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Endovascular Thrombectomy for Patients with Ischemic Stroke: A Review of Guidelines

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Context and Policy Issues

An ischemic stroke occurs when there is a blockage or clot in a blood vessel in the brain. This blockage or clot can occur when plaque accumulates on the inside wall of an artery.[1] As cells pass through the artery, they stick to the plaque and the blockage or clot (also known as a thrombus) grows large enough to block normal blood flow.[1] The primary observable signs of stroke are a drooping face, the inability to raise both arms, and slurred or jumbled speech. Treatments for stroke can include rehabilitation and medications, including tissue plasminogen activator, blood thinners, and blood pressure lowering medications. A stroke can result in long-term effects including physical changes (ability to communicate, ability to move, and bowel and bladder issues), relationship changes, legal and financial issues (ability to earn a living, return to work), and less visible changes, such as emotional changes, fatigue, changes in perception (e.g., vision, sensation, spatial relations, time awareness, unilateral body neglect, visual neglect). The Heart and Stroke Foundation of Canada reports that as of 2017, more than 400,000 Canadians are living with long-term disability from stroke and this will almost double in the next 20 years.[2]

Endovascular therapy (EVT) is a treatment for patients with acute ischemic strokes that removes the clot or thrombus from the brain, which ultimately caused the stroke.[3] EVT involves thrombectomy, the mechanical disintegration of vessel-occluding thrombi or blood clots, with or without intra-arterial administration of thrombolytic medications.[4,5] Across Canada, EVT is being incorporated into the current standard of care for strokes, which is typically a pharmaceutical intervention using tissue plasminogen activator (tPA; also called alteplase, a thrombolytic drug).[6] Despite some concerns around the implementation of EVT (namely, few hospitals currently provide the treatment and the treatment must be given within a very short timeframe), EVT is being used across Canada.

The purpose of this review is to evaluate the guidelines for endovascular thrombectomy for patients who have had ischemic stroke. A previous Summary with Critical Appraisal was conducted in 2015 reviewed EVT. The report found that the incidence of favourable outcomes was higher in patients treated with EVT compared with patients treated with a comparator.[7] As the clinical effectiveness of EVT has been well established,[6] guidelines regarding patients selection and optimal treatment regime for EVT can be useful for clinicians and patients who are involved with this treatment.

Research Question

What are the evidence-based guidelines associated with endovascular thrombectomy for patients who have undergone ischemic stroke?

Key Findings

One evidence-based guideline was identified examining endovascular thrombectomy for patients who have undergone ischemic stroke. The high-quality guideline provides detailed recommendations regarding screening, patient selection, and optimal treatment methods. Although the guideline was established in the United States from the American Stroke Association, the recommendations are still relevant for the Canadian context.

Methods

This report makes use of a literature search developed for a previous CADTH report. The original literature search was conducted in July 2015 on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to guidelines. The original search was limited to English language documents published between January 1, 2010 and July 16, 2015. For the current report, database searches were rerun on May 14, 2018 to capture any articles published since the initial search date. The search of major guideline agencies was also updated to include documents published since July 2015.

Literature Search Methods

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults patients who have had an ischemic stroke whose clots have been visualized using either computed tomography angiography (CTA) or magnetic resonance angiography (MRA)
Intervention	Endovascular thrombectomy (EVT) therapy
Comparator	No comparator
Outcomes	Guidelines
Study Designs	Evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2015.

Critical Appraisal of Individual Studies

The included guideline was critically appraised with the AGREE II instrument.[8] A summary score was not calculated for the included study; rather, the strengths and limitations of the included study were described.

Summary of Evidence

Quantity of Research Available

A total of 504 citations were identified in the literature search. Following screening of titles and abstracts, 502 citations were excluded and two potentially relevant reports from the

electronic search were retrieved for full-text review. Six potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, seven publications were excluded for various reasons, while one publication met the inclusion criteria and was included in this report. Appendix 1 presents the PRISMA flowchart of the study selection.

Summary of Study Characteristics

Details of the included guideline characteristics are found in Appendix 2.

Study Design

One evidence-based guideline from the American Heart Association/American Stroke Association was identified examining endovascular thrombectomy for patients who have undergone ischemic stroke.[9] The guideline provides a very detailed guide on recommendations from screening with brain imaging to treatment with carotid artery revascularization. The intended users of the guideline are clinicians who treat adult patients with acute arterial ischemic stroke. Draft recommendations and supporting evidence were discussed by the writing group, who were appointed by the American Heart Association Stroke Council's Scientific Statements oversight Committee, which included individuals from various areas of medical expertise.

Country of Origin

The included guideline was developed in the United States and was published in 2018.[9]

Patient Population

The included guideline makes recommendations specific to adult patients who have had an acute arterial ischemic stroke.[9] The intended users of the document are clinicians, including prehospital care providers, physicians, allied health professionals, and hospital administrators.

Interventions and Comparators

The included guideline provides recommendations on prehospital care, urgent and emergency evaluation and treatment with intra-arterial therapies, and in-hospital management.[9]

Summary of Critical Appraisal

Additional details regarding the strengths and limitations of the included publication are provided in Appendix 3.

The included guideline provided good detail about the methodology used in its development. The overall objectives, the intended users, and the target population of the guideline are well described. The target users of the guideline are clearly defined. In terms of rigour of development, systematic methods were used to search for evidence and the criterion for selecting evidence is clearly described. In fact, two systematic reviews were published in conjunction with this guideline in order to support the recommendations. The strengths and limitations of the body of evidence and methods for formulating the recommendations are also clearly described. The health benefits, side effects, and risks were considered in formulating the recommendations. There is also an explicit link between the recommendations and the supporting evidence. The guideline was externally reviewed by experts prior to its publication. With respect to clarity of presentation, the

recommendations are specific and unambiguous, the different options for management of the condition are clearly presented, and key recommendations are easily identifiable. Moreover, the guideline provides advice and/or tools on how the recommendations can be put into practice and the potential resource implications of applying the recommendations are considered. Finally, competing interests of the guideline development group members were recorded and addressed.

Nevertheless, the guideline also had some limitations. It is unclear if the guideline development group included individuals from all professional groups; the report states the guideline development group was "representing various areas of medical expertise", but these areas are not described. It is also unclear if the views and preferences of the target population were sought in the development of the recommendations. Moreover, it is unclear if the guideline presents monitoring and/or auditing criteria. Despite a few unclear methods, the guideline is of fairly high quality.

Summary of Findings

Additional details regarding main study findings and author's conclusions, including level of evidence for each recommendation, is provided in Appendix 4.

Screening

The guideline recommends that systems should be established so that brain imaging studies can be performed within 20 minutes of arrival to the emergency department (ED) in at least 50% of patients who may be candidates for mechanical thrombectomy and/or intravenous alteplase (note: it was unclear why the 50% threshold was chosen).[9] Reducing time from ED presentation to brain imaging reduces time to initiate treatment. It has been shown that earlier treatment within the therapeutic window will lead to larger benefits.[9] Authors add that patients who meet the criteria for EVT, a non-invasive intracranial vascular study is recommended during initial imaging of the acute stroke patient.[9] If patients are being considered for mechanical thrombectomy, observation after IV alteplase to assess for clinical response should not be performed.

Patient Selection

Specific criteria for patient selection were recommended as: pre-stroke modified Rankin scale of 0 to 1; causative occlusion of the internal carotid arteria or middle cerebral artery segment 1; 18 years of age or older; National Institutes of Health Stroke Scale (NIHSS) of ≥6; Alberta Stroke Program Early CT score (ASPECTS) of ≥6.[9] If the patient meets all specific criteria treatment can be initiated (groin puncture) within six hours of symptom onset. Mechanical thrombectomy is recommended in patients with acute ischemic stroke (AIS) within 6-16 hours of last known normal (last known normal [LKN] time is a critical determinant of IV tPA eligibility) who have large vessel occlusion (LVO) in the anterior circulation and meet other DAWN or DEFUSE 3 eligibility criteria. Mechanical thrombectomy is reasonable 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 eligibility criteria.[9]

Treatment

The guideline recommends that mechanical thrombectomy devices may be reasonable as a first-line device in some circumstances, but stent retrievers remain the first choice for first-line devices.[9] In patients who receive mechanical thrombectomy, a blood pressure of ≤180/105 millimeter of mercury (mm Hg) during and for 24 hours after the procedure is

reasonable to maintain; patients with successful reperfusion, it might be reasonable to maintain BP at a level <180/105 mm Hg.

Limitations

One limitation of this review is that the guideline was published and reviewed in the United States, which has a significantly different health care system than Canada. While it would be ideal to have a Canadian guideline, most of the recommendations are likely still relevant in Canada, as the two countries do have many similarities (e.g., demographics, economy, infrastructure). The guideline may not be applicable to remote populations, as EVT is not widely available and usually only accessible in major urban centres. Most of the data used to formulate recommendations came from the major randomized controlled trials that were conducted in 2015 examining the use of EVT in stroke patients. Another concern regarding this report is that the guideline development group is not explicitly described, rather it states that the group was represented by various areas of medical expertise. Moreover, only one guideline was identified, which may be a potential limitation because it is uncertain if there consensus across multiple guidelines.

Conclusions and Implications for Decision or Policy Making

One evidence-based guideline was identified examining endovascular thrombectomy for patients who have undergone ischemic stroke.[9] The guideline provides recommendations on the use of mechanical thrombectomy in adult patients with acute ischemic stroke from screening and patient selection to treatment. The guideline included in this report provided good detail about the methodology used in its development and it was a high-quality guideline. Although the guideline was developed in the United States by the American Stroke Association, the recommendations are likely still relevant for the Canadian context.

A consensus statement approved at the European Stroke Organisation-Karolinska Stroke Update conference in November 2014[10] corroborates some of the key recommendations reported in this guideline; both guidelines recommend that mechanical thrombectomy is recommended to treat acute stroke patients with large artery occlusions in the anterior circulation within six hours after symptom onset. Both guidelines also recommend implementation access to mechanical thrombectomy in a stroke centre or in a network which includes stroke centres.

As the clinical effectiveness of EVT has been established,[6] future research and guidelines addressing the use of mechanical thrombectomy with stent retrievers and how to better implement EVT in a way that treatment can be made available to all stroke patients across Canada would be useful in the Canadian context.

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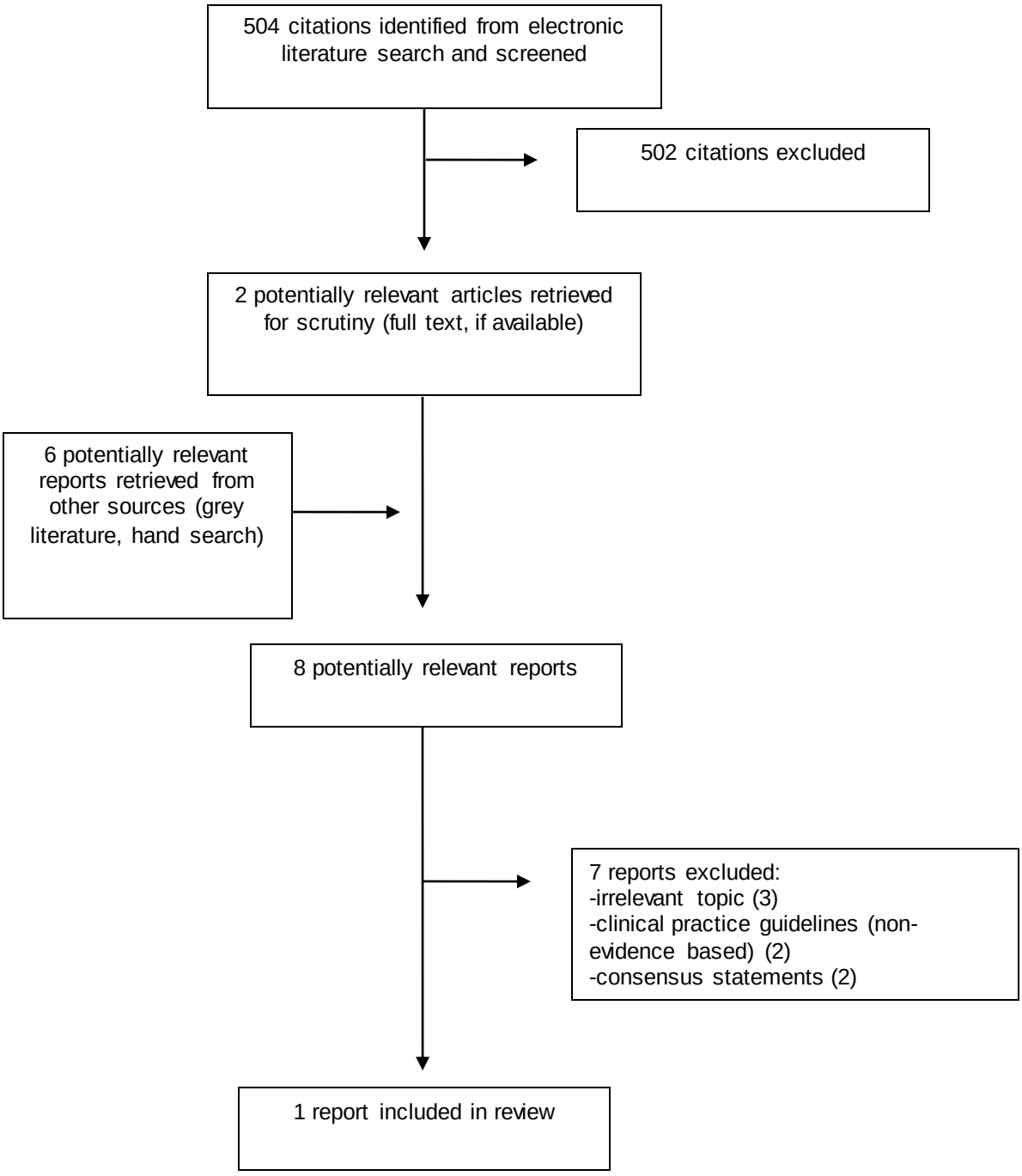
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publication

Table 2: Characteristics of Included Guideline

Intended Users, Target Population	Intervention and Practice Considered	Major Outcomes Considered	Evidence Collection, Selection and Synthesis	Evidence Quality Assessment	Recommendations Development and Evaluation	Guideline Validation
Powers, 2018[9]						
Clinicians including prehospital care providers, physicians, allied health professionals, and hospital administrators Adults	Early management for adult patients with acute arterial ischemic stroke	Prehospital care Urgent and emergency evaluation and treatment with intravenous and intra-arterial therapies In-hospital management	Two systematic reviews were published in conjunction with the guideline to support the development of recommendations	The American College of Cardiology 2015 Class of Recommendations and Levels of Evidence were used	Draft recommendations and supporting evidence were discussed by the writing group, and the revised recommendations for each topic were reviewed by a designated writing group member; the full group then evaluated the complete guidelines	Prerelease review of the draft guideline was performed by four expert peer reviewers and by the members of two different committees

Appendix 3: Critical Appraisal of Included Publication

Table 3: Strengths and Limitations of Included Guideline using AGREE II

Strengths	Limitations
Powers, 2018[9]	
Scope and Purpose • The overall objectives of the guideline are described. • The population to whom the guideline is meant to apply is specifically described. **Stakeholder Involvement** • The target users of the guideline are clearly defined. **Rigour of Development** • Systematic methods were used to search for evidence. • The criteria for selecting the evidence are clearly described. • The strengths and limitations of the body of evidence are clearly described. • The methods for formulating the recommendations are clearly described. • The health benefits, side effects, and risks have been considered in formulating the recommendations. • There is an explicit link between the recommendations and the supporting evidence. • The guideline was externally reviewed by experts prior to its publication. **Clarity of Presentation** • The recommendations are specific and unambiguous. • The different options for management of the condition or health issue are clearly presented. • Key recommendations are easily identifiable. **Applicability** • The guideline provides advice and/or tools on how the recommendations can be put into practice. • The potential resource implications of applying the recommendations have been considered. **Editorial Independence** • Competing interests of guideline development group members have been recorded and addressed.	**Stakeholder Involvement** • It is unclear if the development group includes individuals from all professional groups; report states the group was "representing various areas of medical expertise", but these areas are not described. • It is unclear if the views and preferences of the target population were sought. **Rigour of Development** • There is no procedure for updating the guideline. **Applicability** • There is no description for facilitators and barriers in the guideline. • It is unclear if the guideline presents monitoring and/or auditing criteria.

Appendix 4: Main Study Findings and Author's Conclusions

Table 4: Summary of Findings of the Included Guideline

Recommendations (Direct Quotes from Guidelines)	Level of Evidence
Powers, 2018[9]	
"Mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and a comprehensive periprocedural care team. Systems should be designed, executed, and monitored to emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures." Page e10	COR i*; LOE C-EO**
"*Systems should be established so that brain imaging studies can be performed within 20 minutes of arrival in the ED in at least 50% of patients who may be candidates for IV alteplase and/or mechanical thrombectomy."* Page e13	COR I*; LOE B-NR**
"In patients who are potential candidates for mechanical thrombectomy, imaging of the extracranial carotid and vertebral arteries, in addition to the intracranial circulation, is reasonable to provide useful information on patient eligibility and endovascular procedural planning." **Page e14**	COR IIa*; LOE C-EO**
"Additional imaging beyond CT and CTA or MRI and magnetic resonance angiography (MRA) such as perfusion studies for selecting patients for mechanical thrombectomy in <6 hours is not recommended." **Page e14**	COR III No benefit*; LOW B-R**
"For patients who otherwise meet criteria for EVT, a noninvasive intracranial vascular study is recommended during the initial imaging evaluation of the acute stroke patient, but should not delay IV alteplase if indicated. For patients who qualify for IV alteplase according to guidelines from professional medical societies, initiating IV alteplase before noninvasive vascular imaging is recommended for patients who have not had noninvasive vascular imaging as part of their initial imaging assessment for stroke. Noninvasive intracranial vascular imaging should then be obtained as quickly as possible." Page e14	COR I*; LOE A**
"For patients who otherwise meet criteria for EVT, it is reasonable to proceed with CTA if indicated in patients with suspected intracranial LVO before obtaining a serum creatinine concentration in patients without a history of renal impairment." Page e14	COR IIa*; LOE B-NR**
"Patients eligible for IV alteplase should receive IV alteplase even if EVTs are being considered." Page e26	COR I*; LOE A**
"In patients under consideration for mechanical thrombectomy, observation after IV alteplase to assess for clinical response should not be performed." Page e26	COR III Harm*; LOE B-R**
"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." Page e27	COR I*; LOE A**
"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." Page e27	COR IIb*; LOE B-R**
"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." Page e27	COR IIb*; LOE C-EO**

Recommendations (Direct Quotes from Guidelines)	Level of Evidence
"Although its benefits are uncertain, the use of mechanical thrombectomy with stent retrievers may be reasonable for patients with AIS 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 internal carotid artery (ICA) or proximal MCA (M1). Additional randomized trial data are needed." Page e27	COR IIb*; LOE B-R**
"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." Page e28	COR I*; LOE A**
"In selected patients with AIS within 6 to 24 hours of last known normal who have LVO in the anterior circulation and meet other DAWN eligibility criteria, mechanical thrombectomy is reasonable." Page e28	COR IIa*; LOE B-R**
"The technical goal of the thrombectomy procedure should be reperfusion to a modified Thrombolysis in Cerebral Infarction (mTICI) 2b/3 angiographic result to maximize the probability of a good functional clinical outcome." Page e28	COR I*; LOE A**
"As with IV alteplase, 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 within the therapeutic window." Page e28	COR I*; LOE B-R**
"The use of mechanical thrombectomy devices other than stent retrievers as first-line devices for mechanical thrombectomy may be reasonable in some circumstances, but stent retrievers remain the first choice." Page e29	COR IIb*; LOE B-R**
"The use of a proximal balloon guide catheter or a large-bore distal-access catheter, rather than a cervical guide catheter alone, in conjunction with stent retrievers may be beneficial. Future studies should examine which systems provide the highest recanalization rates with the lowest risk for nontarget embolization." Page e29	COR IIa*; LOE C-LD**
"Use of salvage technical adjuncts including intra-arterial thrombolysis may be reasonable to achieve mTICI 2b/3 angiographic results." Page e29	COR IIb*; LOE C-LD**
"EVT of tandem occlusions (both extracranial and intracranial occlusions) at the time of thrombectomy may be reasonable." Page e29	COR IIb*; LOE B-R**
"It is reasonable to select an anesthetic technique during endovascular therapy for AIS on the basis of individualized assessment of patient risk factors, technical performance of the procedure, and other clinical characteristics. Further randomized trial data are needed." Page e29	COR IIa*; LOE B-R**
"In patients who undergo mechanical thrombectomy, it is reasonable to maintain the BP ≤180/105 mm Hg during and for 24 hours after the procedure." Page e30	COR IIa*; LOE B-NR**
"In patients who undergo mechanical thrombectomy with successful reperfusion, it might be reasonable to maintain BP at a level <180/105 mm Hg." Page e30	COR IIb*; LOE B-NR**

AIS = acute ischemic stroke; BP = blood pressure; COR = class of recommendation; CTA = computer tomography angiography; ED = emergency department; EVT = endovascular thrombectomy; ICA = internal carotid artery; IV = intravenous; LOE = level of evidence; MCA = middle cerebral artery stroke; MTICI = modified treatment in cerebral ischaemia score; RCT = randomized controlled trial

***Class (Strength) of Recommendation**

Class I (Strong): Benefit >>> Risk
- is recommended
- is indicated/useful/effective/beneficial
- should be performed/administered/other

Class IIa (Moderate): Benefit >> Risk
- is reasonable
- can be useful/effective/beneficial

Class IIb (Weak): Benefit ≥ Risk
- may/might be reasonable
- may/might be considered
- usefulness/effectiveness is unknown/unclear/uncertain or not well established

Class III No Benefit (Moderate: Benefit = Risk
- is not recommended
- is not indicated/useful/effective/beneficial
- should not be performed/administered/other

Class III Harm (Strong) Risk > Benefit
- potentially harmful
- causes harm
- associated with excess morbidity/mortality
- should not be performed/administered/other

****Level (Quality) of Evidence**

Level A
- high-quality evidence from more than 1 RCT
- meta-analyses of high-quality RCTs
- one or more RCTs corroborated by high-quality registry studies

Level B-R
- moderate-quality evidence from 1 or more RCTs
- meta-analyses of moderate-quality RCTs

Level B-NR
- moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- meta-analyses of such studies

Level C-LD
- randomized or nonrandomized observational or registry studies with limitations of design or execution
- meta-analyses of such studies
- physiological or mechanistic studies in human subjects

Level C-EO
- consensus of expert opinion based on clinical experience