

Effective Health Care Program

Neurothrombectomy Devices for Treatment of Acute Ischemic Stroke

Executive Summary

Background

Acute ischemic strokes are associated with poor outcomes and high health care burden. In patients with occlusions of large cerebral vessels, patients with high baseline stroke severity scores as defined by the National Institute of Health Stroke Score (NIHSS), and patients unlikely to benefit or having failed treatment with intravenous (IV) recombinant tissue plasminogen activator (rtPA), there is a need for alternative methods of revascularization which can improve outcomes without increasing the risk for intracranial hemorrhage. The uses of various neurothrombectomy devices (clot retrievers, aspiration/suction devices, snare-like devices, ultrasonography technologies, and lasers) have been examined in these populations. Currently, two neurothrombectomy devices are FDA-cleared through the FDA 510(k) process: the MERCI clot retriever and the Penumbra System. Various ongoing clinical trials are currently evaluating the impact of these devices, as well as other (off-label) neurothrombectomy devices, for the treatment of acute ischemic stroke. The goal of this technical brief is to describe neurothrombectomy devices currently

Effective Health Care Program

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being used or actively investigated in the treatment of patients with acute ischemic stroke and to summarize the evidence supporting their use.



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Methods

We developed a list of neurothrombectomy devices based on the FDA Center for Device and Radiological Health (CDRH) guidance definition of a neurothrombectomy device, published literature, and a search of the FDA CDRH's database to identify neurothrombectomy devices that have received FDA clearance (510(k) documents).

Systematic literature searches were conducted of MEDLINE, the Cochrane Central Register of Controlled Trials, SCOPUS, Web of Science, and the Cochrane Database of Systematic Reviews, from the earliest possible date through November 2010. Grey literature searches were also conducted, utilizing Google, clinicaltrials.gov, and manual searching techniques.

Two investigators independently screened citations at the abstract level to identify potentially relevant studies, case series, and case reports. Throughout this technical brief, our use of the terminology “studies” will refer only to prospective, single-arm studies or retrospective studies enrolling consecutive patients. The terminology “reports” will refer to the latter studies in addition to case series and case reports. Potentially eligible citations were retrieved for full-text review. We included human studies of any design, case series, and case reports as long as they included patients with an acute ischemic stroke and reported at least one outcome of interest. We included only reports in English in our qualitative review of the literature.

Two investigators independently abstracted data from eligible reports, and disagreements were resolved by a third investigator. We obtained the following information from each report: author identification, year of publication, study design characteristics, study population, patient baseline characteristics, disease severity, location of occluded artery, time from symptom onset to device deployment or angiography, use of concurrent standard medical therapies, whether outcomes assessment was blinded, and the device used. Effectiveness outcomes included: recanalization as measured by post-Thrombolysis in Myocardial Infarction (TIMI) flow grade or similar methodology,

mortality, modified Rankin Scale (mRS), National Institutes of Health Stroke Scale (NIHSS) score, Barthel Index, and Glasgow Outcome Scale (GOS). Harms included failure to deploy the device or remove the clot, device breakage or fracture, perforation, dissection, thrombus formation, vasospasm, or hemorrhage.

We used descriptive statistics and summative tables to synthesize data regarding study designs, clinical and treatment characteristics, effectiveness outcomes, and adverse events reported. We created study density figures to summarize the totality of information available on the effectiveness and safety of these devices.

Results

Key Question 1. What are the different types of neurothrombectomy devices in use or in development for treatment of acute ischemic stroke?

Table A provides a list of the various neurothrombectomy classes (clot retrievers, aspiration/suction devices, snare-like devices, ultrasonography technologies, and lasers) and devices in those classes.

Neurothrombectomy devices: (1) allow patients to avoid or reduce the use of pharmacologic thrombolysis, thereby minimizing the risk for intracerebral hemorrhage (ICH); (2) can be used beyond the short timeframe to which rtPA is limited; (3) may provide more rapid recanalization than thrombolytics; and (4) can provide a treatment option for thrombi more resistant to fibrinolytic breakdown. However, the technical difficulty of navigating mechanical devices into the intracranial circulation may result in direct trauma to the neurovasculature (including vasospasm, vessel dissection, perforation, or rupture), and fragmenting thrombi may subsequently embolize into previously unaffected vessels and cerebral territories. In addition, the procedure itself carries risks, including the need for intubation and heavy sedation, which have been associated with worse outcomes.

Only the MERCI clot retriever and the Penumbra System are FDA cleared for use in patients with an acute ischemic stroke to restore perfusion. Other devices have FDA indications ranging from retrieval of intravascular foreign bodies to infusion of fluids into the peripheral vasculature. Data on the utilization of these various devices are limited.

Recent and ongoing studies are evaluating the use of “retrievable” intracranial stents that are meant to provide immediate recanalization and then be removed

along with clot trapped within the stent matrix. A recent prospective, single-center pilot study reported on the safety and efficacy of a retrievable stent in 20 acute stroke patients with a large vessel occlusion who were either refractory to or ineligible for IV rtPA therapy. The stents were deployed for from 1 to 2 minutes before retrieval, with 18 of 20 (90 percent) of patients achieving successful revascularization. Six patients (30 percent) had asymptomatic ICH while 2 patients (10 percent) experienced symptomatic ICH.

Table A. Neurothrombectomy devices in use

Device Class	Company Name	FDA Indication	In Clinical Use?
Aspiration/Suction			
Amplatz Thrombectomy	Ev3 Medical	Mechanical dissolution of thrombus within dialysis fistulae	No longer marketed
AngioJet	Possis	Breaking apart or removing of thrombus in peripheral veins or arterio-venous access conduits	Yes
NeuroJet	Possis	N/A	No longer marketed
Oasis Thrombectomy	Boston Scientific	Removing thrombus from hemodialysis access grafts	No longer marketed
Penumbra	Penumbra, Inc.	Revascularization of patients with acute ischemic stroke	Yes
Vasco +35	Balt Extrusion	N/A	Not in U.S.
Clot Retriever			
Attractor-18	Boston Scientific	N/A	No longer marketed
Catch	Balt Extrusion	N/A	Not in U.S.
In-Time	Boston Scientific	Retrieval of intravascular foreign objects in peripheral vascular, neurovasculature, and cardiovascular	No longer marketed
MERCI	Concentric Medical	Restore blood flow in the neurovasculature	Yes
Phenox	Phenox GmbH	N/A	Not in U.S.
TriSpan	Boston Scientific	N/A	No longer marketed

Table A. Neurothrombectomy devices in use (continued)			
Device Class	Company Name	FDA Indication	In Clinical Use?
Ultrasonography			
EKOS	EKOS Corporation	Infusion of fluids into peripheral vasculature	Yes
OmniWave	OmniSonics	Removal of thrombus and infusion of fluids into peripheral vasculature	No longer marketed
Snare			
Alligator	Chestnut Medical Technologies, Inc.	Peripheral and neurovasculature foreign body removal	Yes
Amplatz Gooseneck	Ev3 Medical	Retrieval and manipulation of atraumatic foreign bodies in coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy	Yes
EnSnare Device	Merit Medical Systems, Inc.	Retrieval and manipulation of foreign objects in the cardiovascular system or hollow viscous	Yes
Neuronet	Boston Scientific	N/A	No longer marketed
Soutenir	Solution	N/A	Not in U.S.
Laser			
EPAR	Endovax Inc.	N/A	No longer marketed
LaTIS	Spectranetics	Removal of thrombus from vascular grafts	No longer marketed

EPAR=Endovascular Photoacoustic Recanalization; FDA=Food and Drug Administration; N/A=not applicable; U.S.=United States.

Key Question 2. From a systematic scan of studies of different types of neurothrombectomy devices, what are the type(s) of devices, study designs and sizes, patient characteristics, comparators used in comparative studies, lengths of followup, concurrent or prior therapies, outcomes measured, and adverse events, harms, and safety issues reported?

A total of 2,054 citations were identified, 378 of which were retrieved for full-text review. A total of 87 articles were ultimately included in the study. Sixty-two articles (71 percent) were case series or case reports, 18 (21

percent) were prospective single-arm studies, and 7 (8 percent) were non-comparative, retrospective studies enrolling consecutive patients. These studies were published in full-text (74 percent) or abstract form (26 percent). Fifteen of 25 studies (60 percent) were published between 2008 and 2010. Only 3 of 18 (17 percent) prospective and 1 of 7 retrospective studies clearly stated that they utilized blinded outcome assessment.

The largest percentage of overall reports (40 percent) and prospective studies (31 percent) were for the MERCI clot retriever. The Penumbra System had 10 reports, of which 4 were prospective. For off-label

devices, two studies were conducted with EKOS, and one each with Phenox, Amplatz Gooseneck, AngioJet, EPAR, Neuronet, and LaTIS.

The size of prospective single-arm studies ranged from 2 to 164 patients, and retrospective studies ranged from 15 to 114 patients. The largest studies evaluated the MERCI clot retriever (numbers ranged from 18 to 164 patients) and the Penumbra System (numbers ranged from 15 to 125 patients). Studies of “off-label” devices ranged from 2 to 45 patients.

The remaining 62 of 87 (71 percent) articles were either case series or case reports. In total, 191 patients were evaluated with a neurothrombectomy device in case series and case reports. The combined number of patients evaluated in a case series or case report with a neurothrombectomy device ranged from 0 (EPAR and LaTIS lasers) to 75 (MERCİ clot retriever). Case series and reports provide the majority of data on off-label use (n=109 patients) of potential neurothrombectomy devices to treat acute ischemic stroke.

Studies typically enrolled patients older than 18 years of age, with baseline NIHSS scores ≥ 8 (or ≥ 10), presenting within 8 hours of stroke symptom onset (or up to 24 hours for EKOS, EPAR, or LaTIS if a posterior circulation occlusion was identified), and having a complete or near complete (TIMI 0-1) occlusion of a treatable large intracranial vessel. Common exclusion criteria included advanced age, large brain infarction, abnormal hemostasis, severe or uncontrolled hypertension, hypoglycemia, and pregnancy. Studies also enrolled patients with contraindications to receive IV rtPA due to risks of adverse events, reporting outside a 3-hour window from symptom onset to IV rtPA, or who failed (target vessel not recanalized as determined by immediate angiography following the procedure) IV rtPA treatment. The one exception was the EKOS study by Tomsick in 2008. The EKOS device is designed to infuse intra-arterial (IA) thrombolytic therapy, and in this study EKOS was used along with reduced-dose IV rtPA within the first 3 hours of stroke symptoms.

The mean/median baseline NIHSS range was 15 to 25 across studies. The range for mean/median age was 42 to 68 years and studies enrolled 20 to 57 percent females. In studies where data were provided, the majority of patients had pre-device TIMI 0 or 1 flow.

Mean/median time from stroke symptom to either angiography or device deployment ranged from 141 to 388 minutes, well within the 8-hour timeframe suggested by the FDA CDRH guidance. The primary embolus was most commonly in an anterior vessel (14 studies enrolled >60 percent anterior occlusion patients). However, some studies focused heavily on posterior occlusions. Only 1 of 25 studies (4 percent) reported including patients with occlusions in other areas and 6 studies were unclear about the location of occlusion.

A majority of case series and case reports included patients who would typically meet prospective study inclusion criteria. However, some case series and reports included both pediatric patients, those older than 80 years of age, and those with a baseline NIHSS score below or above the typical enrollment threshold of 8 to 10. Finally, some case series and reports for the Penumbra System, MERCI clot retriever, TriSpan clot retriever, In-Time clot retriever, and Neuronet and Amplatz Gooseneck snares, enrolled patients with symptom-to-angiography or device deployment times outside the 8-hour window used in prospective and retrospective studies of these devices. The location of emboli reported in case series and case reports was predominantly anterior (72 percent) and posterior circulation (24 percent).

No direct human comparative studies were identified during our scan of the neurothrombectomy literature. All prospective and retrospective studies reported recanalization success after neurothrombectomy device deployment. The longest durations of followup in the majority of prospective and retrospective studies reporting effectiveness outcomes were either 30 days or 90 days post-procedure. The timing of NIHSS evaluation was more variable with the longest duration of followup ranging from 24-hours to 90-days post-procedure. Safety endpoints were typically monitored over shorter lengths of time, such as the first 24 hours or until discharge. The reporting of followup outcomes in case series and case reports was variable. Of the 71 total device reports, nearly half did not report data on effectiveness or safety outcomes after patient discharge. In those reports that did, length of followup ranged from 6 weeks to 24 months; the most commonly reported length of followup was 90 days.

Prospective and retrospective neurothrombectomy studies focus on patients contraindicated to receive IV rtPA, reporting outside the recommended 3-hour window, or refractory to or failing IV rtPA treatment. Consequently, the use of IV rtPA among studies ranged from 0 to 100 percent. The one exception was the aforementioned EKOS study. Concurrent or rescue therapies in identified studies, case series, and reports

included intra-arterial thrombolytics, cerebral artery angioplasty, and stenting.

Table B summarizes all identified reports (prospective and retrospective studies, case series, and reports) of neurothrombectomy devices by device classification and the effectiveness endpoints evaluated.

**Table B. Effectiveness evidence for neurothrombectomy devices (n=1,311)
(Reported as prospective/retrospective/case series or reports)**

		Devices															
		Clot Retriever (n=847)			Aspiration/Suction (n=411)			Snare (n=94)			Ultrasound Technology (n=50)			Laser (n=36)			
Reported Outcomes		P	R	C	P	R	C	P	R	C	P	R	C	P	R	C	
	Recanalization	Studies	7	4	34	5	3	10	2	0	24	1	0	1	2	0	0
		Patients	524	220	98	211	173	24	14	0	74	29	0	7	36	0	0
	mRS	Studies	5	1	11	5	3	4	2	0	9	1	0	1	1	0	0
		Patients	440	18	11	213	173	16	12	0	33	14	0	1	34	0	0
	Death#	Studies	5	1	16	5	3	7	2	0	9	1	0	0	1	0	0
		Patients	450	18	38	184	173	23	2	0	53	14	0	0	34	0	0
	NIHSS	Studies	3	0	15	4	3	5	2	0	11	1	0	0	1	0	0
		Patients	371	0	31	211	173	12	12	0	53	14	0	0	34	0	0
	BI	Studies							1	0	0	1	0	0			
Patients								5	0	0	14	0	0				
GOS	Studies										1	0	0				
	Patients										14	0	0				

Darker shading represents more frequent evaluation or larger number of patients evaluated.

BI=Barthel Index; C=case report/case series; GOS=Glasgow Outcome Scale; mRS=modified Rankin Scale; n=the total number of patients evaluated for any effectiveness or safety endpoint; NIHSS=National Institutes of Health Stroke Scale; P=prospective; R=retrospective.

#Death included if patients were followed up for any duration of time after hospital discharge.

All prospective or retrospective studies reported recanalization results. The NIHSS score was reported in 13 of 25 (52 percent) identified studies and mRS \leq 2 was reported in 17 of 25 (68 percent) studies. NIHSS, mRS \leq 2, and mortality endpoints were reported in 20 percent, 50 percent, and 50 percent of MERCI clot retriever; 100 percent, 100 percent, and 100 percent of Penumbra System; and 50 percent, 63 percent, and 63 percent of off-label device studies.

Table C summarizes all identified reports of neurothrombectomy devices by device classification and the safety endpoint(s) evaluated.

Other adverse events evaluated in the neurothrombectomy literature included perforation/dissection, other types of hemorrhage (not intracerebral), thrombus formation (proximal, adjacent, or distal to the clot site), failure to deploy the device, device breakage/fracture, and vasospasm. During prospective or retrospective studies, the proportion of

patients per study experiencing an instance of symptomatic or asymptomatic ICH, other bleeding, perforation or dissection, or thrombus formation were reported in 50 percent, 50 percent, 30 percent, 40 percent, and 20 percent of MERCI clot retriever, respectively; 100 percent, 71 percent, 29 percent, 43 percent, and 43 percent of Penumbra System; and 63 percent, 38 percent, 0 percent, 63 percent, and 38 percent of off-label device studies, respectively. Device failure-to-deploy, device fracture or breakage, and vasospasm data were infrequently reported in studies.

Key Question 3: What are the variables associated with use of the devices that may impact outcomes (e.g. time to deployment, training/expertise of interventionalist, location of infarct, concurrent therapies)?

The effects of predictor variables on select outcomes identified by researchers during neurothrombectomy studies are summarized in Table D.

Table C. Safety endpoint evidence for neurothrombectomy devices (n=1,311) (Reported as prospective/retrospective/case series or reports)																		
Devices																		
		Clot Retriever (n=847)			Aspiration/ Suction (n=411)			Snare (n=94)			Ultrasound Technology (n=50)			Laser (n=36)				
Reported Adverse Events			P	R	C	P	R	C	P	R	C	P	R	C	P	R	C	
	SICH	Studies		5	0	8	5	3	3	1	0	10	2	0	0	1	0	0
		Patients		382	0	39	213	173	10	7	0	37	49	0	0	34	0	0
	AICH	Studies		5	0	8	5	2	3	1	0	10				1	0	0
		Patients		382	0	39	213	158	10	7	0	37				34	0	
	Perforation/ Dissection	Studies		3	0	2	3	1	2	1	0	4	2	0	0	1	0	0
		Patients		190	0	17	157	15	14	7	0	21	49	0	0	34	0	0
	Thrombus Formation	Studies		2	0	5	3	1	1	2	0	3						
		Patients		165	0	20	157	15	4	12	0	9						
Other Hemorrhage	Studies		2	0	4	1	1	0	0	0	3							
	Patients		166	0	25	20	15	0	0	0	13							

Darker shading represents more frequent evaluation or larger number of patients evaluated.

AICH=asymptomatic intracerebral hemorrhage; C=case report/case series; n=the total number of patients evaluated for any effectiveness or safety endpoint; P=prospective; R=retrospective; SICH=symptomatic intracerebral hemorrhage.

Table D. Effect of various variables on post-neurothrombectomy device outcomes

Predictor Variables	Clinical Outcomes				
	Recanalization	NIHSS Improvement	Hemorrhage*	mRS≤2	Death
Recanalization [∞]	–	B	–	B	B
Older Age	–	–	–	H	H
Higher SBP	–	H	–	H	H
Higher Baseline NIHSS	I	–	–	H	H
ICA Occlusion Site (vs. mostly MCA)	I	–	–	I	H
Abnormal Hemostasis#	I	–	I	H	I
Prior IV rtPA	I	–	I	I	I
Concomitant IA thrombolytics	B	–	I	I	I
Prior Stroke	–	–	–	–	H
Longer Procedure Duration	–	–	–	H	I
Right Brain Infarct	–	–	–	H	–

B=beneficial; H=harmful; I=indeterminate (no statistically significant effect); IA=intra-arterial; ICA=internal carotid artery; IV rtPA=intravenous recombinant tissue plasminogen activator; MCA=middle cerebral artery; mRS=modified Rankin Scale; NIHSS=National Institutes of Health Stroke Scale; SBP=systolic blood pressure.

*including symptomatic and asymptomatic hemorrhage.

#INR>1.7, PTT>45 and/or platelet count <100,000.

[∞]Revascularization as defined by achieving TIMI 2-3 flow at the site of primary occlusion.

Evaluated predictors of outcome (Table D) in these patients treated with a neurothrombectomy device include demographic, co-morbid disease, stroke severity, and stroke treatment variables. These predictors were evaluated in studies (or pooled analyses) of the MERCI clot retriever and the Penumbra System. Of particular note, recanalization was the only variable that was found to be predictive of clinical benefit (achieving a mRS≤2) as well as lower mortality. These results are similar to those found in an earlier meta-analysis as well as a pooled analysis of the IMS I and II trials, where reduced-dose IV followed by IA thrombolysis was associated with good outcomes. In addition to these variables, researchers have suggested that the presence of collateral circulation, lesion volume, and cerebral perfusion pressure have also been linked to outcomes in acute ischemic stroke patients.

In a meta-analysis by Stead and colleagues evaluating neurothrombectomy devices, younger age and lower NIHSS score at presentation had beneficial effects on achieving a mRS≤2 (p=0.001). Patients with posterior circulation occlusions were found to have higher odds of 90-day mortality compared to those with anterior occlusions (either internal carotid or middle cerebral arteries).

No studies provided data assessing the relationship between the training of interventionalists and outcomes in patients treated with neurothrombectomy devices. However, studies of emerging technologies over the past 20 years have suggested that inadequate physician training and experience can adversely affect clinical outcomes. Of note, upon qualitative review, the proportion of patients recanalized in retrospective

(real-world) studies did not appear to be lower than that of the prospective, single-arm studies, for either MERCI or Penumbra System studies. This suggests that practicing clinicians may be achieving outcomes similar to those clinicians involved with clinical trials, which would indicate that practicing clinicians are receiving adequate training.

Two reports have been written and approved by multiple neuroscience societies detailing the minimum training requirements for those performing neuroendovascular procedures (including neurothrombectomy devices) in patients with acute ischemic stroke, and setting out performance standards that should be adopted to assess outcomes.

Discussion

Neurothrombectomy devices are a treatment option in patients with an acute ischemic stroke. The specific population most likely to benefit from these devices is still under investigation. Current studies have involved patients with large vessel occlusions, high baseline NIHSS scores, and those either unlikely to respond or who have failed IV rtPA therapy. Only two neurothrombectomy devices, the MERCI clot retriever and the Penumbra System, are cleared by FDA to restore perfusion in patients with acute ischemic stroke. A majority of available data relates to the two cleared devices.

We did not identify any direct human comparative studies of neurothrombectomy devices to IV rtPA or each other. Instead, investigators frequently studied devices as part of prospective single-arm studies, non-comparative retrospective studies enrolling consecutive patients, or case series or case reports. In this technical brief, our main objective was limited to describing neurothrombectomy devices currently being used or actively investigated in the treatment of patients with acute ischemic stroke and summarizing the evidence supporting their use. We did not draw conclusions regarding their effectiveness or safety.

A previous systematic review of neurothrombectomy devices by Stead and colleagues was identified during our literature scan. The literature search on which their review was based extended only through March 2006 and consequently did not include the majority of the

highest quality data on neurothrombectomy devices (including that of the MERCI and Penumbra Systems). Thus, our technical brief should represent the most up-to-date review of the literature at this time. Unlike our review, Stead and colleagues quantitatively compared pooled device results to a control group derived from their own institution's stroke population. They found that when compared with a similar matched cohort, the neurothrombectomy patients had good functional recovery ($mRS \leq 2$) in 34.5 percent of patients compared with 10.7 percent of patients matched for age, sex, and NIHSS score, suggesting that the neurothrombectomy group was nearly 15 times more likely than the control group to have good functional recovery. While perhaps the best "controlled" data available to date, this analysis is fraught with limitations, including the fact that the neurothrombectomy cohort was not homogeneous, the comparison was to a single-center historically concurrent cohort, and individuals were not randomly allocated.

Eleven ongoing studies are evaluating at least one neurothrombectomy device in acute ischemic stroke listed on the <http://www.clinicaltrials.gov/> Web site or mentioned in previous review articles. The first of these eleven studies is estimated to end sometime in 2010. All studies appear to be enrolling patients based upon inclusion and exclusion criteria that are similar to those already used by the prospective and retrospective studies detailed throughout this report. One exception is the Mechanical Retrieval and Recanalization of Stroke Clots Using Embolectomy (MR RESCUE) trial, which will allow patients to receive IV rtPA up to 4.5 hours after symptom onset. Seven of these studies have randomized, controlled designs with projected enrollment ranging from 20 to 900. The other four studies have prospective, observational designs ranging from 200 to 2000 projected participants. Six of the seven randomized controlled trials are allowing the use of multiple neurothrombectomy devices; most compare the use of neurothrombectomy devices to best medical therapy (with or without IV rtPA). Both the MERCI clot retriever and the Penumbra System have prospective observational studies in progress. Compared to previous, similarly designed studies of these agents, these studies will enroll much larger sample sizes ($n=2,000$ and $3,000$, respectively).

The use of advanced imaging techniques should be incorporated into future randomized controlled trials to aid in identifying those patients most likely to benefit from neurothrombectomy devices. In addition, for those patients with contraindications or who are refractory to IV rtPA, it is unclear which device is the most efficacious or safe. It would seem reasonable to conduct studies to answer such research gaps using a randomized controlled trial design, powered to show equivalency or non-inferiority of devices. These studies should also evaluate the impact on health-related quality of life of neurothrombectomy devices.

Summary

Currently available neurothrombectomy devices offer intriguing treatment options in patients with acute ischemic stroke, although a paucity of high quality research currently exists. There remains a need for further research on the topic, including randomized controlled trials to determine the optimal device(s) to use, and the patient populations most likely to benefit from their use. Additionally, studies of neurothrombectomy devices against contemporaneous controls investigating whether these devices truly treat final health outcomes associated with stroke rather than improving recanalization alone are warranted. Results of ongoing studies will likely only begin to address some of these questions.

Full Report

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