will cover the "fresh" lesion and reestablish flow. Some clinicians prefer crossing the lesion under flow arrest by using a balloon guide catheter or a specially designed catheter, such as the Moma device (Medtronic, Inc.), whereas others rely on a conventional guide catheter and instead use distal filters to prevent embolic complications. In cases where urgent carotid stenting is anticipated, the patient should receive a loading dose of two antiplatelet agents prior to intervention. Once flow through the cervical ICA is reestablished, the clinician may proceed with treatment of the intracranial blockage. Cases involving tandem occlusion can be technically challenging, and thrombectomy of the downstream lesion must be performed more carefully to prevent the stent retriever from snagging on the carotid stent. Other techniques such as delivering the guide catheter beyond the carotid stent or the use of aspiration-type devices can also potentially reduce stent-related complications.

CONCLUSION

Endovascular treatment for ELVO is rapidly evolving. Refined endovascular techniques and novel devices have improved our capacity to effectively reach and remove clots. Endovascular therapy is at the forefront of stroke treatment, and new innovations have shown promise toward extending our ability to help patients who are experiencing this potentially devastating condition. ■

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