

Performance and Training Standards for Endovascular Ischemic Stroke Treatment

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Stroke is the third-leading cause of death in the United States, Canada, Europe, and Japan. According to the American Heart Association and the American Stroke Association, 750,000 new strokes occur each year, resulting in 200,000 deaths (or 1 of every 16 deaths) per year in the United States alone. Endovascular therapy for patients with acute ischemic stroke is an area of intense investigation. The American Stroke Association has given a qualified endorsement of intra-arterial (IA) thrombolysis in selected patients. IA thrombolysis has been studied in 2 randomized trials and numerous case series. Although 2 devices have been granted FDA 3 approval with an indication for mechanical stroke thrombectomy, none of these devices has demonstrated efficacy in improving patient outcomes. This report defines what constitutes adequate training to perform neuroendovascular procedures in patients with acute ischemic stroke and identifies the performance standards that should be adopted to assess outcomes. These guidelines have been written and approved by multiple neuroscience societies that historically have been directly involved in the medical, surgical, and endovascular care of patients with acute stroke, including the Neurovascular Coalition and its participating societies: the Society of NeuroInterventional Surgery; American Academy of Neurology; American Association of Neurological Surgeons, Cerebrovascular Section; and Society of Vascular & Interventional Neurology. **Key Words:** Stroke—endovascular therapy—training standards—performance—intra-arterial—fellowship—endovascular.

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Stroke is the third-leading cause of death in the United States, Canada, Europe, and Japan. According to the American Heart Association and the American Stroke Association, 750,000 new strokes occur each year, resulting in 200,000 deaths (or 1 of every 16 deaths) per year in the United States alone.¹ Ischemic stroke accounts more than 80% of the total number of strokes, with hemorrhagic stroke comprising the remainder. Stroke is the leading cause of adult disability in North America² and the primary cause for in-patient Medicare reimbursement for long-term adult care.^{3,4} The National Institutes of Health estimates that the cost of stroke now exceeds \$62 billion annually.¹

At present, the only therapy demonstrated to improve clinical outcomes from acute ischemic stroke is thrombolysis of the clot responsible for the ischemic event.⁵ Specifically, the only FDA-approved therapy for stroke is intravenous tissue plasminogen activator (tPA) administered within 3 hours of stroke onset.⁵ Endovascular therapy for patients with acute ischemic stroke is an area of intense investigation. The American Stroke Association has given a qualified endorsement of intra-arterial (IA) thrombolysis in selected patients. IA thrombolysis has been studied in 2 randomized trials^{6,7} and numerous case series that have demonstrated clinical efficacy for IA prourokinase in proximal middle cerebral artery occlusion.⁷ Although 2 devices have been granted FDA approval with an indication for mechanical stroke thrombectomy,⁸ neither of these devices has demonstrated efficacy in improving patient outcomes despite a high rate of recanalization awaiting randomized trials.

In this report we define what constitutes adequate training to perform neuroendovascular procedures in patients with acute ischemic stroke and identify the performance standards that should be adopted to assess outcomes. Neuroendovascular procedures are technically challenging and not directly transferable from other vascular systems, involve an organ with unique physiology and anatomy, and require careful patient selection because of the risk of potentially fatal brain hemorrhage. Studies of emerging technologies over the past 20 years have made it abundantly clear that inadequate physician training and experience can adversely affect clinical outcomes.^{9,10} Overexuberance by both physicians and industry has led unqualified physicians to perform endovascular carotid revascularization procedures, yielding inferior results.^{9,10} Thus, it is especially important that the involved physicians strictly adhere to appropriate standards when performing high-risk procedures such as those involved in treating endovascular stroke. Standardization of training requirements is critically important as the interest in and utilization of endovascular methods increases among various specialties.

These guidelines are modeled after earlier standards documents, such as the training, competency, and credentialing standards for diagnostic cerebral angiography, carotid stenting, and treatment of acute stroke, written and

endorsed by multispecialty groups¹¹⁻¹³ and training standards for the performance of uterine artery embolization written by the Society of Interventional Radiology.¹⁴ These guidelines also parallel the training standards of successful subspecialty training programs such as interventional cardiology, and the credentialing standards for the performance of acute coronary interventions.¹⁵ These guidelines have been written and approved by multiple neuroscience societies that historically have been directly involved in the medical, surgical, and endovascular care of patients with acute stroke and considered expert in the field of endovascular stroke therapy, including the Society of NeuroInterventional Surgery; American Academy of Neurology; American Association of Neurological Surgeons, Cerebrovascular Section; and Society of Vascular & Interventional Neurology.

Minimum Training Requirement for Acute Stroke Interventions

Cognitive training and qualifications:

1. Accreditation Council for Graduate Medical Education (ACGME)-approved residency training including documented cerebrovascular training, including the diagnosis and management of acute stroke and the interpretation of cerebral arteriography and brain imaging under the supervision of a board-certified neurologist, neurosurgeon, or neuroradiologist with the American Board of Medical Speciality (ABMS) eligibility or certification. A minimum of 6 months during a 4-year residency is suggested.
2. One year of graduate medical education in endovascular surgical neuroradiology. An ACGME-approved program is preferred but not required.

Technical training and qualifications:

1. Documented prior training and experience in catheter arteriography, including 100 cerebral arteriograms. Clinical outcomes must meet or exceed the American College of Radiology (ACR) benchmarks for technical success and complications.^{11,16}
2. Documented prior training and experience in intracranial microcatheter (≤ 3 French) and microguidewire (≤ 0.014 inch) navigation under the supervision of fellowship-trained and credentialed neurointerventionalist(s).
3. Documented prior experience in assessment and performance of endovascular stroke interventional procedures as the primary operator in 10 patients under the supervision of fellowship-trained and credentialed neurointerventionalists(s).
4. Previously credentialed physicians who perform IA catheter-directed stroke procedures at their local institutions should have documented procedural

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