Clinical UM Guideline

Subject:	Mechanical Embolectomy for Treatment of Stroke		
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Description

This document addresses the use of intra-arterial mechanical embolectomy devices, also known as endovascular thrombectomy, for the treatment of acute thrombotic or embolic stroke. Mechanical embolectomy is designed to reopen occluded blood vessels in the brain by extracting occlusive thrombi or emboli from the cerebral vasculature.

Clinical Indications

Medically Necessary:

Intra-arterial mechanical embolectomy or thrombectomy is considered **medically necessary** in the treatment of ischemic stroke when any of the following criteria sets (I, II, or III) have been met:

Criteria Set I:

A. Angiographic studies have confirmed proximal arterial occlusion of the anterior circulation of the brain, in any of the following anterior intracranial arteries:
   1. Intracranial carotid; **or**
   2. Middle cerebral artery (M1 or M2); **or**
   3. Anterior cerebral artery (A1 or A2); **and**
B. Intra-arterial mechanical embolectomy is performed within 6 hours of onset of symptoms; **and**
C. NIH Stroke Scale (NIHSS) score of 2 or greater; **and**
D. CT or MRI scan has ruled out intracranial hemorrhage or arterial dissection; **and**
E. Procedure is done with a stent retriever device;

or

Criteria Set II:

A. The individual was last known to be well 6 to 24 hours earlier; **and**
B. There is occlusion of the intracranial internal carotid artery or first segment (M1) of the middle cerebral artery; **and**
C. There is a mismatch between the severity of the clinical deficit and the infarct volume, as defined below:
   1. The individual is 80 years of age or older: NIHSS score of 10 or higher and an infarct volume of less than 21 ml; **or**
   2. Less than 80 years of age: NIHSS score of 10 or higher and an infarct volume of less than 31 ml; **or**
   3. Less than 80 years of age: NIHSS score of 20 or higher and an infarct volume from 31 to 50 ml; **and**
D. CT or MRI scan has ruled out intracranial hemorrhage or arterial dissection; **and**
E. Procedure is done with a stent retriever device;

or

Criteria Set III:

A. The individual was last known to be well 6 to 16 hours earlier; **and**
B. The individual has baseline NIHSS score greater than or equal to 6; **and**
C. The individual had a modified Rankin Scale score less than or equal to 2 prior to qualifying stroke (functionally independent for all Activities of Daily Living [ADLs]); **and**
D. There is occlusion of the intracranial internal carotid artery or proximal middle cerebral artery (M1); **and**
E. There is a mismatch between ischemic tissue and infarct volume, as defined below:
   1. Initial infarct volume of less than 70 ml; **and**
   2. A ratio of the volume of ischemic tissue to infarct volume of 1.8; **and**
F. CT or MRI scan has ruled out intracranial hemorrhage or arterial dissection; **and**
G. Procedure is done with a stent retriever device.

Not Medically Necessary:

Intra-arterial mechanical embolectomy or thrombectomy is considered **not medically necessary** in the treatment of stroke in all other circumstances when the criteria above have not been met, including, but not limited to, embolectomy or thrombectomy of precerebral arteries.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

	For the following procedure codes when describing embolectomy/thrombectomy of middle cerebral, anterior cerebral or intracranial carotid arteries:
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)

ICD-10 Procedure

03CG3Z7	Extirpation of matter from intracranial artery using stent retriever, percutaneous approach
03CG3ZZ	Extirpation of matter from intracranial artery, percutaneous approach
03CG4ZZ	Extirpation of matter from intracranial artery, percutaneous endoscopic approach

ICD-10 Diagnosis

G45.0-G45.9	Transient cerebral ischemic attacks and related syndromes

I63.30	Cerebral infarction due to thrombosis of unspecified cerebral artery
I63.311-I63.319	Cerebral infarction due to thrombosis of middle cerebral artery
I63.321-I63.329	Cerebral infarction due to thrombosis of anterior cerebral artery
I63.39	Cerebral infarction due to thrombosis of other cerebral artery
I63.40	Cerebral infarction due to embolism of unspecified cerebral artery
I63.411-I63.419	Cerebral infarction due to embolism of middle cerebral artery
I63.421-I63.429	Cerebral infarction due to embolism of anterior cerebral artery
I63.49	Cerebral infarction due to embolism of other cerebral artery
I63.81-I63.9	Cerebral infarction other or unspecified
R29.702-R29.709	NIHSS score 2-9
R29.710-R29.719	NIHSS score 10-19
R29.720-R29.742	NIHSS score 20-42
Z92.82	Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility

When services are Not Medically Necessary:
For the following procedure and diagnosis codes, or when the code describes a procedure indicated in the Clinical Indications section as not medically necessary.

CPT

	For the following procedure codes when describing embolectomy/thrombectomy of other cerebral or precerebral arteries:
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)

ICD-10 Procedure

03CH3Z7-03CJ4ZZ	Extirpation of matter from common carotid artery [right or left, by approach, with or without stent retriever; includes codes 03CH3Z7, 03CH3ZZ, 03CH4ZZ, 03CJ3Z7, 03CJ3ZZ, 03CJ4ZZ]
03CK3Z7-03CL4ZZ	Extirpation of matter from internal carotid artery [right or left, by approach, with or without stent retriever; includes codes 03CK3Z7, 03CK3ZZ, 03CK4ZZ, 03CL3Z7, 03CL3ZZ, 03CL4ZZ]
03CM3Z7-03CN4ZZ	Extirpation of matter from external carotid artery [right or left, by approach, with or without stent retriever; includes codes 03CM3Z7, 03CM3ZZ, 03CM4ZZ, 03CN3Z7, 03CN3ZZ, 03CN4ZZ]
03CP3Z7-03CQ4ZZ	Extirpation of matter from vertebral artery [right or left, by approach, with or without stent retriever; includes codes 03CP3Z7, 03CP3ZZ, 03CP4ZZ, 03CQ3Z7, 03CQ3ZZ, 03CQ4ZZ]
03CS3ZZ-03CT4ZZ	Extirpation of matter from temporal artery [right or left, by approach; includes codes 03CS3ZZ, 03CS4ZZ, 03CT3ZZ, 03CT4ZZ]

ICD-10 Diagnosis

G45.0-G45.9	Transient cerebral ischemic attacks and related syndromes
I63.00-I63.09	Cerebral infarction due to thrombosis of precerebral arteries
I63.10-I63.19	Cerebral infarction due to embolism of precerebral arteries
I63.20-I63.29	Cerebral infarction due to unspecified occlusion or stenosis of precerebral arteries
I63.331-I63.349	Cerebral infarction due to thrombosis of posterior cerebral or cerebellar artery
I63.431-I63.449	Cerebral infarction due to embolism of posterior cerebral or cerebellar artery
I63.50-I63.59	Cerebral infarction due to unspecified occlusion or stenosis cerebral arteries
I63.81-I63.9	Cerebral infarction other or unspecified
Z92.82	Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility

Discussion/General Information

A stroke is a condition where blood flow to the brain is interrupted to the extent that proper brain function is disrupted. Over 750,000 strokes occur annually in the United States. Some strokes are caused by blockage of the blood vessels to the brain, which frequently results in neurologic emergencies. The use of tissue plasminogen activator (tPA), a drug that dissolves blood clots, is frequently given intravenously within 3 hours of symptoms for treatment of strokes due to blocked blood vessels. Another treatment, called mechanical embolectomy, has been proposed to reopen occluded vessels in the brain, either alone or in conjunction with tPA treatment, by physically extracting occlusive thrombi from the cerebral vasculature.

Several mechanical embolectomy devices have received FDA clearance through the 510(k) process; including the EmboTrap II device, the Merci Retrieval System, the Penumbra System, the Solitaire FR Revascularization Device, and the Trevo Retriever. These devices are designed to be placed into an artery of a stroke victim and, with the guidance of x-ray imaging technology, advanced to the site of the clot in the brain. Once near the site of the blood clot, these types of devices use one of several methods to capture the clot and remove it. It is proposed that by removing the clot, normal blood flow to the brain is restored, which in turn may reduce any damage caused by the lack of blood flow.

Two different design types of mechanical embolectomy devices have been marketed in the U.S. The first are referred to as "stent retrievers", which use a stent-like metal structure to ensnare the target clot and remove it. The EmboTrap II device, Penumbra System, Solitaire FR Revascularization Device, and Trevo Retriever are all of this type. The other type involves the use of a metal coil at the end of the device, similar to a corkscrew, which is placed into the clot to remove it. The Merci Retrieval System is of this type.

Mechanical removal of emboli or thrombi after an acute stroke, particularly for those who are ineligible for thrombolytic therapy, has been the focus of intense research. Several devices have been approved or cleared by the U.S. Food and Drug Administration (FDA) for the treatment of individuals with acute ischemic stroke (AIS). There are two additional systems that received 510(k) clearance from the FDA; the AXS Vecta™ Aspiration System (Stryker Neurovascular, Fremont, CA) was granted clearance in 2019 and the Riptide™ Aspiration System (Micro Therapeutics Inc., Irvine, CA) was granted clearance in 2020. The 510(k) clearance indicates the systems are substantially equivalent to predicate devices, however there is no peer-reviewed literature published for either device.

EmboTrap® and EmboTrap II® Revascularization Device

Use of the EmboTrap Revascularization device (Neuravi Ltd., Galway, Ireland) has been described in several studies. The prospective case series ARISE I study (Analysis of Revascularization in Ischemic Stroke With EmboTrap), which involved 40 subjects with large vessel occlusion AIS (Mattle, 2019), found rates of revascularization after 3 or fewer passes with EmboTrap of 75%. The high revascularization rates in ARISE I converted into 64% good clinical outcomes assessed by modified Rankin Scale (mRS ≤ 2), vs. 50% in the composite analysis results (p=0.32).

Zaidat (2018a) published the results of EmboTrap use in the follow-up ARISE II study, a single-arm, prospective, multicenter study evaluating the use of the device to a composite measure based on results of the SWIFT and TREVO 2 trials. A total of 227 subjects with large-vessel occlusions and moderate-to-severe neurological deficits within 8 hours of symptom onset were included in the analysis. The primary efficacy end point (mTICI ≥ 2b within 3 passes) was achieved in 80.2% of subjects (p<0.0001). The primary safety end point, a composite rate of symptomatic intracerebral hemorrhage (sICH) or serious adverse device effects, was 5.3%. Functional independence and all-cause mortality at 90 days were 67% and 9%, respectively.

Brouwer (2018) reported the results of a registry-based study involving 201 subjects with AIS of the internal carotid artery (ICA, 15.5%), middle carotid artery (MCA, 61.2%), the posterior circulation (11.9%), anterior cerebral artery (ACA, 0.5%), and a carotid T-occlusion (10.9%) receiving treatment within the 4.5-hour time window after arrival at the hospital. Intravenous tissue tPA was administered to 95 (47.3%) subjects prior to EmboTrap treatment. mTICI 2b–3 was achieved in 170 (84.6%) subjects treated with the EmboTrap, with or without tPA. In anterior circulation occlusions, 85.3% achieved mTICI 2b–3, while 79.2% with posterior circulation occlusions achieved mTICI 2b–3. Peri-procedural complications occurred in 11 subjects (5.4%; 5 non-flow limiting dissections, 2 vasospasms, 4 emboli to a new uninvolved territory). When corrected for the subjects with pre-existing poor mRS scores (mRS ≥ 3), good functional outcome was achieved in 52.8%. Twenty-six subjects (12.9%) had died at 3-month follow-up.

Valente (2019) published the results of a single-arm, prospective, case series study that involved 29 subjects with large vessel occlusion AIS treated with the EmboTrap II device (Neuravi Ltd., Galway, Ireland). MCA was involved in 90% of subjects (M1 in 80%, M2 in 10%) and terminal ICA was involved in 10%. Successful reperfusion was obtained in 25 subjects (86%), with 4 requiring additional device use (Solitaire, Sophia Plus, or Trevo). Of the subjects treated only with EmboTrap II, successful reperfusion was reported in 76% of cases. No major device-related complications or distal emboli were reported.

Merci® Retrieval System

The Merci Retrieval System was the first mechanical embolectomy device to reach market in the U.S. and laid the groundwork for subsequent other stent retriever devices. As of late 2022 this device is no longer available.

Penumbra System©

In September 2007, the FDA granted 510(k) clearance to the Penumbra System (Penumbra, Inc., Alameda, CA) which is a mechanical device designed to reduce clot burden in acute stroke due to large-vessel occlusive (LVO) disease, similar to the Merci Retrieval System. The FDA clearance was based in part on the Penumbra Pivotal Stroke Trial study, a prospective, multicenter, single-arm study, involving 125 participants with neurological deficits as defined by an NIHSS score of ≥ 8, who presented within 8 hours of symptom onset, and had an angiographic occlusion (Penumbra Pivotal Stroke Trial Investigators, 2009). The results of the study showed neurological recovery and functional outcomes improvement, with 31 of 125 (25%) of the participants having either an NIHSS score of 0 to 1 or ≥ 0-point improvement at discharge (with 25% of subjects having an mRS score of ≤ 2 at 90 days).

Tarr and others conducted a 90 day post-procedure follow-up retrospective case series study of 157 subjects who underwent treatment with the Penumbra system (the POST Trial, 2010). The results of the POST trial were in line with those from the Pivotal trial with regard to the rate of successful recanalization, indicating that the results of the Pivotal study can be replicated. While this uncontrolled trial included several approaches to the use of the Penumbra system, with subjects receiving care with the system alone, and in conjunction with IV tPA, IA tPA, and with both IV and IA tPA together, the authors argued that this condition reflects real-world use of the Penumbra device.

Tarr and others (2018) published a follow-up POST trial, which described the initial post-market experience with the Penumbra system. This retrospective case series study involved the first 157 consecutive subjects treated with the Penumbra system at 7 stroke centers. The author reported that 87% of the treated vessels were revascularized to TIMI 2 (54%) or TIMI 3 (33%), vs. 82% reported in the Pivotal trial. All-cause death was significantly improved in the POST study vs. the Pivotal study (20% vs. 33%, $p<0.05$). Likewise, the POST study results indicated a higher rate of post treatment functional independence (41% vs. 25%, $p<0.05$). There were 9 serious adverse events reported (5.7%), including intracranial hemorrhage, dissection, perforation and hematoma. All-cause mortality was 20% (32/157).

Zaidat (2022) published the results of a study from the prospective COMPLETE post-marketing registry involving 650 subjects with large vessel occlusion treated with the Penumbra system. In summary, the authors reported that in this real-world, registry based study that angiographic, clinical, and safety outcomes were comparable to results reported from RCTs.

Solitaire™ FR Revascularization Device

The Solitaire FR device (Covidien, Mansfield, MA) received FDA 510(k) clearance in March 2012. The FDA determined that this device was substantially equivalent to the Merci Retriever device, based on data from a randomized controlled trial (RCT) submitted to the FDA comparing the Merci and Solitaire devices (the SWIFT trial) (Saver, 2012). The SWIFT trial was a multicenter, randomized, non-inferiority study involving 113 subjects with acute stroke in the proximal carotid arteries. A total of 58 individuals were assigned to receive treatment with the Solitaire device and 55 to receive treatment with the Merci device. The reported results demonstrated that the Solitaire group had more frequent successful recanalization (61% vs. 24%, p=0.0001), better time to successful recanalization (36 min vs. 52 min, p=0.038), and more frequent 90-day good neurological outcomes (58% vs. 33%, p=0.017). Additionally, the Solitaire group had a lower incidence of intracranial hemorrhage (both symptomatic and asymptomatic) compared to the Merci group (17% vs. 38%, p=0.02), as well as fewer all-cause deaths at 90 days (17% vs. 38%, p=0.02). No differences between groups were noted with regard to device or procedure-related

adverse events. The study was halted early, after the data safety monitoring board and trial steering committee agreed that pre-specified criteria for stopping the trial had been met.

Pereira and colleagues (2013) report on a prospective case series study involving 202 subjects between 10 and 85 years of age with occlusion of the anterior intracranial artery presenting within 8 hours after onset and who were refractory to IV thrombolysis. All participants were treated with the Solitaire device and a total of 59% of the subjects received intravenously administered tPA before the treatment with mechanical embolectomy. In the intent-to-treat analysis, the rate of the primary outcome of successful revascularization as measured by TICI $\geq$ 2b after $\leq$ 3 passes of the study device was reported as 79.2% (160/202). At the 90-day follow-up visit, favorable neurological outcome (mRS, 0-2) was seen in 57.9% of subjects. The frequency of total device- and procedure-related serious adverse events was 7.4%. Intracerebral hemorrhage (ICH) was found in 18.8% of subjects at 24 hours and sICH occurred in 1.5% of the subjects.

Campbell and others (2014, 2015) reported on the results of the Extending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial (EXTEND-IA) trial, which was a prospective open-label, blinded endpoint RCT involving 70 subjects with radiologically confirmed intracranial occlusion. Subjects were assigned on a 1:1 basis to treatment with IV tPA alone (n=35) or IV tPA plus mechanical embolectomy with the Solitaire FR device (n=35). All subjects were treated within 6 hours of stroke onset and followed for 90 days post-intervention. The authors reported that the device group showed significantly better outcomes compared to controls with regard to the primary endpoints of probability of reperfusion without symptomatic intracranial hemorrhage at 24 hours (89% vs. 34%; p<0.001).

Two other similarly designed studies were published in 2015. Jovin and colleagues published the results of the Randomized Trial of Revascularization with Solitaire FR Device versus Best Medical Therapy in the Treatment of Acute Stroke Due to Anterior Circulation large Vessel Occlusion Presenting within Eight Hours of Symptom Onset (REVASCAT) study, which involved 206 subjects with radiologically confirmed intracranial occlusion. Subjects were assigned on a 1:1 basis to treatment with IV tPA alone (n=103) or IV tPA plus mechanical embolectomy with the Solitaire FR device (n=103). Unlike the EXTEND-IA study, subjects were treated within 8 hours of symptom onset. Recruitment was stopped early due to loss of equipoise at the first interim analysis. In addition, the publication of the Goyal, Campbell, and Berkhemer studies had raised ethical concerns of study continuation.

Dávalos and colleagues (2017) published the 1-year results of the REVASCAT study. Data was available for 205 of the original 206 subjects involved in the study (99.5%). The authors reported that at 12 months post-treatment the adjusted OR for improvement in mRS score was 1.8 in favor of the device group.

The other study, named Thrombectomy as Primary Endovascular Treatment (SWIFT PRIME), was reported by Saver and colleagues (2015). As with the previously reported studies, use of thrombectomy plus intravenous tPA significantly reduced disability at 90 days vs. tPA alone, as measured by mRS score (p<0.001). Additionally, the rate of functional independence (mRS score, 0 to 2) was higher in the experimental group than in the control group (60% vs. 35%, p<0.001). No significant differences between groups were reported with regard to 90-day mortality (9% vs. 12%, p=0.50) or symptomatic intracranial hemorrhage (0% vs. 3%, p=0.12).

In 2018, Al-Ajlan and colleagues published the results of a follow-up study of data from the REVASCAT trial. The authors concluded, "Endovascular treatment saves brain and improves 90-day clinical outcomes primarily through a beneficial effect on the 24-hour stroke severity."

Use of the Solitaire device in subjects with ASPECTS 0-5 was investigated in the BEYOND-SWIFT registry study (Kaesmacher, 2019). This retrospective, international, multicenter observational study involved 1532 subjects, 237 with ASPECTS 0–5 and 1295 with ASPECTS > 5. The overall rates of favorable outcome (mRS 0-3 at day 90) and mortality at day 90 were 40.1% and 40.9%. The authors reported that successful reperfusion was independently associated with favorable outcome (adjusted odds ration [aOR], 5.534), functional independence (aOR, 5.583), reduced mortality (aOR, 0.180), and lower rates of sICH (aOR, 0.235). The mortality-reducing effect remained in subjects with ASPECTS 0-4 (aOR, 0.167).

Trevo® Retriever

The Trevo Retriever device (Concentric Medical, Mountain View, CA) received FDA 510(k) clearance in August 2012 with the indication to treat individuals with acute ischemic stroke due to large intracranial vessel occlusion who are ineligible for or fail intravenous tPA. The FDA determined that this device was substantially equivalent to the Merci Retriever device, based on data from the TREVO2 study, an RCT of 178 subjects from 27 centers in the U.S. and Europe that compared the Trevo device with the Merci device (Nogueira, 2012). This prospective, open label, non-inferiority study involved 88 subjects randomized to receive treatment with the Trevo device and 90 to be treated with the Merci device. The primary efficacy endpoint was revascularization success defined as TICI ≥ 2, and the primary safety endpoint was a composite of procedure-related adverse events. The authors reported that overall, the Trevo group had significantly fewer vessel perforations when compared to the Merci group (1 vs. 10, p=0.0182), had higher rates of successful reperfusion (92% vs. 77%, p<0.0068), and had higher rates of 90-day "good" outcomes as measured by mRS 0-2 (40% vs. 22, p=0.0130). No significant differences were reported with regard to any other measures, including symptomatic intracranial hemorrhage, rates of neurological deterioration, and 30- and 90-day mortality.

In 2017, Nogueira and colleagues published the results of the DAWN trial, an unblinded, multicenter RCT involving 206 subjects with occlusion of the intracranial carotid artery or proximal (first segment, M1) middle cerebral artery who had last been known to be well between 6 and 24 hours prior to treatment, who were randomized to treatment with either the Trevo Retriever device plus standard care (n=107) or standard care alone (n=99). Subjects were further stratified into three groups, with group A being 80 years of age or older, having a score of 10 or higher in the NIHSS and an infarct volume less than 21 ml. Group B was younger than 80, had a NIHSS score of 10 or higher, and an infarct volume less than 31 ml. Group C was younger than 80, had an NIHSS score of 20 or higher, and an infarct volume of 31 to less than 51 ml. At 31 months, enrollment in the trial was stopped because of the results of a prespecified interim analysis. The mean score on the utility-weighted mRS at 90 days was 5.5 in the thrombectomy group vs. 3.4 in the control group (adjusted difference [Bayesian analysis], 2.0 points; 95% credible interval, 1.1 to 3.0; posterior probability of superiority, >0.999), and the rate of functional independence at 90 days was 49% in the thrombectomy group vs. 13% in the control group (adjusted difference, 33 percentage points; 95% credible interval, 24 to 44; posterior probability of superiority, > 0.999). The rate of sICH did not differ significantly between the two groups (6% in the thrombectomy group vs. 3% in the control group, p=0.50), nor did 90-day mortality (19% and 18%, respectively; p=1.00).

Another RCT reported on the use of mechanical embolectomy beyond 6 hours of onset of symptoms (Albers, 2018). This study, which was stopped early due to the primary efficacy endpoint being met during an interim analysis, involved 182 subjects with occlusion of the cervical or intracranial carotid artery or the proximal middle cerebral artery with an initial infarct volume of less than 70 ml and a ratio of volume of ischemic tissue to initial infarct volume of 1.8 or greater. Subjects were assigned on a 1:1 basis to receive treatment with mechanical embolectomy plus medical therapy (n=92) or medical therapy alone (n=90). Treatment was initiated 6 to 16 hours after the subject was last known to be well, including if they had awoken from sleep with symptoms. Assessments were conducted by blinded assessors with mRS and NIHSS score at 24 hours, 30 days, and 90 days. At 90 days mRS scores were significantly better in the embolectomy group (OR, 2.77, p<0.001). The authors concluded:

> Endovascular thrombectomy for ischemic stroke 6 to 16 hours after a patient was last known to be well plus standard medical therapy resulted in better functional outcomes than standard medical therapy alone among patients with proximal middle-cerebral-artery or internal-carotid-artery occlusion and a region of tissue that was ischemic but not yet infarcted.

Zaidat and others (2018c) reported results from the TREVO Stent-Retriever Acute Stroke (TRACK) multicenter Registry, which reported real-world results of the use of the Trevo device in 23 centers. A total of 634 subjects were included in the report, and 80.3% of subjects had achieved TICI ≥ 2b, and 90-day mRS ≤ 2 was achieved in 47.9%.

In 2018 Binning and colleagues published the results of a study involving data from the prospective Trevo Retriever Registry. The intent-to-treat population included 2008 subjects with large vessel occlusion with median NIHSS score of 16. The authors reported occlusion sites were ICA (17.8%), MCA (73.5%), posterior circulation (7.1%), and distal vascular locations (1.6%). The results included that mTICI 2b or 3 was achieved in 92.8% of subjects, with 55.3% achieving RS ≤ 2 at 3 months. They also reported that subjects meeting revised 2015 American Heart Association (AHA) criteria for thrombectomy had a 59.7% mRS of 0 to 2 at 3 months, whereas 51.4% treated outside of AHA criteria had mRS of 0 to 2. The symptomatic intracranial hemorrhage rate was 1.7%.

Nogueira (2022) published a study involving data from 2008 subjects from the prospective Trevo Retriever Registry, which includes real-world data from subjects who underwent endovascular therapy for large vessel occlusion stroke with the Trevo stent retriever. The authors concluded that their results demonstrated "favorable generalizability data for the safety and efficacy of thrombectomy in the ''real world'' setting and supports that patients may be safely treated outside the constraints of randomized clinical trials."

Non-Device-Specific or Mixed-Device Studies

In 2014, Berkhemer and others published the results of the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN). This RCT involved 500 subjects with imaging-confirmed intracranial major vessel occlusion who were eligible for treatment within 6 hours of stroke onset. Subjects were assigned to receive treatment with either usual care or usual care plus intra-arterial treatment, which may have included intra-arterial thrombolysis, mechanical embolectomy, or both. The selection of embolectomy device was left to the discretion of the treating investigator, and any FDA approved or CE marked device was eligible for use. Primary outcome of interest was 90-day mRS score, with secondary outcomes including scores on the NIHSS, Barthel index, EuroQol self-report questionnaire, and the ASPECTS. In total, 233 subjects

were assigned to the experimental group and 267 to the control group. No intra-arterial therapy was undertaken in 37 of the experimental group subjects, mechanical treatment was done in 195 subjects (of which 24 received additional intra-arterial thrombolysis), and 1 subject received intra-arterial thrombolysis only. Of the 195 subjects receiving mechanical therapy, 190 involved the use of retrievable stents (for example, the Penumbra System, Solitaire FR, and Trevo thrombectomy) and the other 5 involved other types of devices (for example, the MERCI retriever). The authors reported that the age-adjusted OR for having a favorable 90-day mRS was 1.67, in favor of the experimental group, regardless of the mRS category except death. The absolute between-group differences in the proportion of subjects who were functionally independent as measured by the mRS scores was 13.5% in favor of the experimental group, with an adjusted OR of 2.16. The NIHSS after 5-7 days was, on average, 2.9 points lower in the experimental group. Recanalization data was available for 394 of 500 subjects, and it was reported that absence of residual occlusion was more common in the intervention group (75.4% vs. 32.9%). No differences between groups were reported in relation to serious adverse events in the 90-day follow-up period. However, 13 of 233 (5.6%) intervention group subjects had clinical signs of new ischemic stroke in non-downstream vascular tree vs. only 1 control subject. Mortality was no different between groups at any time point measured. The results of this study demonstrate significant benefit to the use of intra-arterial mechanical interventions.

In 2017 van den Berg and others published the 2-year outcome data from the MR CLEAN study. A total of 391 (78.2%) of the original 500 subjects had data available for the analysis of functional outcomes. The adjusted common OR mRS was 1.68, in favor of the experimental group vs. controls (p=0.007). The authors reported that subjects in the experimental group were more likely to have a good outcome vs. controls (mRS of 0 to 2, 37.1% vs, 23.9%, respectively, p=0.003).

The Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times (ESCAPE) trial was a prospective open-label, blinded endpoint RCT involving 316 subjects with radiologically confirmed intracranial occlusion randomized to undergo treatment with either standard treatment with IV tPA or standard of care plus mechanical embolectomy (Goyal, 2015). Due to the positive outcomes reported in the MR CLEAN trial, the data safety and monitoring board recommended early suspension and interim analysis of the study with only 243 completing the 90-day endpoint. Following analysis, the board concluded that recruitment should be ended and the existing subjects followed to endpoint completion. The common OR of 2.6 was reported, favoring the experimental group (p<0.001). The median mRS at 90 days was 2 in the experimental group and 4 in the control group (p<0.0010). Mortality at 90 days was 10.4% for the experimental group vs. 19.0% in controls (p=0.04). No differences between groups were reported for the incidence of intracerebral hemorrhage (p=0.75).

Together these studies support the positive net health benefit achieved in select individuals when mechanical embolectomy is used for the treatment of stroke within 6 hours of onset.

Comparative Studies

A small number of nonrandomized comparative studies of different types of endovascular interventions have been published, for example: Broussalis and colleagues (2012) and Fesl and colleagues (2012) These studies offer some information on the comparative efficacy of different devices, but do not offer relevant evidence on the comparison of endovascular interventions versus standard stroke care.

In 2018, Yi and colleagues published a retrospective study involving 200 subjects who were treated with either the Solitaire (n=102) or Trevo (n=99) devices. They reported that there was no statistically significant difference in NIHSS or mRS outcomes between the 2 groups. However, the Trevo group had shorter procedure time, fewer stent passages, and more one-pass cases than the Solitaire group (p=0.009, p=0.014, p=0.030). Additionally, the Trevo group achieved a higher successful recanalization (TICI 2b or 3) rate (89.7% vs. 82.3%, p=0.018). In multivariate logistic regression analysis, the use of the Trevo stent was predictive for successful recanalization. (OR, 1.40, p=0.028). The authors concluded that the Trevo device results in higher recanalization rates, fewer stent passages, and shorter procedure time than the Solitaire stent.

Haussen and colleagues (2019) published the results of a retrospective comparative analysis of the Penumbra 3MAX™ aspiration (Penumbra, Alameda, California) and the 3 mm Trevo for the treatment of distal arterial occlusions. First-pass mTICI 2b-3 (62% 3 mm Trevo versus 44% 3MAX; p=0.03) and final mTICI 2b-3 (84% 3 mm Trevo versus 69% 3MAX; p=0.05) was higher for individuals treated with 3 mm Trevo; the rate of adjuvant therapy was lower in the 3 mm Trevo group compared with 3MAX (15% versus 31%; p=0.03). The overall safety was comparable between the two groups. The authors concluded that the use of 3 mm Trevo may lead to better outcomes as demonstrated by higher rates of first-pass reperfusion when compared with the 3MAX for the treatment of distal occlusions.

Other Information

The American Heart Association and American Stroke Association (AHA/ASA) *Focused Update of the 2013 Guidelines for the Early Management of Patients with Acute Ischemic Stroke* (Powers, 2015) recommends that:

2. Patients should receive endovascular therapy with a stent retriever if they meet all the following criteria (Class I; Level of Evidence A). (New recommendation):
    a. Prestroke mRS score 0 to 1,
    b. Acute ischemic stroke receiving intravenous r-tPA within 4.5 hours of onset according to guidelines from professional medical societies,
    c. Causative occlusion of the ICA or proximal MCA (M1),
    d. Age ≥18 years,
    e. NIHSS score of ≥6,
    f. ASPECTS of ≥6, and
    g. Treatment can be initiated (groin puncture) within 6 hours of symptom onset
3. As with intravenous r-tPA, reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TICI grade 2b/3 should be achieved as early as possible and within 6 hours of stroke onset (Class I; Level of Evidence B-R). (Revised from the 2013 guideline)
4. When treatment is initiated beyond 6 hours from symptom onset, the effectiveness of endovascular therapy is uncertain for patients with acute ischemic stroke who have causative occlusion of the ICA or proximal MCA (M1) (Class IIb; Level of Evidence C). Additional randomized trial data are needed. (New recommendation)
5. In carefully selected patients with anterior circulation occlusion who have contraindications to intravenous r-tPA, endovascular therapy with stent retrievers completed within 6 hours of stroke onset is reasonable (Class IIa; Level of Evidence C). Inadequate data are available at this time to determine the clinical efficacy

of endovascular therapy with stent retrievers for those patients whose contraindications are time based or not time based (eg, prior stroke, serious head trauma, hemorrhagic coagulopathy, or receiving anticoagulant medications). (New recommendation)

6. Although the benefits are uncertain, the use of endovascular therapy with stent retrievers may be reasonable for carefully selected patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the M2 or M3 portion of the MCAs, anterior cerebral arteries, vertebral arteries, basilar artery, or posterior cerebral arteries (Class IIb; Level of Evidence C). (New recommendation)
7. Endovascular therapy with stent retrievers may be reasonable for some patients <18 years of age with acute ischemic stroke who have demonstrated large-vessel occlusion in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset, but the benefits are not established in this age group (Class IIb; Level of Evidence C). (New recommendation)
8. Although its benefits are uncertain, the use of endovascular therapy with stent retrievers may be reasonable for patients with acute ischemic stroke in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have prestroke mRS score >1, ASPECTS <6, or NIHSS score <6 and causative occlusion of the ICA or proximal MCA (M1) (Class IIb; Level of Evidence B-R). Additional randomized trial data are needed. (New recommendation)
9. Observing patients after intravenous r-tPA to assess for clinical response before pursuing endovascular therapy is not required to achieve beneficial outcomes and is not recommended. (Class III; Level of Evidence B-R). (New recommendation)
10. Use of stent retrievers is indicated in preference to the MERCI device. (Class I; Level of Evidence A). The use of mechanical thrombectomy devices other than stent retrievers may be reasonable in some circumstances (Class IIb, Level B-NR). (New recommendation)

It must be noted that these new recommendations primarily address the use of "stent retrievers," which would include the Solitaire and Trevo devices, but not the Merci or Penumbra devices. These latter devices are referred to as mechanical clot disruption/extraction devices in the 2013 Guideline (Jauch, 2013), and are mentioned in statement # 10 above as alternatives in some cases. Unfortunately, the guidelines do not provide guidance as to what those circumstances may be.

Mokin and others (2018) evaluated pooled real-world data from 830 subjects with anterior circulation acute ischemic stroke in the NASA and TRACK registries to compare outcomes of subjects presenting within the first hours 6 vs. beyond 6 hours of stroke symptom onset. A total of 32.7% (271/830) underwent thrombectomy beyond the first 6 hours of symptom onset. Subjects were stratified to those treated within 6 hours, between 6 and 16 hours, and between 16 and 24 hours. The authors reported that the rates of "good" clinical outcome, defined as mRS of 0-2 at 90 days, were similar between groups (48.1% for ≤ 6 hours, 46.2% for > 6 ≤ 16 hours, and 38% for > 16 hours, p=0.08). Mortality was likewise similar (20.6%, 21.6%, and 3.3%, respectively, p=0.06), as was symptomatic intracranial hemorrhage (8.0%, 10.9%, and 5%, respectively, p=0.5). The rates of successful recanalization, defined as TICI 2b/3, were 79.4% in subjects with stroke within 0-6 hours, 72.6% within 6-16 hours, and 85.0% within 16-24 hours (p=0.04). They concluded that the real-world experience in subjects with anterior circulation AIS treated with the Solitaire and Trevo devices beyond the first 6 hours of symptom onset proved to be equally safe and effective as for individuals with symptom onset within the first 6 hours.

In 2018 the American Heart Association Council on Cardiovascular Radiology and Intervention and Stroke Council published their indications for the performance of intracranial endovascular neurointerventional procedures (Eskey, 2018). In this document they provided the following recommendations:

2. Endovascular therapy with stent retrievers is recommended over intra-arterial fibrinolysis as first line therapy.
4. Use of stent retrievers is preferred over other mechanical thrombectomy devices. The use of mechanical thrombectomy devices other than stent retrievers may be reasonable in some circumstances but is not yet supported by large RCTs.
5. In carefully selected patients with anterior circulation occlusion who have contraindications to intravenous r-tPA, endovascular therapy with stent retrievers completed within 6 hours of stroke onset is reasonable. Inadequate data are available at this time to determine the clinical efficacy of endovascular therapy in such patients (eg, those with prior stroke, serious head trauma, hemorrhagic coagulopathy, or receiving anticoagulant medications).
8. When treatment is initiated beyond 6 hours from symptom onset, the effectiveness of endovascular therapy is uncertain for patients with AIS who have causative occlusion of the ICA or proximal MCA (M1). New trial results addressing this topic will be available in the near future.
9. Patients should receive endovascular therapy with a stent retriever if they meet all the following criteria: (1) prestroke mRS score of 0 to 1, (2) AIS receiving intravenous r-tPA within 4.5 hours of onset according to guidelines from professional medical societies, (3) causative occlusion of the ICA or proximal MCA (M1), (4) age ≥18 years, (5) NIHSS score of ≥6, (6) ASPECTS of ≥6, and (7) ability to initiate treatment (groin puncture) within 6 hours of symptom onset.

Mechanical Embolectomy in the Posterior Circulation

Treatment for AIS within the anterior circulation is well established; the role of mechanical embolectomy for posterior circulation occlusions continues to be evaluated, and is not considered in accordance with generally accepted standards of medical practice (Meyer, 2020; Stambo, 2020; Watson, 2020; Zhao, 2020). A systematic review conducted by Meyer (2020) found that successful recanalization occurred in 86% (37/43) of individuals. The Thrombolysis in Cerebral Infarction Scale (TICI) measured 3 (2b is successful with ≥ 50% reperfusion) in those with a first past-effect (48.8%, 21/43). sICH occurred in 7% (3/43), 1 perforation and 2 iatrogenic vessel dissections; the in-hospital mortality rate was 9.3% (4/43). Strambo and colleagues (2020) published results of a retrospective cohort study of individuals with posterior cerebral artery occlusions treated with endovascular treatment (utilizing stent retrievers) or best medical therapy. Of the individuals treated with stent retrievers, 68% (13/19) had complete recanalization at 24 hours. Although initial outcomes were promising, the frequency of sICH and 3-month mortality were similar between those treated with stent retrievers and individuals treated with best medical therapy. Watson and colleagues (2020) published the results of a systematic review for mechanical thrombectomy treatment of acute posterior circulation occlusions. A total of 1612 individuals with acute posterior circulation AIS were treated and successful reperfusion was achieved in 86%. However, there was also an average rate of 16% (132/840, with numerous studies not reporting adverse events) of periprocedural and postoperative complications and a 30% mortality rate. Zhao and colleagues (2020) conducted a meta-analysis and systematic review for the safety and efficacy of mechanical thrombectomy for posterior versus anterior large vessel occlusions. The authors reported that reperfusion rates were similar for anterior and posterior recanalization, but the mortality rate was higher for individuals with posterior occlusions (OR=1.98; 95% confidence interval [CI], 1.37-2.87; p=0.0003).

Meinel (2019) reported the results of a study involving 1739 subjects included in the retrospective observational BEYOND-SWIFT registry who had large vessel occlusion treated with the Solitaire device. Mechanical embolectomy was conducted in subjects with either basilar artery occlusion (n=165) or anterior circulation large vessel occlusion (ACLVO) (n=1574). Complete 90-day follow-up data were available in 152 (91.1%) of the basilar group. It was not clear what percentage of the ACLVO group has complete 90-day data. Compared to the ACLVO group at baseline, the basilar group was significantly different with regard to age (younger), gender (more males), transferred from other hospitals (more frequent), symptom severity and glucose (both higher), anticoagulation pretreatment, hypertension, and dyslipidemia (all lower) ($p<0.05$ for all). Time from symptom onset to groin puncture was longer in basilar group vs. the ACLVO group ($p<0.001$). Recanalization of mTICI 2b/3 was achieved in 90.3% of Basilar group subjects vs. 82.7% of ACLVO subjects ($p=0.11$). Intracranial stents were used in significantly more basilar group subjects (17.0% vs 2.3%, $p<0.001$). Longer times from symptom onset to groin puncture were also reported (300 min vs 225 min, $p<0.001$). The authors reported no significant differences in the rates of sICH, systemic bleeding, craniectomy, and complication rates. However, subjects in the basilar group had significantly more frequent nonhemorrhagic worsening postoperatively. Overall, the basilar group had worse outcomes, with mRS scores 0-3 reported in 46.1% in the basilar group vs. 56.7% in the ACVLO group ($p=0.013$), and higher mortality rates of 36.2% vs. 24.4%, respectively ($p=0.002$). However, the authors stated that after adjustment for baseline differences, no significant differences in outcomes were found, with the exception of futile recanalization, which was more frequent in the basilar group (aOR, 2.146). On unadjusted analysis, better outcomes were observed in basilar group subjects vs. those without successful recanalization. However, significantly higher rates of independence at 3 months were found only in the cohort of subjects presenting with ACLVO. The authors concluded that in selected individuals, similar outcomes can be achieved with mechanical embolectomy of the basilar artery as those in the anterior circulation, but that additional research was needed to establish proper selection criteria and interventional strategies to avoid futile recanalization.

Liu and colleagues (2020) reported the findings of a randomized, open-label, blinded outcome assessment study involving 131 subjects with vertebrobasilar occlusion presenting at < 8 hours. The trial was terminated early due to high crossover rate and poor recruitment. The intention-to-treat analysis included 130 subjects who were treated with either thrombectomy (n=66) or medical therapy (n=65). The type of thrombectomy devices were not specified but included both stent retrievers and aspiration catheters. The authors reported evidence of a difference in the proportion of participants with mRS 0-3 at 90 days according to treatment (42% in the thrombectomy group vs. 32% in the control group; OR, 1.74). A secondary, prespecified analysis of the primary outcome was done to assess the effect of crossovers. It demonstrated higher rates of mRS 0-3 at 90 days in subjects who received thrombectomy vs. those who received medical therapy alone in both per-protocol analysis (44% vs. 25%, aOR, 2.90) and in the intent-to-treat analysis (47% vs. 24%, aOR, 3.02) at 90-days. Mortality was similar between groups despite a higher prevalence of sICH in the thrombectomy group (33% vs. 38%, $p=0.54$). The authors concluded,

> There was no evidence of a difference in favorable outcomes of patients receiving endovascular therapy compared with those receiving standard medical therapy alone. Results might have been confounded by loss of equipoise over the course of the trial, resulting in poor adherence to the assigned study treatment and a reduced sample size due to the early termination of the study.

Meyer and colleagues (2021) reported the results of the TOPMOST study, a multicenter case-control trial involving subjects with primary distal occlusion of the P2 or P3 segments of the posterior cerebral artery treated with either mechanical embolectomy or medical therapy. The type of embolectomy devices used was not specified, but it was

stated that both stent retrievers and aspiration catheters were used. Of the 313 subjects with posterior circulation distal medium vessel occlusion (DMVO) receiving treatment, 243 met inclusion criteria, and 184 subjects were compared by treatment group after 1:1 propensity score matching (n=92 subjects in each group, thrombectomy vs. medical therapy). At baseline, diabetes as a cardiovascular risk factor was significantly higher in the control group vs. the thrombectomy group (30 vs. 14, respectively, p=0.006). Additionally, the medical therapy group received intravenous thrombolysis significantly more frequently than and thrombectomy group, both before and after propensity matching, (39% vs. 56%, p=0.01 and 40% vs. 57.7%, p=0.01, respectively). A total of 141 subjects received mechanical thrombectomy, with first pass being done with a stent retriever with or without aspiration in 72% of subjects and 26% of subjects undergoing direct distal aspiration. Successful first pass reperfusion (mTICI 3) occurred in 45.5% of cases. Additional passes increased the overall success rate to 76.2%. Distal embolization to another vessel was reported in 5 subjects (3.5%), with successful recanalization of those locations in 3 subjects. Post-propensity score matching, mean baseline NIHSS scores had decreased from admission in both groups, with there being no significant differences between groups (-2 in the thrombectomy group vs. -1.5 in the medical group, p=0.06). However, there was a significant benefit in favor of subjects in the thrombectomy group with > 10 NIHSS score on admission vs. the medical group (mean difference 5.6, p=0.04). No significant differences between groups were also noted in the subgroup of subjects with an mTICI of 2a or lower (p=0.13). In the thrombectomy group two independent factors were identified for predicting successful early neurological improvement, higher NIHSS scores (p<0.001) and successful first pass effect (p=0.04). In the medical group, only the presence of P3 occlusions were predictive of successful early neurological improvement (p=0.021). At 90 days, excellent neurological outcomes (mRS ≤ 1) were reported in 66.2% of thrombectomy group subjects vs. 54.4% of medical group subjects. No p-values were provided for this comparison. sICH was reported in 4.3% of subjects in both groups. Similarly, overall mortality was 4.9% in both groups at 90 days. The authors concluded that the study suggested that "…mechanical thrombectomy for posterior circulation DMVO is a safe, and technically feasible treatment option for occlusions of the P2 or P3 segment of the PCA compared with standard medical treatment with or without IVT." However, additional rigorous studies should be conducted to confirm these findings.

Langezaal (2021) reported the results of an RCT involving 300 subjects with basilar artery occlusion assigned to treatment with either mechanical embolectomy (n=154) or medical therapy (n=146). The investigators used a variety of devices, including the MERCI, Penumbra, Solitaire, and Trevo devices. All subjects were followed for a minimum of 90 days. At baseline, the embolectomy group had a significantly higher rate of atrial fibrillation (28.6% vs. 15.1%, no p-value provided). Crossover occurred in 3 subjects (1.9%) in the embolectomy group and 7 (4.8%) in the medical therapy group. No significant differences were reported between groups in the number of subjects with favorable outcomes as defined as an mRS 0-3 at 90 days (44.2% vs. 37.7%, p=0.19). Favorable reperfusion (mTICI of 2b or 3) was reported in 72% of the endovascular subjects, but no data was provided for the medical therapy group. However, arterial patency based on CTA was reported in 84.5% in the embolectomy group vs. 56.3% in the medical group (no p-value provided). No difference in 90-day mortality was reported (38.3% vs. 43.2%, respectively, p=0.29). Similarly risk of sICH at 3 days was not significantly different (4.5% vs. 0.7%, p=0.06). The authors concluded,

> Among patients with stroke from basilar-artery occlusion, endovascular therapy and medical therapy did not differ significantly with respect to a favorable functional outcome, but, as reflected by the wide confidence interval for the primary outcome, the results of this trial may not exclude a substantial benefit of endovascular therapy. Larger trials are needed to determine the efficacy and safety of endovascular therapy for basilar-artery occlusion.

Hendrix (2022) reported the results of a case series study involving 831 subjects with large vessel occlusions treated with mechanical embolectomy, 77 of which were in the posterior circulation. The investigators conducted a univariable analysis in 77 subjects with posterior circulation obstructions to assess clinical predictors of a favorable functional outcome among posterior circulation LVO. They reported that lower baseline NIHSS, negative smoking history, primary aspiration, and TICI 2b/3 revascularization were associated with mRS 0-3. In multivariable analysis, primary aspiration and TICI 2b/3 revascularization remained independently associated with achieving mRS 0-3 among posterior circulation obstruction. Futile revascularization was observed in 32 of 63 (50.8%) cases. The authors concluded that subjects with anterior and posterior vessel obstructions undergoing mechanical embolectomy have distinct clinical profiles and the use of primary aspiration appears fundamental for beneficial outcomes in subjects with posterior vessel obstruction.

Xun (2021) reported on a meta-analysis of 33 studies to investigate the prognostic factors for successful mechanical embolectomy in subjects with posterior vessel occlusion. Gender (p=0.428), atrial fibrillation (p=0.870), smoking (p=0.118), or coronary artery disease (p=0.361) were not found to be prognostic factors for poor outcomes. However, the pre-event presence of hypertension (p<0.001), diabetes mellitus (p<0.001), hyperlipidemia (p<0.021), and previous stroke history (p=0.042) were prognostic for poor outcomes.

Further study is warranted to delineate the role of mechanical embolectomy on posterior circulation occlusions versus medical therapy. The available evidence does not currently support mechanical embolectomy on posterior circulation occlusions as a treatment modality in accordance with generally accepted standards of medical practice.

Non-FDA approved devices

Several additional devices are under investigation but have not received FDA approval, including the Embolus Retriever with Interlinked Cages (ERIC) device, the ReVive SE Thrombectomy Device, and the RECO Flow Restoration Device. There is limited data addressing these devices (Cao, 2021, Gruber, 2018; Sakai, 2018; Zhang, 2019), and while the results are promising, additional data are needed to demonstrate equivalency to the currently available, FDA approved devices.

Conclusion

The available evidence addressing the use of mechanical embolectomy devices is extensive; with earlier studies there was significant heterogeneity with regard to subject populations, devices compared, control or comparison groups and other methodologic limitations. However, more recent data from large, well-designed, and conducted studies (Berkhemer, 2014; Campbell, 2014, 2015; Goyal, 2015; Joval, 2015; Saver, 2015) have demonstrated significant benefits to mechanical embolectomy/thrombectomy in select individuals. Furthermore, recently published postmarketing registry data have demonstrated continued significant benefit to the use of stent retriever devices outside the trial setting.

Definitions

Alberta Stroke Program Early Computed Tomography Score (ASPECTS): A 10-point quantitative topographic CT scan score developed to assess early ischemic changes on pretreatment CT studies in individuals with acute

ischemic stroke of the anterior circulation. ASPECTS is determined from evaluation of two standardized regions of the MCA territory, including the basal ganglia level and the supraganglionic level. The abnormality should be visible on at least two consecutive cuts to ensure that it is truly abnormal rather than a volume averaging effect. To compute the ASPECTS, 1 point is subtracted from 10 for any evidence of early ischemic change for each of the defined regions. A normal CT scan receives ASPECTS of 10 points. A score of 0 indicates diffuse involvement throughout the MCA territory.

Embolectomy: Surgical removal of an obstructing clot or foreign material which has been transported from a distant vessel by the bloodstream.

Emboli: Material (usually a blood clot but may be fat or a bone fragment, etc.) that travels through the circulation and eventually obstructs blood flow through a smaller caliber vessel.

National Institute of Health Stroke Scale (NIHSS): A systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit. The scale is widely used as a clinical assessment tool to evaluate acuity of stroke patients, determine appropriate treatment, and predict patient outcome. It is a 15-item neurologic examination evaluating the effect of acute cerebral infarction on the levels of consciousness, language, neglect, visual-field loss, extraocular movement, motor strength, ataxia, dysarthria, and sensory loss. The Score is intended to be used by a trained observer who rates an individual's ability to answer questions and perform activities. Ratings for each item are scored with 3 to 5 grades with 0 as normal, and there is an allowance for untestable items. The single assessment requires less than 10 minutes to complete.

Neurovasculature: The blood vessel network of the neck and brain.

Plasmin: A proteolytic enzyme that is formed from plasminogen in blood plasma and dissolves the fibrin in blood clots; also called fibrinolysin.

Precerebral arteries: An arterial blood vessel leading to the cerebrum (but not in the cerebrum), including the vertebral artery, basilar artery, carotid artery, and ascending aorta.

Stroke: A condition where blood flow to the brain is interrupted to the extent that proper brain function is disrupted.

Thrombolytics: Drugs that dissolve blood clots.

Tissue plasminogen activator (tPA): An enzyme that dissolves blood clots. It can be produced naturally by cells in the walls of blood vessels, or prepared through the use of genetic engineering. Tissue plasminogen activator is used in the coronary arteries during heart attacks and in the cranial arteries in certain types of strokes.

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Mechanical embolectomy
Mechanical thrombectomy
Merci Retrieval System
Penumbra System
RECO Flow Restoration Device
ReVive SE Thrombectomy Device
Solitaire FR Revascularization Device
Stroke
Trevo Retriever

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	11/10/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of SURG.0098 Mechanical Embolectomy for Treatment of Acute Stroke to new clinical utilization management guideline document with a similar title.