Reimbursement for Thrombectomy Devices in Patients Who Are Ineligible for Intravenous Tissue-Type Plasminogen Activator

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Intravenous tissue-type plasminogen activator (t-PA) is an effective treatment for acute ischemic stroke for which efficacy is very time dependent and its greatest benefit occurs with early treatment. Not all patients with ischemic stroke who arrive within 2 to 3 hours after stroke onset are eligible for IV t-PA because they have contraindications, such as recent major surgery, ongoing anticoagulation at the time of stroke, etc. These t-PA–ineligible patients with moderate and severe strokes are often treated with intra-arterial t-PA via an endovascular procedure and, more recently, thrombectomy devices. Moreover, a sizable proportion of patients with moderate to severe stroke who do receive IV t-PA still have a poor outcome because IV t-PA was unable to lyse the clot or did so after the brain was irreversibly destined for infarction. Thus, there is a great need for more rapid and effective approaches to reperfusion.

The Interventional Management of Stroke (IMS) III trial, a National Institute of Neurological Disorders and Stroke–funded study recently published in NEJM, reported similar safety and clinical outcomes for subjects treated with endovascular therapy after IV t-PA compared with subjects treated within IV t-PA alone. Newer FDA-cleared thrombectomy devices, such as stent retrievers, have been demonstrated to produce higher recanalization rates than the devices most commonly used in IMS III. The recently published SYNTHESIS (Local Versus Systemic Thrombolysis for Acute Ischemic Stroke) trial also reported similar safety and clinical outcomes for subjects treated with endovascular therapy alone compared with subjects treated with IV t-PA within 4.5 hours of onset. The key principle of treatment is that reperfusion therapy, whether pharmacological with IV t-PA or mechanical with endovascular thrombectomy, results in good outcomes when applied early.

Insurance companies in the United States are currently considering whether the data from these 2 trials justify withdrawal of reimbursement for thrombectomy devices for all ischemic stroke patients, including those patients who arrive within the t-PA treatment window but who are ineligible for IV t-PA. We argue that withdrawal of reimbursement for t-PA–ineligible patients who are treated with thrombectomy devices within the first 4.5 hours is unwarranted and would penalize patients. Reperfusion therapy with IV t-PA administered within 4.5 hours has been demonstrated to improve outcome in stroke patients compared with placebo, and hospitals in the United States are reimbursed at a higher rate for patients treated with t-PA compared with patients not treated with any reperfusion therapy because of the greater costs associated with treatment of IV t-PA patients. Yet, without reimbursement for thrombectomy devices, patients with a moderate to severe stroke who can be treated with a reperfusion therapy within 4.5 hours, but who are ineligible for IV t-PA, may receive no reperfusion therapy and are likely to have unfavorable outcome.

For example, a 60-year-old woman who is anticoagulated with warfarin has the onset of a severe stroke of 2-hour duration secondary to an embolus in her terminal internal carotid artery. She is considered for thrombectomy by endovascular therapy because her international normalized ratio is 2.5 and IV t-PA is contraindicated. Either she would not receive endovascular therapy because the hospital will be denied reimbursement for this procedure or she would be forced to pay for the endovascular procedure if she undergoes treatment with a thrombectomy device, regardless of outcome.

Data from the IMS III and SYNTHESIS trials cannot address the role of thrombectomy devices for patients beyond the therapeutic window for t-PA, and future randomized trials are needed to demonstrate the efficacy of the newest generation of thrombectomy devices compared with standard medical therapy. These trials should include reimbursement by Centers for Medicare and Medicaid Services and commercial insurers for patients treated with thrombectomy devices, as has occurred to this point. However, we strongly recommend that insurance companies continue to reimburse hospitals for t-PA–ineligible patients treated with an endovascular reperfusion therapy within the 4.5-hour time window from stroke onset, whether or not they are part of a randomized treatment trial.

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References


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