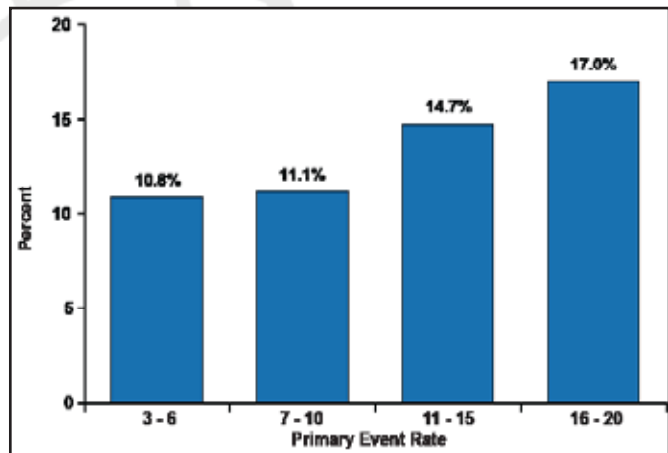


Significant and other select factors for ischemic strokes (n=19) included having diabetes (p=0.017), mean age (p=0.024), and symptomatic artery (p=0.059). For procedural perforator strokes, significant factors included lesion length (p=0.075), mean age (p=0.072), and symptomatic artery (p=0.017). For procedural embolic strokes (n=5), they included serum glucose (p=0.058), baseline stenosis percentage (local; p=0.096), and baseline Dn (local) mm (p=0.076). Most procedure-related ischemic strokes were local perforator territory, and most were in the basilar artery.

Periprocedural primary event rate as a function of wingspan volume is shown in Figure 1. Thirty-day primary endpoint rates at sites with the most experience in registries and in SAMMPRIS are shown in Table 1. Interventionists that came into the trial with less wingspan experience did not have higher rates of 30-day primary endpoints than those with more experience. These data suggest that the credentialing process selects physicians with good technical expertise.

Figure 1. Operator Wingspan Credentialing Volume.



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Table 1. Thirty-Day Primary Endpoint Rates at Sites With The Most Experience in Registries and in SAMMPRIS.

	Medical Arm	PTAS Arm
Top 10 Recruiting Sites in Registries	2/83 (2.4%)	12/84 (14.3%)
Top 10 Recruiting Sites in SAMMPRIS	2/101 (2.0%)	14/101 (13.9%)

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Dr. Derdeyn concluded that angioplasty and stenting in a SAMMPRIS-eligible population carries high risk, owing to increased hemorrhage risk in smaller diameter

vessels and increased ischemic stroke risk in perforator-rich vessel segments. Unfortunately, most symptomatic intracranial stenoses involve either small-diameter vessels or perforator-rich vessel segments. The relative lack of experience with the wingspan device was not a factor in the outcomes in the stenting arm of the trial.

AMM Benefits Those Who Fail Antithrombotic Therapy

Written by Rita Buckley

As landmark trials have shown no outcome improvement with vascular bypass or percutaneous angioplasty and stenting, aggressive medical management (AMM) remains the gold standard for symptomatic intracranial artery disease [Augoustides JG. *J Cardiothorac Vasc Anesth* 2012]. Helmi L. Lutsep, MD, FAHA, Oregon Health & Science University, Portland, Oregon, USA, presented outcomes of patients in the SAMMPRIS trial who had failed antithrombotic therapy at study enrollment.

The analysis compared AMM and percutaneous transluminal angioplasty and stenting (PTAS) in group-on and group-off antithrombotic therapy at the qualifying event. The primary endpoints were stroke and death at 30 days or stroke in the territory of the qualifying artery beyond 30 days.

Data showed that 63% of SAMMPRIS patients (284/451) had their qualifying events while on antithrombotic therapy; 140 were randomized to AMM, and 144 were randomized to PTAS. Thirty-seven percent of patients (167/451) were not on antithrombotic therapy; 87 were randomized to AMM, and 80 were randomized to PTAS. Of the 284 patients who had a qualifying event on antithrombotics, 95.8% were on antiplatelet therapy only (clopidogrel+aspirin; 22.5%), 1.4% were taking anticoagulants only, and 2.8% were on both antiplatelet and anticoagulant therapy.

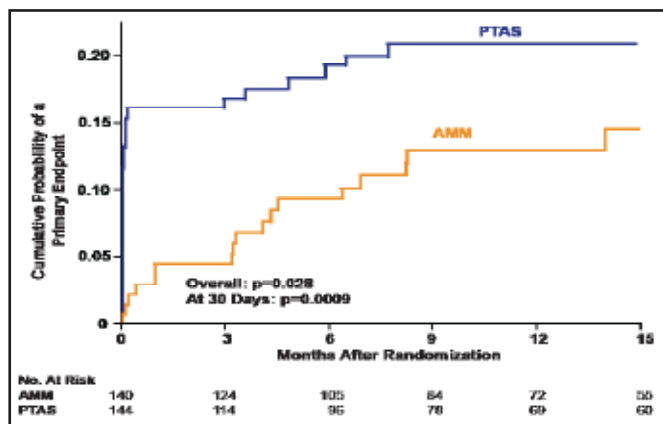
The patient characteristics were different in the group with a qualifying event on antithrombotic therapy compared with the group that was off of antithrombotic therapy. The group that had been on antithrombotic therapy at the time of the qualifying event was older and had a longer history of hypertension, lipid disorders, coronary artery disease, and stroke prior to the qualifying event. In this group, the qualifying event was also more often a stroke rather than a transient ischemic attack, and the symptomatic artery differed, more commonly involving a vertebral or basilar artery.

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).

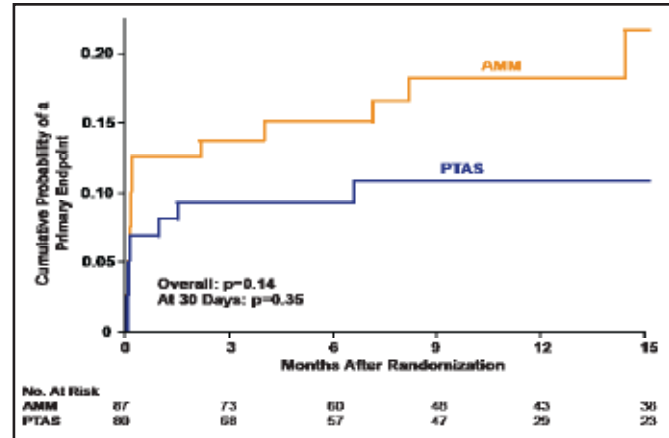
Figure 1. Qualifying Event On Antithrombotic Therapy.



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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.



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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,