



Multisociety Consensus Quality Improvement Revised Consensus Statement for Endovascular Therapy of Acute Ischemic Stroke

From the American Association of Neurological Surgeons (AANS), American Society of Neuroradiology (ASNR), Cardiovascular and Interventional Radiology Society of Europe (CIRSE), Canadian Interventional Radiology Association (CIRA), Congress of Neurological Surgeons (CNS), European Society of Minimally Invasive Neurological Therapy (ESMINT), European Society of Neuroradiology (ESNR), European Stroke Organization (ESO), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), Society of NeuroInterventional Surgery (SNIS), and World Stroke Organization (WSO)

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ABBREVIATIONS

ASPECTS = Alberta Stroke Program Early Computed Tomography Score, EVT = endovascular therapy, mRS = modified Rankin scale, mTICI = modified thrombolysis in cerebral infarction, NIHSS = National Institutes of Health Stroke Scale, QI = quality improvement, SAH = subarachnoid hemorrhage, SICH = symptomatic intracranial hemorrhage, SITS-MOST = Safe Implementation of Thrombolysis in Stroke Monitoring Study, TICI = thrombolysis in cerebral infarction, TIMI = thrombolysis in myocardial infarction, TPA = tissue plasminogen activator

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Table E1 is available online at www.jvir.org.

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INTRODUCTION

Endovascular therapy (EVT) for acute ischemic stroke in selected patients has recently been proven effective in several clinical trials, and the widespread adoption of thrombectomy into routine clinical practice has begun. However, these acute stroke services are resource-intensive, including advanced cerebral imaging and highly trained multidisciplinary hospital teams rapidly responding to emergency activation. Despite the previous acceptance of intravenous fibrinolysis for acute ischemic stroke and the development of designated stroke centers (1), ischemic stroke remains a leading cause of adult death and disability (2). Many patients are not candidates for fibrinolysis, and intravenous therapy is relatively ineffective for severe strokes as a result of large cerebral artery occlusions. Moreover, it is uncertain if the benefits of endovascular stroke treatment in the trial setting can be generalized to clinical care provided by hospitals and teams of varying training, experience, and case volume. In other medical disciplines, rapid technologic advancement required guidelines to utilize these tools effectively and responsibly (3). Quality-improvement (QI) metrics for the outcomes of endovascular ischemic stroke treatment were published by a multisociety, multispecialty, international consensus group in 2013 (4). These QI metrics have been accepted at a national level in Great Britain and Ireland (5) but have yet to be included into stroke center accreditation requirements in the United States. Subsequent to the publication of the prior QI guidelines, 8 randomized trials and several meta-analyses of EVT have been published (6–20). These randomized trials have established EVT as standard of care when available (5,21–23), and provide additional data on which to update the metrics and benchmarks of the previous paper (4). Therefore, it is now appropriate to revise the prior QI document based on new evidence.

Revision of this QI consensus statement remains focused on processes of care and patient outcomes. Other documents address standards for physician training (24,25) and recommendations for patient selection and treatment methods (5,23). As in the previous guidelines, it is intended that these benchmarks be used in a quality-improvement program to assess and improve processes and outcomes in acute stroke revascularization. The benchmarks provide the consensus process and outcome consensus measures called for by the Stroke Treatment Academic Industry Roundtable (STAIR) IX academic industry roundtable for the next generation of endovascular trials (26). The benchmarks may also be suitable for accreditation of stroke intervention programs. Most of the metrics apply to the role of the interventional physician, regardless of specialty or particular board certification, but comprehensive stroke care requires a broad multidisciplinary process involving care that ranges from emergency dispatch of paramedics through acute hospital care and post-treatment subacute rehabilitation. Therefore, although it is not the intention of this document to assess in detail the quality of facilities, some of the metrics also apply to institutional policies and procedures for stroke care.

MATERIALS AND METHODS

A literature search was conducted using Ovid and EMBASE from 2012 (from the last date of the literature search for the first publication of these metrics) (4) to October 2015 using article titles that included the following: (acute ischemic stroke OR cerebrovascular accident OR stroke) AND (intra-arterial OR intraarterial OR endovascular OR angioplasty OR stent OR stent retriever OR mechanical thrombectomy OR thrombolysis OR tissue plasminogen activator [TPA] OR TPA OR urokinase OR streptokinase OR alteplase OR tenecteplase). Additional articles were then solicited from writing group members. An evidence table (Table E1, available online at www.jvir.org) was constructed by using articles that were randomized controlled trials, registries, or case series of at least 100 patients, and some case series of less than 100 patients were included if the series provided uniquely useful data. From the evidence table, metrics were chosen that were believed to be important markers of quality of care. Thresholds for metrics were then chosen by consensus of the writing group based on review of the evidence table. Consensus was defined as 80% of the writing group. If consensus was not achieved during discussion, a modified Delphi process was used to obtain consensus (27). If consensus was not achieved after the modified Delphi process, a threshold

was not chosen. The evidence table was then updated by using the same search terms in February 2017 at the time of completion of the draft of the document to allow updating of the metrics if appropriate.

Standards for developing clinical practice guidelines were reviewed (28). It was determined that the majority of these standards were not applicable for this document that updates quality benchmarks for processes and outcomes of care rather than creating recommendations for types of patient care. For this reason, this revision has been changed to a consensus statement rather than a guideline.

DEFINITIONS

Measures and metrics will depend on the definition of a good outcome or a complication and the time at which patients are assessed for these outcomes, as many patients show gradual improvement following an ischemic stroke. Numerous trials have used varying definitions for similar concepts. The definitions used in this document were derived from review of these trials and then consensus of the writing group.

Ischemic central nervous system infarction.—A uniformly accepted simple definition of central nervous system infarction remains elusive. A successful multidisciplinary attempt arrived at a definition as follows (29):

Central nervous system infarction is defined as brain, spinal cord, or retinal cell death due to ischemia, based on:

1. Pathological, imaging, or other objective evidence of cerebral, spinal cord, or retinal focal ischemic injury in a defined vascular distribution; or
2. Clinical evidence of cerebral, spinal cord, or retinal focal ischemic injury based on symptoms persisting at least 24 hours or until death, and other etiologies excluded.

Door-to-event time.—The term “door” is used to determine the time of onset of medical care, as in “door to time of computed tomography (CT) imaging.” It is defined as the time of arrival in the emergency department for an outpatient or the time first discovered to have a stroke for an inpatient. When patients are transferred, “door” refers to the arrival (ie, registration) time at the receiving facility.

Time to thrombus.—Time to thrombus is considered to represent the start of endovascular lytic infusion or first placement of a mechanical device in the target vessel.

Successful revascularization.—Successful revascularization is considered to represent modified thrombolysis in cerebral infarction (mTICI) (30,31) grade 2b or 3 flow through the previously occluded vessel segment (Table 1).

Symptomatic intracranial hemorrhage.—Symptomatic intracranial hemorrhage (SICH) is a parenchymal hematoma type II (per the Safe Implementation of Thrombolysis in Stroke Monitoring Study [SITS-MOST] definition) (32) or subarachnoid hemorrhage (SAH) with neurologic deterioration leading to an increase in National Institutes of Health Stroke Scale (NIHSS) score > 4 or leading to death within 36 hours of treatment. Because of the risk of vessel perforation during endovascular procedures, SAH has been added as a cause of intracranial hemorrhage to the SITS-MOST SICH definition (33).

This definition is similar to that used in the recent randomized trials of EVT (7,11,15). Several of the authors of those trials have joined others in proposing a new definition of SICH (34). These new definitions have not yet been validated on a larger scale, adopted in stroke trials, or applied to the outcomes of the recent randomized trials. Therefore, the original definition of SICH is maintained in the present revision of the consensus statement and modified to include any intracranial hemorrhage associated with a decrease in NIHSS score > 4 or death within 24 hours of the end of the revascularization procedure (20).

Good clinical outcome.—A good clinical outcome is a measure of neurologic functional with a score of 0–2 on the modified Rankin scale

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