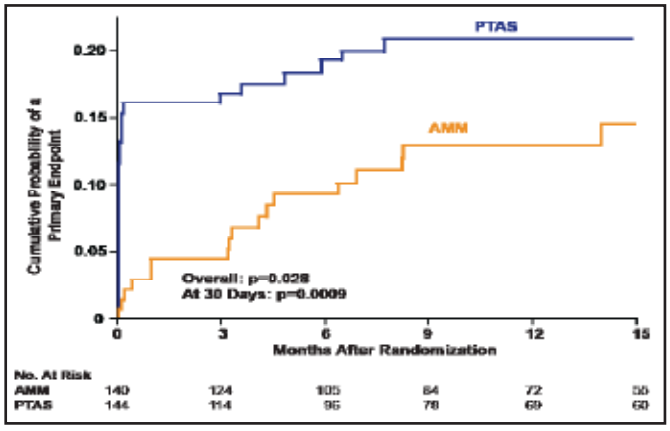
Baseline measures of risk factors between the two groups were similar, except that glycated hemoglobin in diabetics was lower in the antithrombotic therapy group (p=0.03). In terms of concomitant medication at the time of study entry, only beta-blockers and nonstatin lipid-lowering medications were different between the group-on (119/284, 42%; 58/284, 20%) and group-off (53/167, 32%; 19/167, 11%) participants (p=0.0319 and p=0.0137, respectively).

The percentage of group-on patients who were on AMM (n=140) who reached the primary endpoint was 12.1%; in the PTAS group (n=144), the primary endpoint was reached by 21.5% of patients. At 30 days, the primary endpoint rates were 4.3% versus 16.0%, respectively; after 30 days, they were 7.9% versus 5.6%, respectively.

Among those who were on antithrombotic therapy with a qualifying event, the cumulative probability of a primary endpoint occurring at 15 months of follow-up was significantly higher in the PTAS group than the AMM group (p=0.028 overall; p=0.0009 at 30 days; Figure 1). Among those who were on antithrombotic therapy and had a history of ischemic stroke with a qualifying event, the difference in the primary endpoint between the AMM (n=49) and PTAS group (n=51) was 14.3% versus 35.3%, respectively. At 30 days, the respective numbers were 8.2% versus 25.5%, and after 30 days, they were 6.1% versus 9.8% (p=0.014 overall; p=0.019 at 30 days).

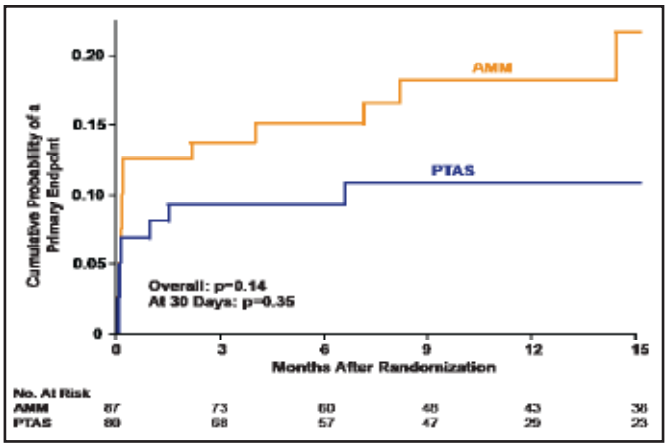
Figure 1. Qualifying Event On Antithrombotic Therapy.



Reproduced with permission from HL Lutsep.

There was no significant difference between the AMM and PTAS groups that had a qualifying event while not on antithrombotic therapy (p=0.14 overall; p=0.35 at 30 days; Figure 2). No significant difference was observed between those patients who were treated with AMM who were either on or off antithrombotics at the time of their qualifying event.

Figure 2. Qualifying Event Not On Antithrombotic Therapy.



Reproduced with permission from HL Lutsep.

The authors pointed out that those patients who had been on antithrombotics had a greater number of risk factors and that those patients with intracranial stenosis had more benefit from AMM than PTAS with the Wingspan stent system, even if they had failed antithrombotic therapy.

The benefit of AMM is similar in patients who are on versus off antithrombotic medication at the time of their qualifying events. These findings support those from the Warfarin Aspirin Symptomatic Intracranial Disease (WASID) trial, showing that antithrombotic therapy failure does not identify a higher-risk subgroup of patients with intracranial stenosis [Chimowitz MI et al. *N Engl J Med* 2005].

Initial Clinical Results with TREVO® Mechanical Thrombectomy Device are Promising

Written by Rita Buckley

Experimental data suggest that the novel Trevo device is highly effective at achieving immediate reperfusion of occluded arteries without causing any clinically significant disruption of vascular integrity [Nogueira RG et al. *J Neurointerv Surg* 2011]. Nils Wahlgren, MD, PhD, Karolinska Institutet, Stockholm, Sweden, also reported promising findings from the Phase 4 Thrombectomy REvascularization of Large Vessel Occlusions in Acute Ischemic Stroke trial [TREVO; NCT01088672].

This multicenter, international, prospective, single-arm clinical trial included 60 patients at 7 sites in Germany,

Spain, Austria, and Sweden. The procedure employs a microcatheter that is placed distal to the thrombus to deliver the Trevo device, which is deployed by unsheathing the microcatheter and allowing clot integration into the device. The Trevo is then retrieved into a proximally placed catheter.

The purpose of the study was to determine the revascularization rate of the Trevo system in large-vessel occlusions in ischemic stroke patients. The primary endpoint was revascularization, defined as at least thrombolysis in cerebral infarction (TICI) score 2a. Secondary endpoints included modified Rankin scale (mRS) clinical outcomes at 90 days; mortality at 90 days; device-related serious adverse events, as determined by an independent clinical events committee; and symptomatic intracranial hemorrhage (sICH) rate within 24 hours according to Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST) criteria, as determined by an independent core lab [Wahlgren N et al. *Lancet* 2007]. Neuroimaging (CT or MR) was required at 24 hours. Clinical evaluation also took place at 7 and 90 days.

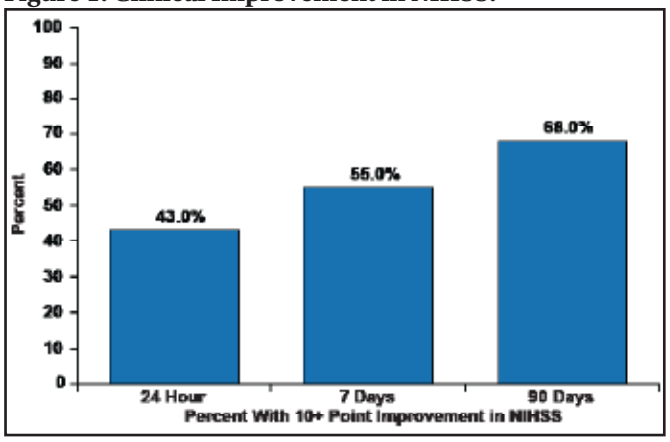
The median patient age was 65 years, with a range from 21 to 84 years; 45% of the patients were male. Atrial fibrillation accounted for most of the strokes (41.7%), followed by unknown cause (25%), large-artery atherosclerosis (20%), other- cardioembolic (8.3%), and other (3.3%). The median National Institute of Health Stroke Score (NIHSS) was 18, with a range of 8 to 28. The majority of occlusions was located in the middle cerebral artery (70%), with 60% in M1 and 10% in M2; 21.7% were in the internal carotid artery, with 8.3% in the vertebrobasilar artery.

Mean hours from symptom onset to arterial puncture was 3.5 ±1.4; 46.7% of patients were treated in ≤3 hours. The majority of patients (60%) received intravenous tissue plasminogen activator (tPA) prior to the embolectomy procedure but had a persistent occlusion. Other adjuvant intraarterial pharmacological agents included intraarterial tPA (10%), IA IIb/IIIa inhibitor (3.3%), and intraarterial vasodilator (3.3%).

Recanalization results showed that 91.7% of patients achieved a TICI score of 2a or higher. A TICI score of 2b or higher was achieved in 78.3% of patients. Intracranial hemorrhage (ICH) occurred in 30% of patients versus sICH (according to SITS-MOST criteria) in 5%, with 1 device-related perforation and asymptomatic ICH in 25%.

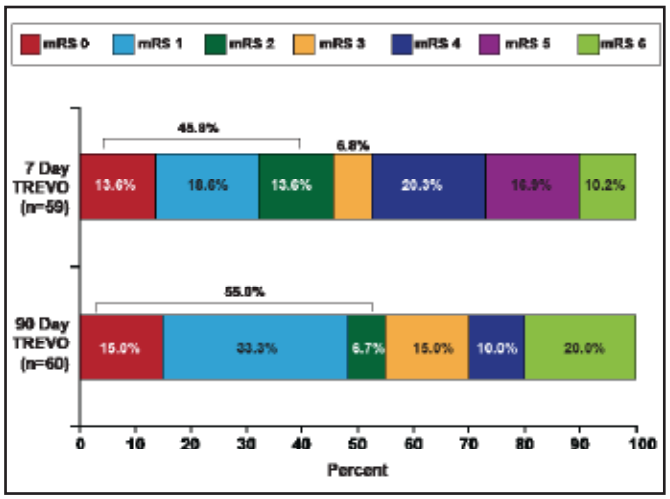
The median NIHSS decreased 47% to 9.5 in 24 hours, 75% to 4.5 at 7 days, and 89% to 2.0 in 90 days. These decreases were mirrored in clinical improvement, as defined by a 10-point improvement in NIHSS (Figure 1) and mRS outcomes (Figure 2).

Figure 1. Clinical Improvement in NIHSS.



Reproduced with permission from N. Wahlgren, MD, PhD.

Figure 2. mRS Outcomes.



Reproduced with permission from N. Wahlgren, MD, PhD.

Although TREVO was not a randomized trial, the results are very encouraging and warrant further development.

Linking sICH Definitions to Outcomes

Written by Rita Buckley

Patients with symptomatic intracranial hemorrhage (sICH) have an increased risk of a poor or fatal outcome [Strbian D et al. *Neurology* 2011]. However, the direct comparison of sICH rates between different thrombolysis studies is complicated by varying definitions of sICH [Gumbinger C. et al. *Stroke* 2012].