

Subject: Mechanical Embolectomy for Treatment of Stroke

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Description

This document addresses the use of mechanical thrombectomy for acute ischemic stroke. Mechanical thrombectomy is an endovascular technique for removal of a thrombus or embolus from an intracranial blood vessel to reestablish blood flow.

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, III, IV or V) have been met:

- I. Anterior cerebral artery (A1 or A2), middle cerebral artery (M1 or M2) or intracranial carotid artery occlusion when **all** criteria are met:
 - A. Mechanical embolectomy is performed within 6 hours of onset of symptoms; **and**
 - B. NIH Stroke Scale (NIHSS) score of 2 or greater; **and**
 - C. Neuroimaging has ruled out intracranial hemorrhage or arterial dissection.
- II. Intracranial internal carotid artery **or** middle cerebral artery (M1) occlusion when **all** criteria are met:
 - A. Mismatch between the severity of the clinical deficit and the infarct volume, as defined in **any** of the following situations:
 1. 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**
 - B. Last known to be well 6 to 24 hours earlier; **and**
 - C. Neuroimaging has ruled out intracranial hemorrhage or arterial dissection.
- III. Intracranial internal carotid artery **or** proximal middle cerebral artery (M1) occlusion when **all** criteria are met:
 - A. Mismatch between ischemic tissue and infarct volume, as defined by **both** of the following:
 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**
 - B. Last known to be well 6 to 16 hours earlier; **and**
 - C. Baseline NIHSS score greater than or equal to 6; **and**
 - D. Modified Rankin Scale (mRS) score less than or equal to 2 prior to qualifying stroke; **and**
 - E. Neuroimaging has ruled out intracranial hemorrhage or arterial dissection.
- IV. Large ischemic core infarct due to intracranial internal carotid artery **or** proximal middle cerebral artery (M1) occlusion (or both) when **all** criteria are met:
 - A. Infarct as defined by **any** of the following:
 1. Alberta Stroke Program Early Computed Tomography Score (ASPECTS) value of 3 to 5 on non-contrast CT; **or**
 2. An estimated ischemic-core volume of 50 ml or greater; **and**
 - B. Last known to be well up to 24 hours earlier; **and**
 - C. Baseline NIHSS score of greater than 6; **and**
 - D. mRS score less than or equal to 2 prior to qualifying stroke; **and**
 - E. Neuroimaging has ruled out intracranial hemorrhage or dissection.
- V. Basilar artery occlusion when **all** of the following criteria are met:
 - A. Last known to be well up to 24 hours earlier; **and**
 - B. Baseline NIHSS falls into **any** of the following categories:
 1. NIHSS score of greater than or equal to 10 if presenting within 12 hours of when last known to be well; **or**
 2. NIHSS score of greater than or equal to 6 if presenting between 12 - 24 hours of when last known to be well; **and**
 - C. mRS score less than or equal to 2 prior to qualifying stroke; **and**
 - D. Neuroimaging has ruled out intracranial hemorrhage or arterial dissection.

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.

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, basilar 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)
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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
I63.12	Cerebral infarction due to embolism of basilar artery
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 procedure and diagnosis codes listed above when criteria are not met, for the following diagnosis codes, or when the code describes a procedure indicated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis

I63.00-I63.09	Cerebral infarction due to thrombosis of precerebral arteries
I63.10-I63.119	Cerebral infarction due to embolism of unspecified precerebral or vertebral arteries
I63.131-I63.19	Cerebral infarction due to embolism of carotid or other precerebral artery
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

When services are also 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.

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. Approximately 795,000 strokes occur annually in the United States. Ischemic strokes, caused by blockage of the blood vessels to the brain, account for approximately 85% of all strokes, and frequently result in neurologic emergencies (Centers for Disease Control [CDC], 2022). Tissue plasminogen activators (tPAs), systemic thrombolytic agents, are frequently given intravenously (IV) within 3 hours of symptoms for treatment of strokes due to blocked blood vessels. Mechanical embolectomy has been used to reopen occluded vessels in the brain, either alone or in conjunction with tPA treatment, by physically extracting occlusive thrombi from the cerebral vasculature. Thrombectomy is considered an effective therapy in appropriate populations, the number needed to treat (NNT) to prevent disability in one individual is 2.3 (Fayad, 2023). The procedure does carry risks associated with potential reperfusion injury of necrotic brain tissue including hemorrhage, edema, disability and death (Fayad, 2023).

Emboli extraction devices are designed to be placed into the affected artery and advanced to the site of the thrombi in the brain via

imaging guidance. The thrombi are extracted using one or a combination of mechanical embolectomy devices. Two types of devices can be used for mechanical thrombectomy. The first type of device is referred to as "stent retriever", which use a stent-like metal structure to ensnare the target clot and remove it. Aspiration devices use negative pressure to remove the targeted clot. The choice between which device is used depends upon provider preference and stroke center availability.

Mechanical Embolectomy in the Anterior Circulation

Brouwer (2018) reported the results of a registry-based study involving 201 individuals with anterior ischemic stroke (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. IV tissue tPA was administered to 95 (47.3%) individuals prior to mechanical embolectomy. A modified Thrombolysis in Cerebral Infarction (mTICI) score of 2b–3 was achieved in 170 (84.6%) individuals treated with mechanical embolectomy, 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 individuals (5.4%; 5 non-flow limiting dissections, 2 vasospasms, 4 emboli to a new, uninvolved territory). When corrected for the individuals with pre-existing poor mRS scores (≥ 3), good functional outcome was achieved in 52.8%. A total of 26 individuals (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 individuals with large vessel occlusion AIS treated with the mechanical embolectomy. MCA was involved in 90% of individuals (M1 in 80%, M2 in 10%) and terminal ICA was involved in 10%. Successful reperfusion was obtained in 25 individuals (86%), with 4 requiring additional device use. Of the individuals treated with one embolectomy, successful reperfusion was reported in 76% of cases. No major device-related complications or distal emboli were reported.

Pereira and colleagues (2013) report on a prospective case series study involving 202 individuals 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 mechanical embolectomy and a total of 59% of the individuals received intravenous tPA before mechanical embolectomy therapy. In the intent-to-treat analysis, the rate of the primary outcome of successful revascularization as measured by TICI $\geq 2b$ after ≤ 3 passes of the study device was 79.2% (160/202). At the 90-day follow-up visit, favorable neurological outcome (mRS, 0–2) was seen in 57.9% of individuals. The frequency of total device- and procedure-related serious adverse events (AEs) was 7.4%. Intracerebral hemorrhage (ICH) was found in 18.8% of individuals at 24 hours and symptomatic intracerebral hemorrhage (sICH) occurred in 1.5% of the individuals.

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 randomized, controlled trial (RCT) involving 70 individuals with radiologically confirmed intracranial occlusion. Individuals were assigned on a 1:1 basis to treatment with IV tPA alone ($n=35$) or IV tPA plus mechanical embolectomy ($n=35$). All individuals 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 the control group with regard to the primary endpoints of probability of reperfusion without symptomatic intracranial hemorrhage at 24 hours (89% versus 34%; $p<0.001$).

Two others similarly designed studies were published in 2015. Jovin and colleagues published the results of the Randomized Trial of Revascularization with mechanical embolectomy 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 individuals with radiologically confirmed intracranial occlusion. Individuals were assigned on a 1:1 basis to treatment with IV tPA alone ($n=103$) or IV tPA plus mechanical embolectomy ($n=103$). Unlike the EXTEND-IA study, individuals 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 individuals involved in the study (99.5%). The authors reported that at 12 months post-treatment the adjusted odds ratio (OR) for improvement in mRS score was 1.8 in favor of the device group.

The Thrombectomy as Primary Endovascular Treatment (SWIFT PRIME) study compared the use of thrombectomy plus IV tPA with IV tPA alone (Saver, 2015). The use of thrombectomy plus IV tPA significantly reduced disability at 90 days versus 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 device group compared to the control group (60% versus 35%, $p<0.001$). No significant differences between groups were reported with regard to 90-day mortality (9% versus 12%, $p=0.50$) or symptomatic intracranial hemorrhage (0% versus 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."

In 2017, Nogueira and colleagues published the results of the DAWN trial, an unblinded, multicenter RCT involving 206 individuals 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 mechanical embolectomy plus standard care ($n=107$) or standard care alone ($n=99$). Individuals 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 a 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 versus 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 versus 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 versus 3% in the control group, $p=0.50$), nor did 90-day mortality (19% and 18%, respectively; $p=1.00$). The results of this study demonstrate significant benefit to the use of intra-arterial mechanical interventions in selected individuals within 6 to 24 hours of time last known to be well.

Another RCT (DEFUSE 3 trial) 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 individuals 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. Individuals 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.

The results of this study demonstrate significant benefit to the use of intra-arterial mechanical interventions in selected individuals within 6 to 16 hours of time last known to be well.

In 2018 Binning and colleagues published the results of a study involving data from a prospective device registry. The intent-to-treat population included 2008 individuals 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 the mTICI score 2b or 3 was achieved in 92.8% of individuals, with 55.3% achieving RS ≤ 2 at 3 months. They also reported that individuals 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%.

In 2014, Berkhemer and others published the results of the Multicenter RCT of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN). This RCT involved 500 individuals with imaging-confirmed intracranial major vessel occlusion who were eligible for treatment within 6 hours of stroke onset. Individuals 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. 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 individuals were assigned to the intra-arterial treatment group and 267 to the control group. No intra-arterial therapy was undertaken in 37 of the experimental group individuals, mechanical treatment was done in 195 individuals (of which 24 received additional intra-arterial thrombolysis), and 1 subject received intra-arterial thrombolysis only. The authors reported that the age-adjusted OR for having a favorable 90-day mRS was 1.67, in favor of the intra-arterial treatment group, regardless of the mRS category except death. The absolute between-group differences in the proportion of individuals who were functionally independent as measured by the mRS scores was 13.5% in favor of the intra-arterial treatment group, with an adjusted OR of 2.16. The NIHSS after 5-7 days was, on average, 2.9 points lower in the intra-arterial treatment group. Recanalization data was AEs available for 394 of 500 individuals, and it was reported that absence of residual occlusion was more common in the intervention group (75.4% versus 32.9%). No differences between groups were reported in relation to serious in the 90-day follow-up period. However, 13 of 233 (5.6%) intervention group individuals had clinical signs of new ischemic stroke in non-downstream vascular tree versus 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 selected individuals within 6 hours of stroke onset.

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 individuals had data available for the analysis of functional outcomes. The adjusted common OR mRS was 1.68, in favor of the intra-arterial treatment group versus controls ($p=0.007$). The authors reported that individuals in the experimental group were more likely to have a good outcome versus controls (mRS of 0 to 2, 37.1% versus 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 individuals 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 individuals 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 versus 19.0% in controls ($p=0.04$). No differences between groups were reported for the incidence of intracerebral hemorrhage ($p=0.75$).

Mechanical Embolectomy in Large Ischemic Stroke

While individuals with large ischemic-core strokes account for approximately one-fifth of large-vessel occlusion strokes, this population has been underrepresented in clinical trials. The prognosis of affected individuals is poor, including progression of stroke symptoms, brain edema and death (Sarraj, 2023). Sarraj and associates (2023) performed a prospective, randomized, open-label, adaptive, international trial evaluating the safety and efficacy of endovascular thrombectomy in this population. Individuals diagnosed within the previous 24 hours with an acute large ischemic core stroke due to an occlusion of the internal carotid artery or the M1 segment of the middle cerebral artery, or both, were included. Eligibility criteria included an ASPECTS value of 3-5 or an estimated ischemic core volume of 50 ml or greater, a pre-stroke mRS of 0 or 1 and no documented evidence of intracranial hemorrhage. Participants received either endovascular thrombectomy and standard medical care or standard medical care alone. The primary outcome was the ordinal mRS score, a measure of functional independence, at 90 days. At 90 days post-therapy, the median mRS score was 4 (interquartile range, 3 to 6) in the thrombectomy group and 5 (interquartile range, 4 to 6) in the standard medical care group. The generalized OR favoring endovascular thrombectomy was 1.51 (95% confidence interval [CI], 1.20 to 1.89; $p<0.001$). A total of 20% of individuals in the thrombectomy group achieved a mRS of 0 to 2 compared to 7.0% in the standard medical care group. Symptomatic intracranial hemorrhage was reported in 0.6% of the endovascular thrombectomy group compared to 1.1% of the standard medical care group. Procedural complications included arterial access-site (3%), vessel perforation (4%) and dissection (6%). The trial was stopped early due to the reported efficacy of endovascular thrombectomy.

Huo and colleagues (2023) conducted a multicenter, prospective, open-label, randomized trial to evaluate the efficacy and safety of endovascular therapy compared to standard medical management in individuals diagnosed with an acute large-vessel occlusion in the anterior circulation within the previous 24 hours. Other inclusion criteria included NIHSS score of 6-30, a pre-stroke mRS score of 0-1 and a large-vessel occlusion of the initial segment of the middle cerebral artery or the intracranial segment of the distal internal carotid artery (or both). Individuals were randomly assigned 1:1 to endovascular therapy and medical management ($n=231$) or medical management alone ($n=225$). The primary outcome was the mRS at 90 days. A total of 50 participants in the endovascular group and 45 in the medical management group died before 90 days. The primary distribution analysis showed a shift in the distribution of the mRS scores toward better outcomes in the endovascular group versus the medical management group (generalized OR: 1.37; 95% CI: 1.11 to 1.69; $p=0.004$). Symptomatic intracranial hemorrhage occurred in 14 individuals in the endovascular group (6.1%) and 6 individuals in the medical management group (2.7%). The trial was stopped early based upon second interim analysis showing the efficacy of endovascular therapy over medical management alone.

Mechanical Embolectomy to Treat AIS in the Posterior Circulation

The effectiveness of embolectomy therapy to treat AIS within the anterior circulation is well established; recent studies have focused on the role of mechanical embolectomy for posterior circulation occlusions continues to be evaluated (Meyer, 2020; Stambo, 2020; Watson, 2020; Zhao, 2020). While initial studies generally reported similar reperfusion rates in anterior and posterior recanalization therapy, there was conflicting results regarding complication and mortality rates between the groups (Langezaal 2021; Liu, 2020; Meinel, 2019).

Meyer and colleagues (2021) reported the results of the TOPMOST study, a multicenter case-control trial involving individuals with primary distal occlusion of the P2 or P3 segments of the posterior cerebral artery treated with either mechanical embolectomy or medical therapy. Of the 313 individuals with posterior circulation distal medium vessel occlusion (DMVO) receiving treatment, 243 met inclusion criteria, and 184 individuals were compared by treatment group after 1:1 propensity score matching (n=92 individuals in each group, thrombectomy versus medical therapy). At baseline, diabetes as a cardiovascular risk factor was significantly higher in the control group versus the thrombectomy group (30 versus 14, respectively, $p=0.006$). Additionally, the medical therapy group received IV thrombolysis significantly more frequently than the thrombectomy group, both before and after propensity matching, (39% versus 56%, $p=0.01$ and 40% versus 57.7%, $p=0.01$, respectively). A total of 141 individuals received mechanical thrombectomy, with a successful first pass reperfusion (mTICI 3) reported in 45.5% of cases. Additional passes increased the overall success rate to 76.2%. Distal embolization to another vessel was reported in 5 individuals (3.5%), with successful recanalization of those locations in 3 individuals. 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 versus -1.5 in the medical group, $p=0.06$). However, there was a significant benefit in favor of individuals in the thrombectomy group with > 10 NIHSS score on admission versus the medical group (mean difference 5.6, $p=0.04$). No significant differences between groups were also noted in the subgroup of individuals 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 individuals versus 54.4% of medical group individuals. sICH was reported in 4.3% of individuals 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.

Tao and associates (2022) reported on the results of a multicenter, prospective RCT which compared the clinical outcomes of individuals who received endovascular thrombectomy or best medical care following basilar artery occlusion stroke in the Endovascular Treatment for Acute Basilar-Artery Occlusion (ATTENTION) trial. Participants had a moderate-to-severe acute ischemic stroke with a NIHSS score of 10 or higher, were seen within 12 hours of last known time to be well and had a prestroke mRS of 2 or less. Participants were randomized to either the endovascular thrombectomy treatment and best medical care group (n=228) or the best medical care group alone (n=114). Best medical care included IV thrombolytic agents, antiplatelet drugs, anticoagulation, or combinations of these treatments. The primary outcome was a good functional status as defined by a mRS of 0-3 at 90 days. Good functional status was achieved in 46% of the treatment group compared to 23% of the control group (adjusted rate ratio [ARR]: 2.06; 95% CI: 1.46 to 2.91; $p < 0.001$). A higher number of individuals in the control group died within 90 days compared to the treatment group (55% versus 37%; (ARR: 0.66; 95% CI, 0.52 to 0.82). The treatment group had a 5% rate of symptomatic intracranial hemorrhage, there were no cases in the control group. A 14% procedural complication rate was reported in the treatment group.

Also in 2022, Jovin and colleagues reported on a second randomized trial comparing thrombectomy plus best medical care (n=110) to best medical care alone (n=108) in the Basilar Artery Occlusion Chinese Endovascular (BAOCHE) trial. Individuals were eligible if there was a confirmed occlusion of the basilar artery or intracranial segment of both vertebral arteries that could be treated within 6 to 24 hours after symptom onset. A prestroke mRS of 0 or 1 and a NIHSS score of 10 or higher was also required. The NIHSS score requirement was later reduced to 6 or higher due to slow recruitment. The primary outcome was a good functional status as defined by a mRS of 0-3 at 90 days. Good functional status was achieved in 46% of the treatment group compared to 24% of the control group (ARR: 1.81; 95% CI: 1.26 to 2.60; $p < 0.001$). Mortality at 90 days was higher in the control group compared to the thrombectomy group (42% versus 31%; ARR: 0.75; 95% CI: 0.54 to 1.04; respectively). The incidence of symptomatic intracranial hemorrhage was higher in the thrombectomy group. The trial was stopped early based on the efficacy of the thrombectomy added to best medical care.

Basilar artery occlusion is typically associated with poor outcomes. The results of the ATTENTION and BAOCHE trials show that embolectomy along with best medical care provides improved clinical outcomes for the treatment of stroke due to basilar artery occlusion in individuals with specific clinical characteristics. These studies were associated with increased risk of complications. Further studies are needed to determine whether the benefit of thrombectomy outweighs the risk in an expanded set of individuals who present with posterior circulation occlusions.

Other Information

The American Heart Association and American Stroke Association (AHA/ASA) 2019 *Update to the 2018 Guidelines for the Early Management of Patients with Acute Ischemic Stroke* (Powers, 2019) notes the following recommendations:

0 to 6 hours from onset

1. Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria: (1) prestroke mRS score of 0 to 1; (2) causative occlusion of the internal carotid artery or MCA segment 1 (M1); (3) age ≥ 18 years; (4) NIHSS score of ≥ 6 ; (5) ASPECTS of ≥ 6 ; and (6) treatment can be initiated (groin puncture) within 6 hours of symptom onset. (Class I; Level of Evidence A). (Revised from the 2015 guideline)
2. Direct aspiration thrombectomy as first-pass mechanical thrombectomy is recommended as noninferior to stent retriever for patients who meet all the following criteria: (1) prestroke mRS score of 0 to 1; (2) causative occlusion of the internal carotid artery or M1; (3) age ≥ 18 years; (4) NIHSS score of ≥ 6 ; (5) ASPECTS ≥ 6 ; and (6) treatment initiation (groin puncture) within 6 hours of symptom onset (Class I; Level of Evidence B-R). (Revised from the 2015 guideline)
3. Although the benefits are uncertain, the use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with AIS in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the MCA segment 2 (M2) or MCA segment 3 (M3) portion of the MCAs. (Class IIb; Level of Evidence B-R). (Revised from the 2015 guideline. LOE revised)
4. Although the benefits are uncertain, the use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with AIS in whom treatment can be initiated (groin puncture) within 6 hours of symptom onset and who have causative occlusion of the anterior cerebral arteries, vertebral arteries, basilar artery, or posterior cerebral arteries (Class IIb; Level of Evidence C-LD).

6 to 24 Hours from onset

1. In selected patients with AIS within 6 to 16 hours of last known normal who have LVO in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria, mechanical thrombectomy is recommended. (Class I; Level of Evidence A). (New recommendation)
2. In selected patients with AIS within 16 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable. (Class IIa; Level of Evidence B-R). (New recommendation)

1. Mechanical thrombectomy with stent retrievers is recommended over intra-arterial fibrinolysis as first-line therapy (Class I; Level of Evidence C-EO). (Revised from the 2015 guideline.)

Mokin and others (2018) evaluated pooled real-world data from 830 individuals with anterior circulation acute ischemic stroke in the NASA and TRACK registries to compare outcomes of individuals presenting within the first 6 hours versus beyond 6 hours of stroke symptom onset. A total of 32.7% (271/830) underwent thrombectomy beyond the first 6 hours of symptom onset. Individuals 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 $> 6 \leq 16$ 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 individuals 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 individuals 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.

Summary

The available evidence addressing the use of mechanical embolectomy devices is extensive. A number of prospective and retrospective studies focusing on specific devices have been published showing improved health outcomes over medical therapy in AIS of the anterior circulation (Kaesmacher, 2019; Mattle, 2019; Nogueira, 2022; Penumbra Pivotal Stroke Trial Investigators, 2009; Tarr, 2010; Tarr, 2018; Zaidat, 2018a; Zaidat, 2018c; Zaidat, 2022). Additionally, 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. Mechanical embolectomy, used in conjunction with medical therapy is associated with greater complications than medical therapy alone, but has the potential to prevent severe disability and improve mortality.

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.

Modified Rankin scale (mRS): A tool defining global disability which has been widely used as a measurement in stroke studies. The tool ranges from 0 (no symptoms at all) to 6 (death).

Modified Thrombolysis in Cerebral Infarction (mTICI) score: A qualitative scale used to evaluate an individual's angiographic intracerebral inflow following endovascular thrombectomy. The AHA recommends a score of 2B or more as an angiographic goal following therapy on the anterior circulation.

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. tPA is used in the coronary arteries during heart attacks and in the cranial arteries ischemic strokes when there is a low risk of hemorrhage.

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Index

Embolus Retriever with Interlinked Cages (ERIC)
EmboTrap and EmboTrap II Revascularization Device
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
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted anterior intracranial artery (criteria I) regarding location of occlusion. Updated Discussion and References section.
Revised	05/11/2023	MPTAC review. Added medically necessary indications for large ischemic core infarct. Reformatted existing medically necessary indications. Removed examples from not medically necessary statements. Updated Description, Discussion and References sections.
Revised	02/16/2023	MPTAC review. Removed requirement that a stent retriever device for medically necessary indications. Added medically necessary indications for basilar artery occlusions. Updated Discussion and References sections. Updated Coding section diagnoses to add I63.12.
New	11/10/2022	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.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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