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).
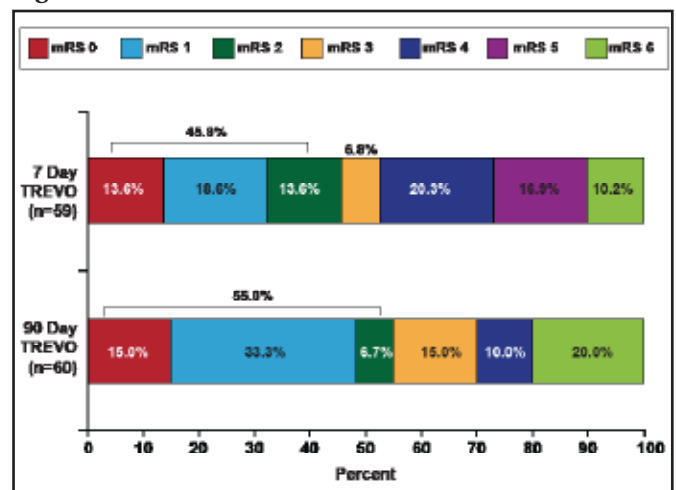
Figure 1. Clinical Improvement in NIHSS.
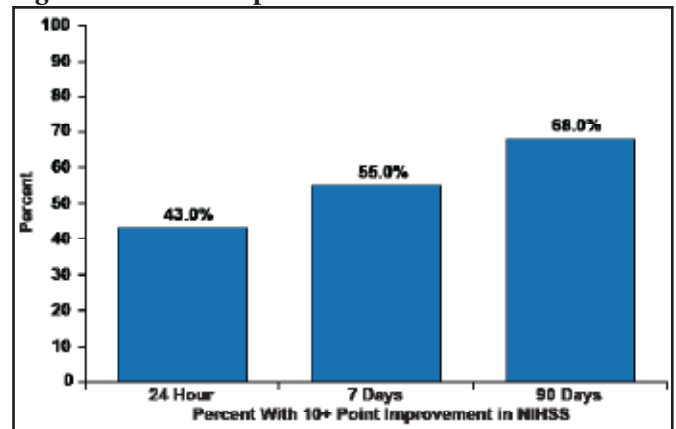
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Figure 2. mRS Outcomes.

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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].

Definitions include those from The National Institute of Neurological Disorders and Stroke-tPA study (NINDS) [The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group. *N Engl J Med* 1995], the second European-Australasian Acute Stroke Study (ECASS-II) [Larrue V et al. *Stroke* 2001], ECASS-III [Hacke W. et al. *N Engl J Med* 2008], and The Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST) [Wahlgren N. et al. *Lancet* 2007]. Outcomes differ according to clinical, radiological, and relational criteria.

Neal M. Rao, MD, University of Colorado School of Medicine, Denver, Colorado, USA, presented results from a study on the most accurate definition of clinically relevant hemorrhagic transformation (HT) after thrombolytic therapy for stroke with IV tissue plasminogen activator (tPA).

The specific aim of this study was to determine which definition of sICH best identifies hemorrhages that alter final patient outcomes after administration of intravenous tPA in acute stroke. Analysis was based on the NINDS database, which defines sICH as any hemorrhagic transformation that is temporally related to any worsening.

Methods included an analysis of candidate definitions—ie, radiological (any radiological hemorrhage or parenchymal hematoma [PH])—and clinical-radiological criteria (NINDS-tPA Study, ECASS-II, and modified SITS-MOST: PH and ≥4 National Institutes of Health Stroke Scale [NIHSS] worsening).

Clinically relevant hemorrhages were defined as those that altered final outcome. A predictive model from the placebo group was derived, and outcomes with tPA were compared with predicted outcomes without tPA using a modified Rankin Scale (mRS).

The data of 312 patients who were treated with IV tPA were analyzed; 48 patients (15.4%) experienced any radiological intracranial hemorrhage (ICH). Hemorrhage frequency varied by definition (6.4%, any [PH]; 6.4%, NINDS-tPA; 5.1%, ECASS-II; and 1.9%, modified SITS-MOST). ECASS-II sICH patients had worse actual (with tPA) versus predicted (without tPA) outcomes. The mean final mRS was 5.6 (observed) versus 3.5 (predicted); death occurred in 75% (observed) versus 25.4% (predicted) of patients.

Radiological hemorrhage patients who did not meet ECASS sICH criteria showed no difference between actual and predicted outcomes. Mean final mRS was 4.2 (observed) versus 4.0 (predicted); death occurred in 35%

(observed) versus 35.1% (predicted) of patients. Table 1 shows actual and predicted mean mRS and mortality with and without the five definitions (any radiographic, PH, NINDS, ECASS-II, and SITS-MOST).

Table 1. Outcomes With and Without Definitions.

	With Definition		Without Definition	
	Mean mRS Actual/ predicted	Mortality Actual/ predicted	Mean mRS Actual/ predicted	Mortality Actual/ predicted
Any Radiographic	4.94/4.22	56.0%/ 37.8%		
PH	4.50/3.53	50.0%/ 26.9%	4.25/4.22	38.0%/ 38.7%
NINDS	4.96/3.82	60.0%/ 32.3%	4.27/3.92	36.0%/ 31.6%
ECASS II	5.56/3.53	75.0%/ 25.4%	4.16/4.02	35.0%/ 35.1%
SITS-MOST	5.67/2.52	36.0%/ 33.6%	4.00/3.92	36.0%/ 33.6%

Study limitations were: only a subset of the proposed definitions of sICH was analyzed, data from the NINDS trials may not fully reflect contemporary practice, and there were a small number of patients in the NINDS dataset.

The authors concluded that the ICH classification that best identifies clinically relevant hemorrhages that alter final global disability and fatal outcome is any radiological HT that is associated with ≥4 early NIHSS worsening. They also determined that asymptomatic hemorrhages under this definition have no adverse impact on final outcomes.

Solitaire™ FR Device Achieves Successful Recanalization Almost Free of Symptomatic Hemorrhage Transformation

Written by Rita Buckley

According to the Primary Results of the Solitaire™ FR With the Intention for Thrombectomy Multicenter, Randomized Clinical Trial [SWIFT; NCT01054560], the Solitaire flow restoration (FR) device is superior to the Merci Retrieval System® in achieving successful recanalization that is almost free of symptomatic hemorrhagic transformation. Jeffrey L. Saver, MD, FAHA, FAAN, UCLA Stroke Center, Los Angeles, California, USA, reported outcomes from the study.